Partners In Health Guide | COVID-19

Annex

Updated: 24 September 2020

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Quick Guide for Interpretation of Diagnostic Tests for SARS-CoV-2

PIH Laboratory Services
June 2020

Purpose: to provide updated recommendations to clinicians, nurses, lab technicians, and medical auxiliaries to aid in the understanding and interpretation of the Antibody and Antigen rapid tests from SD Biosensor, which have been deployed across a number of PIH supported countries.

Section 1. Testing for SARS-CoV-2

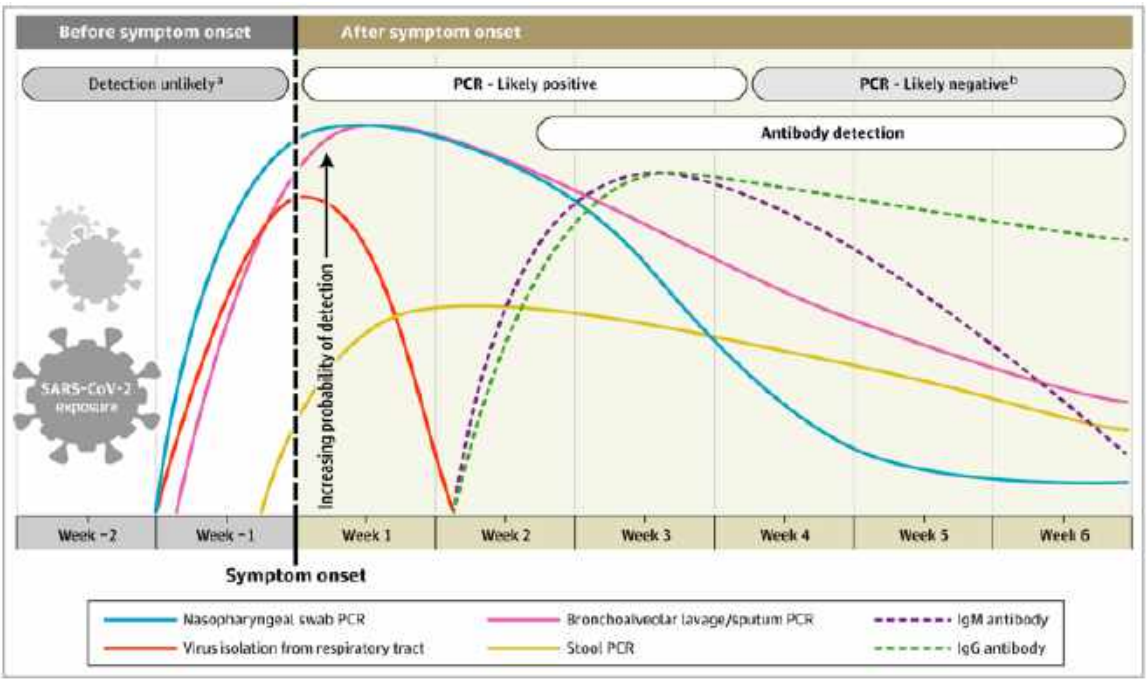
Below is a brief summary of three tests for SARS-CoV-2: reverse transcription (RT)-PCR, Ab RDT, and Ag RDT.

TABLE 1: Types of Diagnostic Tests and Comparison of Key Characteristics

Characteristic	RT-PCR	Antibody (IgM/IgG) RDT	Antigen (Ag) rapid RDT
Target	Viral RNA	Host immune response	Viral protein
Sample	Nasopharyngeal swab, oral swab or sputum	Blood (finger stick or blood draw)	Nasopharyngeal swab
Ideal time for sample collection (see Figure 1)	Acute phase of infection (1-21 days after symptom onset) A few days before the onset of symptoms, the viral load may be low and virus cannot be detected.	7-10 days after symptoms onset. As such, Ab testing should *not* be utilized for screening asymptomatic persons.	Acute phase of infection (1-14 days after symptom onset) A few days before the onset of symptoms, the viral load may be low and virus cannot be detected.
False positives	**Almost none**	**Low to moderate** Cross-reactivity with other coronaviridae can occur.	**Very low**
False negatives	**Low to moderate** Especially if sample taken before symptom onset or as a patient is starting to clear infection and viral load is decreasing. Can also be due to unideal time of sample collection or deficiency in sampling technique.	**Variable** High at onset of symptom (due to being in the window period at low concentration of Ab).	**Moderate** Not as sensitive as RT-PCR; same limitations of RT-PCR.
Turn-around time	**Hours to 1-2 days** (more if referred to another lab)	15 minutes	15 minutes
Personnel and Laboratory requirements	High - previous experience with molecular technique recommended. Laboratory with high technical capacity required.	Low- no laboratory required.	Low- no laboratory required.

Adapted from: PIH Guide COVID-19. Part I: Testing, Contact Tracing and Community Management of COVID-19. 21 April 2020.

FIGURE 1: Estimated Variation Over Time of Diagnostic Tests for Detection of SARS-CoV-2 Relative to Symptom Onset



Sethuraman N, Jeremiah SS, Ryo A. Interpreting Diagnostic Tests for SARS-CoV-2. JAMA. Published online May 06, 2020. doi:10.1001/jama.2020.8259

Estimated time intervals and rates of viral detection are based on data from several published reports. Because of variability in values among studies, estimated time intervals should be considered approximations and the probability of detection of SARS-CoV-2 infection is presented qualitatively. Most of the available data are for adult populations who are not immunocompromised. The time course of RT-PCR positivity and seroconversion may vary in children and other groups.

Section 2. Performance and Diagnostic Accuracy of the RDTs from SD Biosensor

PIH has purchased two RDTs from the Korean company, SD Biosensor:

1. **Antibody (Ab) test (STANDARD Q COVID-19 IgM/IgG Combo Test)**
   - We recommend to continue the utilization of this test under certain conditions, which are explained in detail in the testing algorithm, and the Interpretation of the Rapid and Molecular Tests used for Diagnosis of COVID-19 table (Section 3).

   - The antibody test measures the immune response to the virus in which, an average of 7 to 10 days is required before the body produces enough antibody to yield a positive antibody test result. As such, antibody testing is not an ideal test for diagnosis during the first 10 days of symptoms and should only be used as a complementary test in COVID-19 diagnosis. In sum:
     - **Less than 10 days after onset of symptoms**: antibody testing is NOT recommended for use in diagnosis of COVID-19 due to the lower sensitivity of the test when administered < 10 days after symptom onset.

     - **More or equal to 10 days after onset of symptoms:** antibody testing can assist in the case management of symptomatic patients presenting late, in addition to the antigen test, RT-PCR, or Xpert.

   - In low prevalence settings: the use of antibody tests to triage symptomatic patients is unlikely to be beneficial due to a low positive predictive value. Antibody tests can be used for seroprevalence surveys to estimate the levels of population exposure and inform public health measures. The test can also be used in the testing of contacts (in general wait ≥ 20 days post-exposure, although more studies are needed in this area) to assess previous exposure.

2. **Antigen test (STANDARD Q COVID-19 Ag Test, lateral flow assay, LFA)**
   - Our recommendation is to use this test with caution as more evaluation data needs to be collected and analyzed. However, the test can be used for screening (not for confirmation/diagnostic) following the PIH testing guidelines and algorithm. Confirmatory testing by either RT-PCR or Xpert, should be performed.
   - Additional data on verification/validation of the Ag test is currently being collected at PIH-supported sites in Rwanda, Lesotho, and Haiti. Further analysis will be done and disseminated, shortly.

For both tests:

- Guidance on the utilization of the rapid tests is provided in the PIH testing algorithm, the FIND resource document, and the Interpretation of the Rapid and Molecular Tests used for Diagnosis of COVID-19 table (see supplementary documentation).

*TABLE 2: STANDARD Q COVID-19 IgM/IgG Combo Test - Clinical Evaluation***

From symptom onset:	Sensitivity*	Specificity*
< 7 days	75% (30/40)	95.74% (225/235)
7-14 days	89.23% (58/65)	
≥ 7days	94.48% (154/163)	
>14 days	96.94% (95/98)	

* Compared to RT-PCR / **Pooled data from:

1) Korea; April 2020; 30 COVID-19 positive and 75 COVID-19 negative sera specimens
2) Korea; April 2020; 176 COVID-19 positive and 160 COVID-19 negative sera specimens

TABLE 3: STANDARD Q COVID-19 Ag Test - Clinical Evaluation

STANDARD Q COVID-19 Ag Test (LFA)	Clinical Report #1	Clinical Report #2
Country	Malaysia	Korea
Type of Samples	Nasopharyngeal swabs collected and stored in VTM	
Number of patients	40 (32 positive, 8 negative)	125 (65 positive, 60 negative)
Sensitivity*	84.4%	89.23%
Specificity*	100%	96.67%

*Compared to RT-PCR

Section 3. Interpretation of the Rapid and Molecular Tests used in COVID-19

Use tables 4, 5, 6, and 7 to help interpret the antigen and the antibody RDTs based on the following factors:

- Is confirmatory molecular testing (RT-PCR or SARS-CoV GeneXpert ("Xpert")) available?
- Is the patient symptomatic with symptoms consistent with COVID-19 disease?
- Is the patient a contact of a confirmed (or highly likely) case of COVID-19?

Table 4 is based on the availability of the *antibody* test (Ab), with or without confirmation by RT-PCR or Xpert.
Table 5 is based on the availability of the *antigen* test (Ag), with or without confirmation by RT-PCR or Xpert.
Table 6 is based on *only* RT-PCR or Xpert testing.
Table 7 is based on the availability of *both* the antibody and antigen tests, with or without confirmation by RT-PCR or Xpert.

KEY:

Green = no COVID-19 infection detected and no quarantine measures are indicated.
Yellow = no COVID-19 infection detected BUT quarantine measures are indicated.
Red = presumed or confirmed COVID-19 infection and isolation is indicated.

TABLE 4: **Interpretation of Ab RDT and RT-PCR/SARS CoV-2 Xpert**

Combination of tests	Ab-IgM	Ab-IgG	Ag	PCR / Xpert	Symptoms	Contact	Interpretation of test and management of patient	Quarantine or isolation
Antibody only (no contact)	NEG	NEG	Not Done	Not Done	No	No	**No COVID-19 infection, medium to high confidence.** Note, antibody testing is not generally used for diagnosis in patients with no symptoms because its low specificity.	NONE REQUIRED
	NEG	NEG	Not Done	Not Done	Yes	No	**No COVID-19 infection, low confidence**. Could be in the window period.	QUARANTINE
	POS	NEG	Not Done	Not Done	Yes	No	**Possible COVID-19 infection**. Manage as presumed COVID-19. False positives can occur.	ISOLATION (PRESUMPTIVE)
	NEG	POS	Not Done	Not Done	Yes	No	**Possible COVID-19 infection (at later stage of infection).** False positive (a cross-reaction to a different coronavirus) is very possible, especially in a low prevalence setting and no contact. Err on side of caution and quarantine.	QUARANTINE
	POS	POS	Not Done	Not Done	Yes	No	**Possible COVID-19 infection**. Manage as presumed COVID-19. False positives can occur.	ISOLATION (PRESUMPTIVE)
Antibody only (with a contact)	NEG	NEG	Not Done	Not Done	No	Yes	**No COVID-19 infection, low confidence.** Could be in the incubation or window period.	QUARANTINE
	NEG	NEG	Not Done	Not Done	Yes	yes	**No COVID-19 infection, very low confidence.** Could be in the incubation or window period. Because the patient is both symptomatic and a contact, isolation should be considered in highly suspected cases.	QUARANTINE or ISOLATE
	POS	NEG	Not Done	Not Done	Yes or No	Yes	**Presumed COVID-19 infection, medium confidence**. False positives can occur.	ISOLATION (PRESUMPTIVE)
	NEG	POS	Not Done	Not Done	Yes or No	yes	**Possible COVID-19 infection (at later stage of infection).** Manage as presumed COVID-19. False positives can occur.	ISOLATION (PRESUMPTIVE)
	POS	POS	Not Done	Not Done	Yes or No	yes	**Presumed COVID-19 infection, medium confidence**. False positives can occur.	ISOLATION (PRESUMPTIVE)
Antibody and RT-PCR / Xpert	NEG	NEG	Not Done	NEG	No	No	**No evidence of COVID-19 infection, high confidence.** No quarantine required.	NONE REQUIRED
	NEG	NEG	Not Done	NEG	Yes or No	Yes	**No COVID-19 infection, medium probability**. Could be a false negative. Quarantine because the patient is a contact. Consider isolation if both symptomatic and a contact.	QUARANTINE or ISOLATE
	POS	NEG	Not Done	NEG	Yes or No	Yes or No	**Presumed COVID-19 infection**. Manage as presumed COVID-19. False positive can occur with antibody test and false negative can occur with RT-PCR test.	ISOLATION (PRESUMPTIVE)
	NEG	POS	Not Done	NEG	Yes or No	Yes or No	**Possible COVID-19 infection (at later stage of infection).** Antibody false positive (a cross-reaction to a different coronavirus) is very possible, especially in a low prevalence setting and no contact. Err on side of caution and quarantine or isolate. Consider isolation if both symptomatic and a contact.	QUARANTINE or ISOLATE
	POS	POS	Not Done	NEG	Yes or No	Yes or No	**Presumed COVID-19 infection**. Manage as presumed COVID-19. False positive can occur with antibody test and false negative can occur with RT-PCR test.	ISOLATION (PRESUMPTIVE)
	NEG or POS	NEG or POS	Not Done	POS	Yes or No	Yes or No	**Confirmed COVID-19 infection.** False positive is rare with RT-PCR testing.	ISOLATION (CONFIRMED)

TABLE 5: **Interpretation of Ag RDT and RT-PCR/SARS CoV-2 Xpert**

Combination of tests	Ab-IgM	Ab-IgG	Ag	PCR / Xpert	Symptoms	Contact	Interpretation of test and management of patient	Quarantine or isolation
Antigen only	Not Done	Not Done	NEG	Not Done	No	No	**No COVID-19 infection, medium confidence**. False negatives can occur.	NONE REQUIRED
	Not Done	Not Done	NEG	Not Done	No	Yes	**No COVID-19 infection detected, low confidence**. False negatives can occur.	QUARANTINE
	Not Done	Not Done	NEG	Not Done	Yes	No	**No COVID-19 infection detected, medium confidence**. False negatives can occur.	QUARANTINE
	Not Done	Not Done	NEG	Not Done	Yes	Yes	**No COVID-19 infection detected, very low confidence.** False negatives can occur. Because the patient is both symptomatic and a contact, isolation should be considered in highly suspected cases.	QUARANTINE or ISOLATE
	Not Done	Not Done	POS	Not Done	Yes or No	Yes or No	**Presumed COVID-19 infection.** False positives are not common with antigen test.	ISOLATION (PRESUMPTIVE)
Antigen and RT-PCR / Xpert	Not Done	Not Done	NEG	NEG	No	No	**No COVID-19 infection, high confidence.** False negatives can occur.	NONE REQUIRED
	Not Done	Not Done	NEG	NEG	No	Yes	**No COVID-19 infection detected, medium confidence**. False negatives can occur, but less common when both antigen and PCR tests are used.	QUARANTINE
	Not Done	Not Done	NEG	NEG	Yes	No	**No COVID-19 infection detected, medium confidence.** False negatives can occur, but less common when both antigen and PCR tests are used.	QUARANTINE
	Not Done	Not Done	NEG	NEG	Yes	Yes	**No COVID-19 infection detected, low confidence.** False negatives can occur. Because the patient is both symptomatic and a contact, isolation should be considered in highly suspected cases.	QUARANTINE or ISOLATE
	Not Done	Not Done	NEG or POS	POS	Yes or No	Yes or No	**Confirmed COVID-19 infection**. False positives are rare with PCR tests.	ISOLATION (CONFIRMED)

TABLE 6: **Interpretation of RT-PCR/ SARS CoV-2 Xpert when RDTs are not performed**

Combination of tests	Ab-IgM	Ab-IgG	Ag	PCR / Xpert	Symptoms	Contact	Interpretation of test and management of patient	Quarantine or isolation
RT-PCR / Xpert only	Not Done	Not Done	Not Done	NEG	No	No	**No COVID-19 infection detected, medium to high confidence.** False negatives can occur.	NONE REQUIRED
	Not Done	Not Done	Not Done	NEG	Yes	No	**No COVID-19 infection detected, medium confidence**. False negatives can occur. Self-quarantine (because of having symptoms).	QUARANTINE
	Not Done	Not Done	Not Done	NEG	Yes or No	Yes	**No COVID-19 infection detected, medium confidence**. False negatives can occur. Self-quarantine (because of being a close contact).	QUARANTINE
	Not Done	Not Done	Not Done	POS	Yes or No	Yes or No	**Confirmed COVID-19 infection**. False positives are rare with PCR tests. Isolate.	ISOLATION (CONFIRMED)

TABLE 7: **Interpretation of Ab, Ag, and RT-PCR/ SARS CoV-2 Xpert**

Combination of tests	Ab - IgM	Ab - IgG	Ag	PCR / Xpert	Symptoms	Contact	Interpretation of test and management of patient	Quarantine or isolation
Antibody and Antigen (with or without) RT-PCR testing / Xpert	NEG	NEG	NEG	NEG or Not done	No	No	**No COVID-19 infection, medium to high confidence.**	NONE REQUIRED
	NEG	NEG	NEG	NEG or Not done	Yes	No	**No COVID-19 infection, medium confidence**. False negatives can occur.	QUARANTINE
	NEG	NEG	NEG	NEG or Not done	Yes or No	Yes	**No COVID-19 infection, medium confidence**. False negatives can occur. Consider isolation if both symptomatic and a contact.	QUARANTINE or ISOLATE
	POS	NEG	NEG	NEG or Not done	Yes or No	Yes or No	**Possible COVID-19 infection**. Manage as presumed COVID-19. False positives can occur.	ISOLATION (PRESUMPTIVE)
	POS	NEG	POS	NEG or Not done	Yes or No	Yes or No	**Presumed COVID-19 infection**. False positives of antigen test are not common.	ISOLATION (PRESUMPTIVE)
	NEG	POS	NEG	NEG or Not done	Yes or No	Yes or No	**Possible old COVID-19 infection.** Antibody false positive are possible, especially in a low prevalence setting and no contact. Quarantine or isolate. Consider isolation if both symptomatic and a contact.	QUARANTINE or ISOLATE
	NEG	POS	POS	NEG or Not done	Yes or No	Yes or No	**Presumed COVID-19 infection**. False positives of antigen test are not common. Isolate.	ISOLATION (PRESUMPTIVE)
	POS	POS	NEG	NEG or Not done	Yes or No	Yes or No	**Possible COVID-19 infection**. Manage as presumed COVID-19. False positives can occur. Isolate	ISOLATION (PRESUMPTIVE)
	NEG or POS	NEG or POS	NEG or POS	POS	Yes or No	Yes or No	**Confirmed COVID-19 infection**. False positives of PCR test are extremely rare. Isolate.	ISOLATION (CONFIRMED)

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RAPID DIAGNOSTIC TESTS FOR COVID-19

RAPID DIAGNOSTIC TESTS (RDTs) CAN DETECT EITHER ANTIGEN (Ag) OR ANTIBODY (Ab), AND BOTH TEST TYPES HAVE IMPORTANT ROLES GIVEN THE CURRENT EPIDEMIC CONTEXT (COMMUNITY TRANSMISSION)

A combination of different test types is needed to facilitate patient management and public health planning for effective control of COVID-19. Tests that **directly detect the virus (polymerase chain reaction [PCR] or Ag) should be prioritized for diagnosis and monitoring**; while tests that detect the immune response to the virus **(Ab)**, can be complementary for clinical care, but **should be prioritized for seroprevalence and epidemiological purposes**. Importantly, the utility of any test is dependent on several factors: 1) the test performance (i.e. sensitivity and specificity), 2) the epidemiological context in which it is used (i.e. the disease prevalence), and 3) the timing of test use in relation to disease kinetics (especially true for Ab tests). (See page 4 for more details.)

GENERAL INFORMATION ON Ag- AND Ab-DETECTION RDTs FOR COVID-19

- RDTs can enable fast (15–40 minutes), decentralized access to testing, but generally have decreased performance compared with lab-based tests:
  - Tests with the **highest possible sensitivity must be prioritized** to minimize false negatives, as these may lead to missing cases.
  - High **specificity** is also important, **particularly as prevalence decreases.**

- Ag tests directly detect SARS-CoV-2 virus, will be positive within a few days after infection, and will become negative as the patient clears the infection and recovers. Therefore, **Ag tests are useful for detection of active infection.**

- Ab tests detect the host response to the virus and take several more days to become positive – they are likely to be most accurate 10–14 days post infection. **Ab tests cannot distinguish between active and previous infection.** Current data are limited on the correlation between antibody detection and immunity/protection.

- **Positive results from either Ag or Ab tests, together with the presence of respiratory symptoms**, indicate that an individual is likely to be actively infected with SARS-CoV-2 (dependent on the positive predictive value of the test). Without waiting for confirmatory testing, the individual should undergo home isolation, or healthcare facility admission if symptoms require advanced care.
  - In individuals **without symptoms and no known contact** with a person suspected to have COVID-19 in the past 14 days, a positive Ab test followed by a negative PCR test indicates prior infection.

- **Negative results from either Ag or Ab tests should be interpreted with caution (dependent on the negative predictive value of the test)**; for suspect cases with negative results, consider accessing a more sensitive test for confirmation (i.e. PCR), and/or home isolation followed by a second test at a later date.

SUGGESTED USES FOR Ag- AND Ab-DETECTION RDTs GIVEN OUR CURRENT UNDERSTANDING

- **Ag RDTs** should be prioritized for **case management** to enable decentralized testing, especially when access to PCR testing is limited.

- **Ab RDTs** should be prioritized for **seroprevalence surveys** to inform public health measures and testing of contacts to establish previous spread of the virus.

Suggested use		Ag	Ab
Case management in high prevalence/ active outbreak settings	Triage suspect cases **Positive:** no confirmatory testing required **Negative:** confirmatory testing with PCR recommended, if available	✓	
	Aid diagnosis in symptomatic cases presenting late (≥10 days post-symptom onset) In addition to PCR/Ag, not a replacement		✓
	Monitor active infection	✓	
Public health measures	Screen contacts for infection	✓	
	Screen contacts for previous exposure (≥10 days post exposure)		✓
	Seroprevalence surveys to define levels of population exposure,* including vaccine trial support		✓

* Insufficient data supporting effectiveness of protection or duration of immunity.

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UNIQUE FEATURES OF SARS-COV-2 THAT ARE IMPORTANT TO CONSIDER WHEN USING RDTs

- SARS-CoV-2 is a **respiratory pathogen**, unlike malaria, HIV, dengue, Zika or chikungunya viruses.

- The immune response to SARS-CoV-2 may be atypical:
  - Other viruses: IgM is detectable in the blood during active infection and then wanes after a few weeks, whereas IgG levels rise after the acute phase.
  - SARS-CoV-2: Preliminary studies suggest that **IgM and IgG rise** during early infection and may remain high for weeks, though more data are needed.

- Respiratory specimens may contain high levels of virus **days before the onset of symptoms**, even in **individuals who remain asymptomatic**.

- In a pandemic situation, where there are no specific treatments and the goal is to minimize spread of the infection by breaking the chain of transmission, tests with the **highest possible sensitivity** must be selected to minimize the possibility of missing any active cases:
  - To reduce the burden on confirmatory testing in high prevalence settings, a positive result from a screening test (even with low specificity and thus a higher probability of false positivity) may not require confirmation.
  - In this scenario, all individuals who screen positive should undergo home isolation, or be admitted to a healthcare facility if symptoms are severe and warrant hospitalization.

OPERATIONAL CHARACTERISTICS AND OVERVIEW		
	Antigen (Ag)	**Antibody (Ab) (IgA, IgM and/or IgG)**
How does it work?	Directly detects the presence of the virus, indicating **active infection** (i.e. replication of the virus)	Detects the body's immune response to the virus, in the form of antibodies (IgA, IgM, IgG or in combination), which are produced during **active infection**, but also persist after the virus is no longer detected, indicating **previous infection**
Sample type	Nasopharyngeal, nasal, or oropharyngeal swab; potentially oral fluid or stool	Fingerstick blood, venous blood; potentially oral fluid
Where and who performs?	Trained healthcare workers, wearing appropriate personal protective equipment (PPE) at decentralized points of need	
Benefits	Enables fast, **decentralized access to direct testing** for the virus, relieving the burden on the laboratory testing system If used for contact tracing, provides an **objective marker to define chains of transmission**	Best biomarker for **estimation of the number of people previously infected**: enables more accurate estimates of case fatality rates, serial sampling can be used to estimate incidence In **high prevalence** settings, may be useful to **triage symptomatic patients in a later phase of disease** and reduce the burden on the laboratory testing system (relieve bottlenecks): positive results can trigger clinical action; negative results should reflex to PCR for confirmatory testing, if available In **low prevalence** settings, the use of Ab tests to triage symptomatic patients is unlikely to be beneficial due to low PPV

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TEST UTILITY IS RELATED TO THE TEST PERFORMANCE (SENSITIVITY/SPECIFICITY) AS WELL AS THE EPIDEMIC SETTING (i.e. PREVALENCE IN THE POPULATION)

The number of true positives and true negatives is dependent on the prevalence of the population being tested, as illustrated in the table on the next page.

INTERPRETATION OF TEST RESULTS		
	Antigen (Ag)	**Antibody (Ab) (IgA, IgM and/or IgG)**
A true positive result…	Means SARS-CoV-2 is present; the person is actively infected and should home isolate or be admitted to a healthcare facility → Continue contact tracing to define chains of transmission and contain disease spread	Indicates an active or past infection → In the absence of symptoms or recent (past 14 days) exposure, indicates previous infection and potential immunity;* followed by a negative PCR test, confirms previous infection and excludes active infection
A true negative result…	Means the person is uninfected → If the test has a low negative predictive value, in the presence of symptoms, the result may be a false negative; home isolate while waiting for a confirmatory PCR test, or a re-test with an Ag RDT in a few days → If the test has a low negative predictive value in the absence of symptoms, monitor for onset of symptoms and consider a confirmatory test	Means the person has no detectable Ab and therefore has not been infected or is early in the course of active infection before antibodies can be detected (i.e. window period) → Difficult to interpret if used to screen for active infection: in the presence of symptoms, could mean that the person is early in the course of active infection, before antibodies can be detected (i.e. window period); follow with a confirmatory test that directly detects the virus (i.e. PCR or Ag)
A false positive result…	Means the person is uninfected, but will be unnecessarily directed to home isolate or be admitted to a healthcare facility to manage symptoms If in the presence of symptoms, means that the person is ill with another febrile/respiratory illness and may not be appropriately treated	If used to screen for active infection, means that the person is uninfected, but will be unnecessarily directed to home isolate or be admitted to a healthcare facility to manage symptoms If in the presence of symptoms, means that the person is ill with another febrile/respiratory illness and may not be appropriately treated If used to screen for exposure during contact tracing or sero-surveys, means that the person is still susceptible and could be put at risk and pose a risk to others
	❗ Tests with poor specificity/high cross-reactivity could be falsely reactive due to other endemic infections	
A false negative result…	Means that the person is infected, but is missed → The person may not receive the care needed and will contribute to community transmission if not in isolation	If used to screen for active infection, means that the person is infected and likely too early in the infection for antibodies to be detected (i.e. window period), so is missed → The person may not receive the care needed and will contribute to community transmission if not in isolation If used to screen for exposure during contact tracing or serosurveys, means that the person has been infected, but no action is taken

* Insufficient data supporting effectiveness of protection or duration of immunity.

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As seen below, a test with **high performance** (95% sensitivity and 98% specificity), when applied to a **low-prevalence setting,** will result in roughly the same number of true positives and false positives (PPV: ~50%), whereas when applied to a higher prevalence population would result in a much higher positive predictive value (PPV: 95%), with the majority of positive results associated with actual cases. Alternatively, the use of a **mid-or lower-performing test** might be considered for a **high prevalence population** (PPV: 68-78%), but would lead to such high numbers of false positives when testing a **low prevalence population that this would likely do more harm than good**. Across a range of sensitivities and prevalence, the negative predictive value remains relatively high, but the consequence of missed cases for epidemic control and case management can be detrimental.

Cohort	Pre-test probability (prevalence)	Sensitivity	Specificity	Cases	Non-cases	True positive (TP)	False negative (FN)	True negative (TN)	False positive (FP)	PPV	NPV
High performance											
1,000	2.0%	95%	98%	20	980	19	1	960	20	49.2%	100%
1,000	5.0%	95%	98%	50	950	48	2	931	19	71.4%	100%
1,000	10.0%	95%	98%	100	900	95	5	882	18	84.1%	99%
1,000	30.0%	95%	98%	300	700	285	15	686	14	95%	98%
Mid performance											
1,000	2.0%	85%	90%	20	980	17	3	882	98	14.8%	100%
1,000	5.0%	85%	90%	50	950	43	8	855	95	30.9%	99%
1,000	10.0%	85%	90%	100	900	85	15	810	90	48.6%	98%
1,000	30.0%	85%	90%	300	700	255	45	630	70	78%	93%
Low performance											
1,000	2.0%	75%	85%	20	980	15	5	833	147	9.3%	99%
1,000	5.0%	75%	85%	50	950	38	13	808	143	20.8%	98%
1,000	10.0%	75%	85%	100	900	75	25	765	135	35.7%	97%
1,000	30.0%	75%	85%	300	700	225	75	595	105	68%	89%

The expected prevalence of active or previous COVID-19 infection will vary across populations being tested and is therefore an important consideration when selecting tests and interpreting results. Example prevalence ranges for some target populations are summarized below.

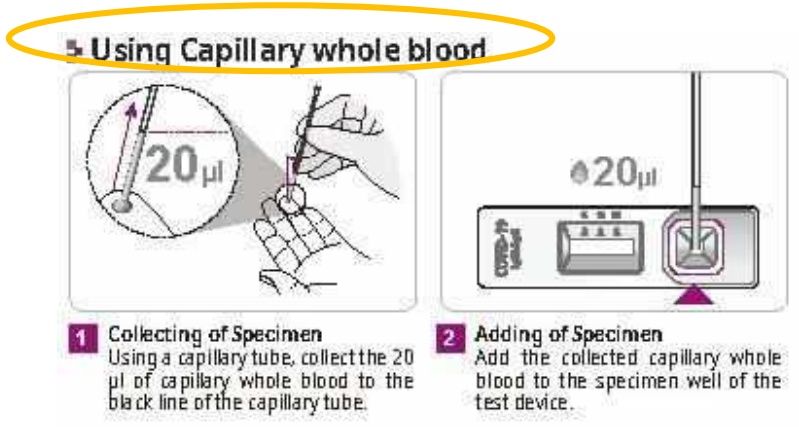
Target population	Example prevalence range
Symptomatic healthcare workers	High to very high (10 – ≥ 30%)
Healthcare workers with significant exposure	High (10%)
Contacts of index patient	Low to high (2 – 10%)
Community testing/contact tracing of hotspots	Medium to high (5 – ≥ 10%)
Symptomatic general population	Low (2%)
Asymptomatic general population	Very low to low (≤ 2%)

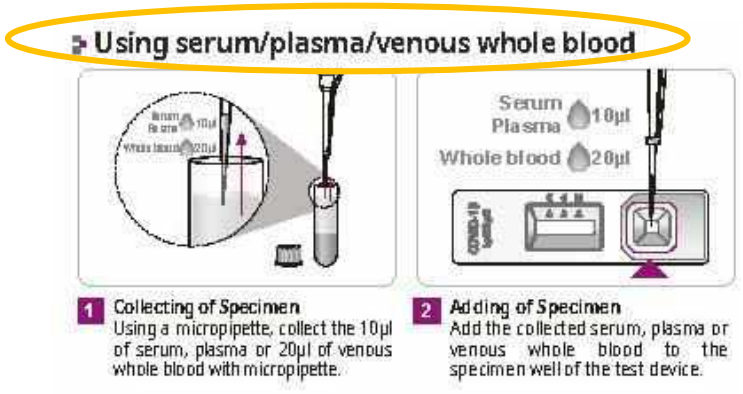
JOB AID: Test Procedure for Ab (IgM/IgG) COVID-19 RDT*

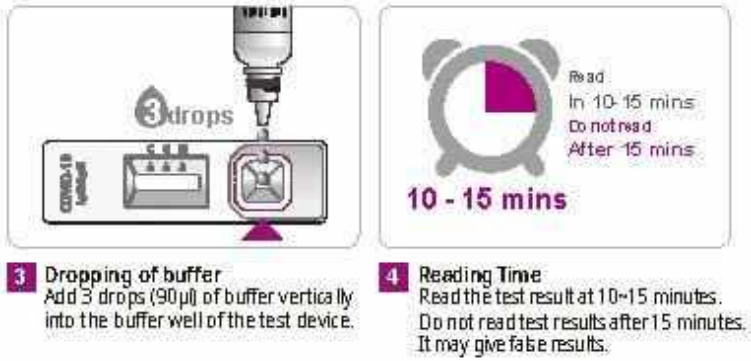
* Test Name: **Standard Q COVID-19 IgM/IgG Combo Test /** Manufacturer: **SD Biosensor**

Steps:

1) **Collect specimen:**
   - Capillary, whole blood (20µL)
   - Venous, whole blood (20µL)
   - Serum/plasma (10µL)
2) **Add specimen to well.**
3) **Place 3 drops of buffer into well.**
4) **Read results at 10-15 minutes.**
5) **Write all results on the laboratory worksheet and report form.**
6) **Dispose the test devices & pipettes as biohazard materials.**
7) **Clean work surfaces and all materials used for the test with disinfectant.**







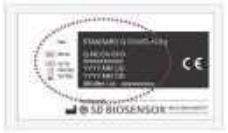
JOB AID: Test Procedure for Ag COVID-19 RDT*

* Test Name: **STANDARD™ Q COVID-19 Ag LFA test /** Manufacturer: **SD Biosensor**

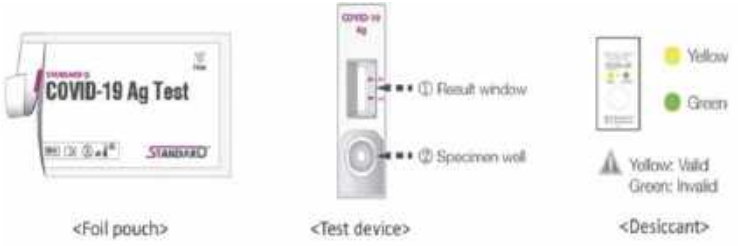
Preparation

1. Carefully read instructions (package insert).

1. Check the expiration date on the back of the foil pouch.



3. Open the foil pouch and check both the test device and the desiccant pack in the foil pouch.



4. Allow test device to warm up to room temperature.

Procedure

1. Safely collect nasopharyngeal swab. Specimen should be tested as soon as possible after collection. Note stability times and temperatures from instructions.

For fresh specimen (no VTM):

2. Insert the swab into an extraction buffer tube. While squeezing the tube, stir the swab **more than 5 times.**

For stored specimen (in VTM)**:

2. Add **300µL** of specimen from the collection tube with VTM to the extraction buffer tube.

3. Press the nozzle cap tightly onto the tube.

Procedure con't

1. Apply **3 drops** of the extracted specimen to the specimen well of the test device.

2. Read the test result at **15-30 minutes** (CAUTION: do not read test results after 30 minutes).

3. Write all results on the laboratory worksheet and report form.
4. Dispose the test devices & buffer tubes as biohazard materials.
5. Clean work surfaces and all materials used for the test with disinfectant.

***PIH Laboratory Services highly recommends not using VTM for this test, as dilution in VTM may result in decreased test sensitivity*

Laboratory procedure for IgM/IgG RDT (SD Biosensor, STANDARD Q COVID-19 IgM/IgG ComboTest)

Standard operating procedure (SOP) for testing performed at laboratories and medical facilities by health care personnel.

Product description and principle

The STANDARD Q COVID-19 IgM/IgG Combo Test Kit is a rapid immunochromatography test designed for the qualitative presumptive detection of specific IgM and IgG to SARS-CoV-2 in humoral fluid (capillary whole blood, venous whole blood, serum, or plasma). Either 10µl (serum, plasma) or 20µl (whole blood) of specimen is required and the results are available within 15 minutes. No extra equipment is needed to perform the test, making this suitable for point-of-care (POC) testing.

Clinical evaluation studies have indicated that this test gives 94.51% % sensitivity (from the 7th day after symptom onset) and 95.74 % specificity.

Note:

1. *Positive results* detect the presence of viral antigens, but clinical observation with patient history and other diagnostic information should be considered in order to determine infection status.
2. *Negative results* do not rule out SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions: recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19 should all be considered in the context of the patient, and confirmed with a molecular assay, if possible.

Warnings and precautions

- Wear PPE such as gown, gloves, surgical mask and face shield when collecting or performing the test. Refer to procedure for the proper use of PPEs.
- Clean work surface with available disinfectant before starting work.
- Place absorbent bench liner on work surface to capture potential splatters and splashes.
- Store test kits at 2 - 30°C / 36 - 86°F.
- Test kits have a shelf-life of 24 months.
- Use universal precautions when handling blood samples.
- Discard all materials used for sample collection and test procedures in a biohazard container and/or sharps bin.
- Good laboratory practice recommends the use of the control materials. Users should follow the appropriate guidelines concerning the frequency and use of external control materials. Refer to Section "Laboratory Procedure for External Quality Controls for Antibody and Antigen Rapid Tests" in the PIH Guide to Community and Clinical Management of COVID-19.

Table. Requirements and sample collection

Materials required but not provided:	▪ Proper PPE (for sample collection and test procedure) ▪ Permanent marker **For capillary whole blood samples:** ▪ Lancet ▪ Alcohol wipes

	For serum/plasma/venous whole blood: ▪ Venipuncture materials (tube with EDTA, heparin or sodium citrate, needle and/or syringe) ▪ Micropipette ▪ Sterile filtered tips for micropipette ▪ Centrifuge (for separating serum and plasma)
Materials provided:	• Capillary tube

Sample collection:

1. Blood by Fingerstick:
   - Use the middle or ring finger, ideally of the non-dominant hand.
   - Note: the puncture should be made slightly off center from the fleshy portion of the finger, near the side of the fingertip.
   - Thoroughly disinfect the puncture site using an alcohol pad and let air-dry.
   - Stick the side of the finger with the lancet. Apply only light pressure to the fingertip, until a blood drop appears. Do not press or milk the finger.
   - Discard the lancet into a sharps bin.
   - Wipe away the first 2-3 drops of blood with the alcohol pad. Ensure there is a free blood flow.
   - Collect 10 µl blood with the capillary tube (refer to Test Procedure, below).
2. Venous blood:
   - Collect blood using a tube with anticoagulant (EDTA, heparin, sodium citrate), as per instructions for phlebotomy.

Table. Test procedure

Materials required but not provided:	• Timer • Permanent marker • Proper PPE • Micropipette • Sterile filtered tips for micropipette
Materials provided:	• Capillary tube • IgM/IgG test device

1. Identify the sample ID number on the test devices.
2. Obtain 20µl of sample using the provided capillary tube (up to the black line of the capillary tube) if the specimen is capillary whole blood. For venous whole blood, micropipette 20µl of specimen. For serum, or plasma, micropipette 10 µl of specimen.
3. Dispense specimen into the specimen well of the test device.
4. Discard the capillary tube in a sharps bin.
5. Add 3 drops (90 µl) of buffer vertically into the buffer well of the test device.
6. Read test result at 10 to 15 minutes, but not after 15 minutes. It may give false results.
7. Record all results on the laboratory worksheet and report form.
8. Dispose of the test devices as biohazard materials.
9. Clean work surface with disinfectant at the end of the work.

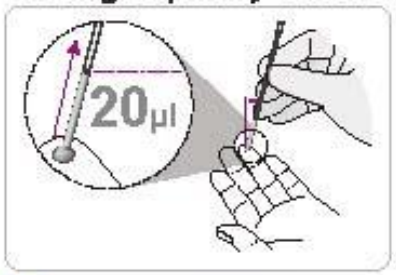
Interpretation of test result

There are three lines in the result window: one control line in the top (C), one test line at the middle for IgG (G), and one test line at the bottom for IgM (M). Look for the presence or absence of colored bands on the corresponding lines:

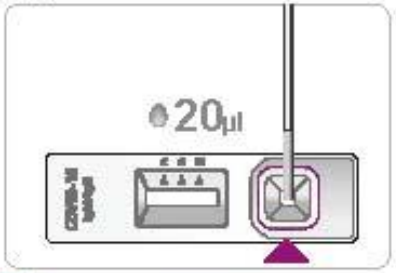
- **Negative Result for IgM:** The band of the control line (C) is colored (dark or faint) and the band of the test line IgM (M) is not colored.
- **Negative Result for IgG:** The band of the control line (C) is colored (dark or faint) and the band of the test line IgG (G) is not colored.
- **Positive Result for IgM**: The band of the control line (C) is colored (dark or faint) and the band of the test line IgM (M) is colored (uniform or not uniform).
- **Positive Result for IgG**: The band of the control line (C) is colored (dark or faint) and the band of the test line IgG (G) is colored (uniform or not uniform).
- **Invalid Result:** No colored band on line C. The band of the test line could be or not colored. Invalid result needs to be repeated with a new test device.

Test Procedure

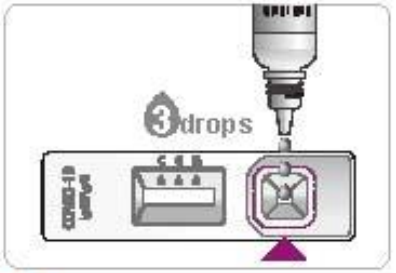
Using Capillary whole blood



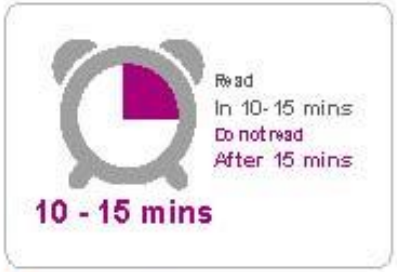
1 Collecting of Specimen
Using a capillary tube, collect the 20 µl of capillary whole blood to the black line of the capillary tube.



2 Adding of Specimen
Add the collected capillary whole blood to the specimen well of the test device.

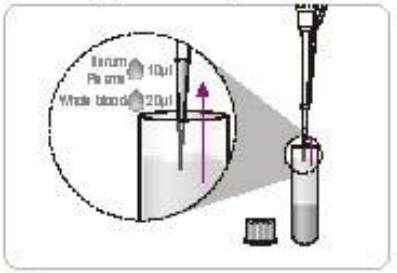


3 Dropping of buffer
Add 3 drops (90µl) of buffer vertically into the buffer well of the test device.

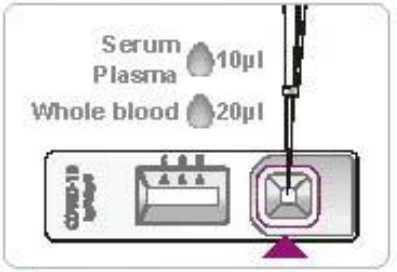


4 Reading Time
Read the test result at 10~15 minutes.
Do not read test results after 15 minutes.
It may give false results.

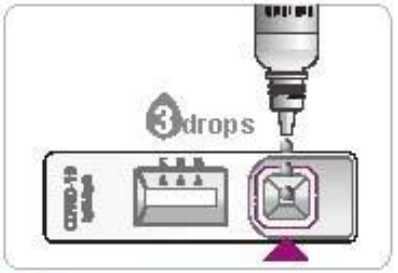
Using serum/plasma/venous whole blood



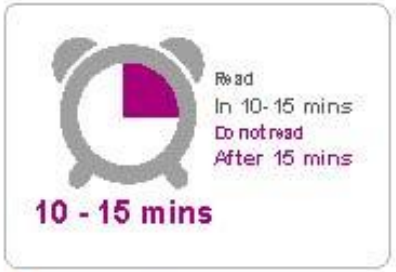
1 Collecting of Specimen
Using a micropipette, collect the 10µl of serum, plasma or 20µl of venous whole blood with micropipette.



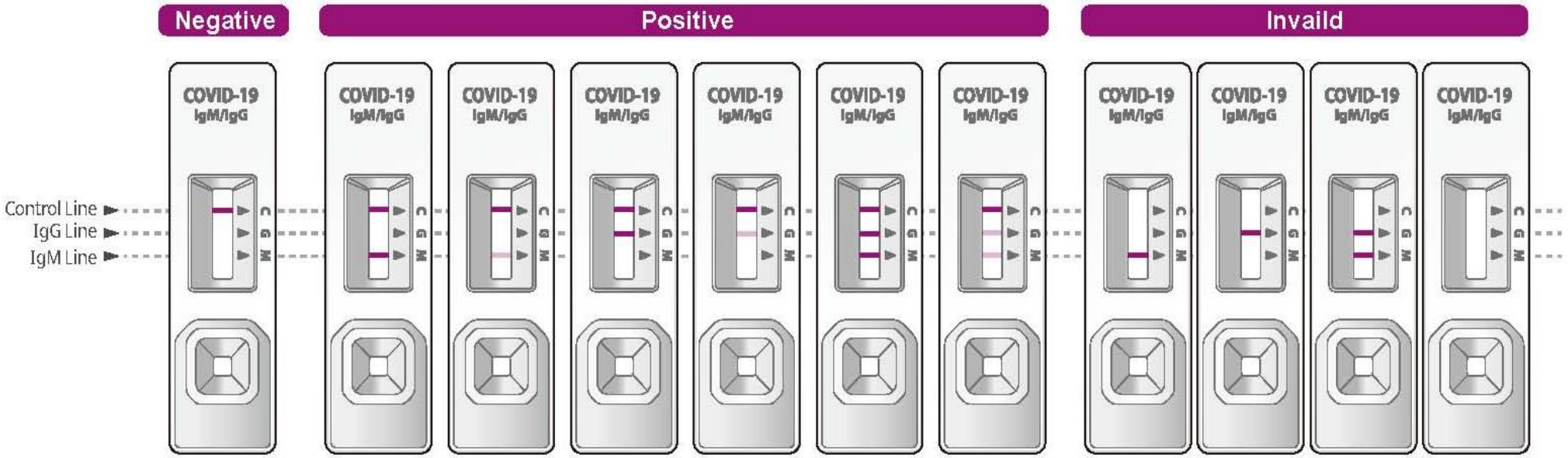
2 Adding of Specimen
Add the collected serum, plasma or venous whole blood to the specimen well of the test device.



3 Dropping of buffer
Add 3 drops (90µl) of buffer vertically into the buffer well of the test device.



4 Reading Time
Read the test result at 10~15 minutes.
Do not read test results after 15 minutes.
It may give false results.



1. A colored band will appear in the top section of the result window to show that the test is working properly. This band is control line (C).
2. A colored bands will appear in the lower section of the result window. These bands are each test line of IgM/IgG (M, G).
3. Even if the control line is faint, or the test line isn't uniform, the test should be considered to be performed properly and the test result should be interpreted as a positive result.

*** STANDARD Q COVID-19 IgM/IgG Combo Test may cross-react with antibody against SARS-CoV-1.**
*** Results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status.**
*** Positive results should be considered in conjunction with the clinical history, RT-PCR results and other data available.**

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Internal quality control

The test device has a built-in control line (C). Appearance of a colored band (dark or faint) at the control line can be considered as an internal positive procedural control. A band at the control line will appear (dark or faint) if the test procedure has been correctly performed. If a band at the control line does not appear, the test is invalid and a new test must be performed.

If the problem persists, please contact your local vendor or SD BIOSENSOR.

Limitations of test

1. The test procedure, precautions, and interpretation of results must be followed strictly.
2. STANDARD Q COVID-19 IgM/IgG Combo test may cross-react with antibodies against SARS-CoV-1.
3. Results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status.
4. Positive test results should be considered in conjunction with clinical history, RT-PCR results, and other data available.
5. For more accuracy of immune status, additional follow-up testing using other laboratory methods is recommended.
6. Neither the quantitative value nor the rate anti- SARS-CoV-2 IgM/IgG concentration can be determined by this qualitative test.
7. Failure to follow the test procedure and interpretation of test results may adversely affect test performance and/or produce invalid results.

Section References:

1. Instructions for using STANDARD Q COVID-19 IgM/IgG Combo Test, http:sdbiosensor.com/xe/product/12509

2. PIH Guide to Community and Clinical Management of COVID-19, https://partnersinhealth.sharepoint.com/:f:/r/sites/COVID19/PIH%20Clinical%20Guides%20Protocols%20%20Job%20Aids%20for%20COVID1/Guides%20for%20Clinical%20and%20Community%20Management%20of%20COVID-19?csf=1&web=1&e=I3oPIb.

Laboratory Procedure for Lateral Flow Immunoassay Ag RDT for Detection of SARS-CoV-2 Antigen (SD Biosensor STANDARD™ Q COVID-19 Ag)

Standard operating procedure (SOP) for testing performed at laboratories and medical facilities by health care personnel.

Product description

The STANDARD Q COVID-19 Ag Test is a lateral flow immunoassay used for the qualitative detection of nucleocapsid antigen protein from SARS-CoV-2 in nasopharyngeal swabs from persons suspected of COVID-19 infection.

Test principle

The STANDARD Q COVID-19 Ag test is a rapid lateral flow immunochromatography test designed for the qualitative presumptive detection of SARS-CoV-2 nucleocapsid antigen from nasopharyngeal swabs collected during the acute phase of infection.

The test device (cartridge or cassette) contains a nitrocellulose membrane with two colorless, pre-coated lines: "C" control line and "T" test line. The control line region is coated with mouse monoclonal anti-chicken IgY antibodies. The test line region is coated with mouse monoclonal anti-SARS-CoV-2 antibodies. These mouse monoclonal anti-SARS-CoV-2 antibodies are conjugated with color particles and serve as indicators for the presence of SARS-CoV-2 antigen. This occurs when SARS-CoV-2 antigen (if present in the specimen) interacts with monoclonal anti-SARS-CoV-2 antibody conjugated with color particles, forming an antigen-antibody color particle complex. Via capillary action, this complex then migrates on the nitrocellulose membrane up to the test line, where (if present), it is captured by the mouse monoclonal anti-SARS-CoV-2 antibody.

A colored test line becomes visible in the result window if SARS-CoV-2 antigens are present in the specimen. The intensity of the colored test line will vary, dependent upon the amount of SARS-CoV-2 antigen present. A test line with no color indicates that SARS-CoV-2 antigens are not present in the specimen. The control line serves as a procedural control and should always appear (with color) if the test procedure was performed properly and the test reagents are working.

Note:

- *Positive results* detect the presence of viral antigens, but clinical observation with patient history and other diagnostic information should be considered in order to determine infection status.
- *Negative results* do not rule out SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions: recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19 should all be considered in the context of the patient, and confirmed with a molecular assay, if possible.

Warnings and precautions

- The package insert must be read completely before performing the test. Failure to do so may yield inaccurate test results.
- Wear PPE such as gown, gloves, surgical mask, and face shield when collecting sample and/or performing the test. Refer to procedure for the proper use of PPEs. Wash hands thoroughly after the test is done.
- Observe biosafety measures and good laboratory practices when handling specimen or performing the test, such as:
    - Clean work surface with disinfectant available before starting work.
    - Place absorbent bench liner on work surface to capture potential splatters and splashes.
    - Clean up spills thoroughly using an appropriate disinfectant.
    - Handle all specimens as if they contain infectious agents.
    - Dispose of all specimens and test materials as bio-hazard waste.
    - Laboratory chemical and biohazard wastes must be handled and discarded in accordance with all local, state, and national regulations.
    - Clean the work bench and all non-disposable materials with disinfectant at the end of the work.
- Store the kit at room temperature or between 2-30°C / 36-86°F and out of direct sunlight.
- Kit materials are stable until the expiration date printed on the outer box.
- Do not freeze the kit.
- Do not re-use the test kit.
- Do not use the buffer of another lot.
- Do not use expired test devices.

- Do not use the test kit if the pouch is damaged or the seal is broken.
- Prior to starting the procedure, all reagents of the test kit must be brought to room temperature (15-25°C / 59-77°F).
- Test results should be read between 15 and 30 minutes after a specimen is applied to the sample well. Results read after 15 minutes may give erroneous results.
- Do not smoke, eat, or drink while handling specimen and performing test.
- Handle all specimens as if they contain infectious agents.
- Observe established precautions against microbiological hazards throughout the entire testing procedure.
- Desiccant is present in the foil pouch to absorb moisture and prevent humidity from affecting products. If moisture is present, the desiccant beads change from yellow to green, indicating that the test device in the pouch should be discarded.
- Good laboratory practice recommends the use of the control materials. Users should follow the appropriate guidelines concerning the frequency and use of external control materials. Refer to Section "Laboratory Procedure for External Quality Controls for Antibody and Antigen Rapid Tests" in the PIH Guide to Community and Clinical Management of COVID-19.

Sample collection

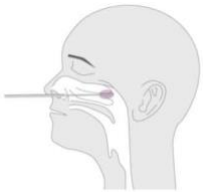
Please note that inadequate sample collection and transport may impact the sensitivity of the PCR or GeneXpert test. A deep nasopharyngeal swab is necessary and often evokes coughing, that is why personnel collecting the sample must be in PPE.

Materials required but not provided:	• Proper PPE • Permanent marker • Viral Transport Medium (VTM) – optional, may not be required
Materials provided:	• Sterile swab

Sample Collection

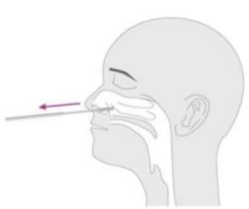
Nasopharyngeal swab

1. Seat the patient comfortably.
2. Using gentle rotation, insert the sterile swab (parallel to the floor of nose without pointing upwards) into the nostril of the patient, reaching the surface of the nasopharyngeal wall (posterior nasopharynx).



3. Rotate the sterile swab a few times against the nasopharyngeal wall.

4. Remove the sterile swab from the nasal cavity, carefully.



5. Specimen should be labeled with sample number and collection date.

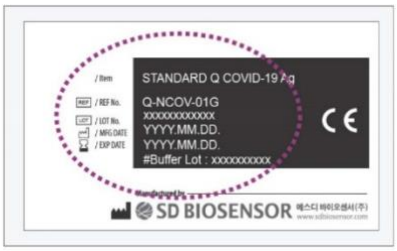
6. Specimen ("fresh specimen") should be tested as soon as possible after collection.
   - Specimen in **extraction buffer** is stable for:
     - Up to 1 hour at room temperature (20 ± 5°C)
     - Up to 4 hours when stored refrigerated at 5 ± 3°C
     - Only for one (1) freeze/thaw cycle when stored frozen at -20°C
   - Specimen in a **clean, dry, closed container (tube)** may be stored:
     - Up to 24 hours at room temperature (20 ± 5°C)
     - Up to 48 hours at 5 ± 3°C / 36-46°F

7. If transport of specimen in Viral Transport Medium (VTM) is required, minimal dilution of the sample is recommended – dilution may result in decreased test sensitivity. (***NOTE**: for this reason, PIH Laboratory Services highly recommends <u>not</u> using VTM for this test).*
   - Specimens in VTM ("stored specimen") are stable for:
     - Up to 8 hours at room temperature (20 ± 5°C)
     - Up to 12 hours when stored refrigerated at 5 ± 3°C
     - Only for one (1) freeze/thaw cycle when stored frozen at -20°C

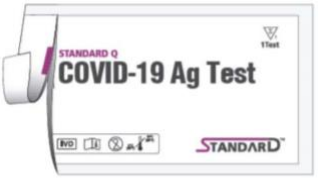
Test Preparation

1. Carefully read the instructions (package insert) for using the STANDARD Q COVID-19 Ag Test.

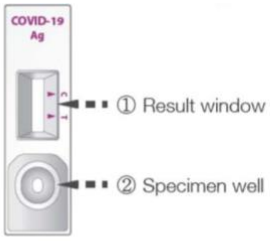
2. Check the expiration date on the back of the foil pouch that the test device is in. Do not use if the expiration date has passed.



3. Open the foil pouch and check both the test device and the desiccant pack in the foil pouch.



<Foil pouch>



<Test device>

<Desiccant>

Test Procedure

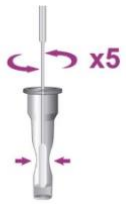
Materials required but not provided:	• Timer • Permanent marker • Proper PPE
Materials provided:	• Test device (individually packed in a foil pouch with desiccant) • Extraction buffer tube with nozzle cap • Filter cap for extraction tube

- Allow specimen (if test is not performed immediately after collection) and test device to be brought up to room temperature (15-25°C / 59-77°F).

- Label the extraction buffer tube with sample number.

For fresh specimen (swab, no VTM)

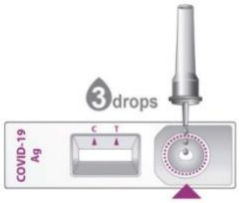
1. Insert the swab into an extraction buffer tube. While squeezing the buffer tube, stir the swab more than 5 times.



2. Remove the swab while squeezing the sides of the tube to extract the liquid from the swab

3. Press the nozzle cap tightly onto the tube.

4. Apply 3 drops of the extracted specimen to the specimen well of the test device.



5. Read the test result at 15-30 minutes (CAUTION: do not read test results after 30 minutes, as it may give false results).

For stored specimen (swab in VTM)

- Using a micropipette, collect 300µL of specimen from the collection tube with VTM.
- Apply the collected specimen into an extraction buffer tube.
- Press the nozzle cap tightly onto the tube (same as for fresh specimen, shown above, step 5).
- Apply 3 drops of extracted specimen to the specimen well of the test device (same as for fresh specimen, shown above, step 6).

- Read the test result at 15-30 minutes (same as for fresh specimen, shown above, step 7). Caution: do not read test results after 30 minutes, as it may give false results.

External Quality Control

Positive and negative controls are not included with the STANDARD Q COVID-19 Ag Test, however, external controls for this test can be separately purchased from SD Biosensor (Cat No. C-NCOV-01G).
These controls serve as a means for additional quality control to demonstrate a positive or negative reaction. External quality controls should be treated and tested the same as patient specimens.
It is recommended that positive and negative controls be run:

a. Once for each new lot
b. Once for each untrained operator
c. Once for each new shipment of test kits
d. As required by test procedures in these instructions and in accordance with local, state, and federal regulations or accreditation requirements

Important: ensure that test results from positive and negative controls are recorded and securely saved for quality purposes.

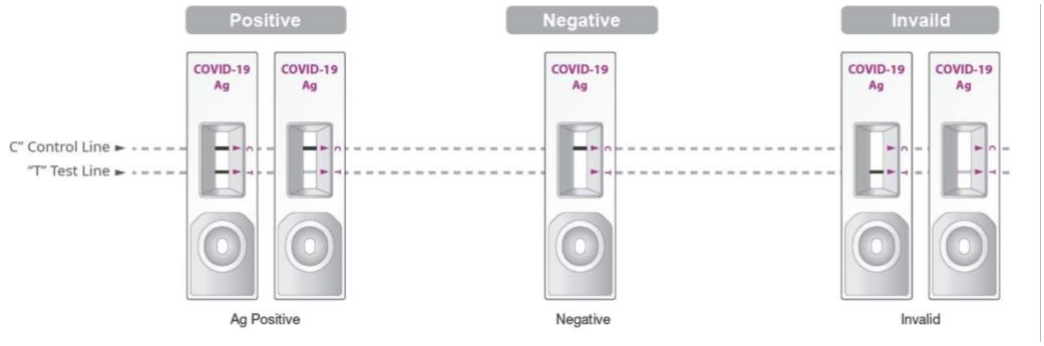
Interpretation of Test

A colored band will appear in the top section of the result window to indicate that the test is working properly. This band is the control line, "C".

A colored band will appear in the lower section of the result window to indicate that SARS-CoV-2 antigen is detected. This is the test line, "T".

Even if the control line is faint or the test line is not uniform, the test should be considered to have performed properly and the test result should be interpreted as a positive result.

Caution: the presence of any line, *no matter how faint the result*, is considered positive. Positive results should be considered in concert with the clinical history and other data available (see "Note" under Test Principle, above).



Limitation of Test

- **Please note that inadequate sample collection and transport may impact the sensitivity of the PCR or GeneXpert test. A deep nasopharyngeal swab is necessary and often evokes coughing, that is why personnel collecting the sample must be in PPE.**
- The test procedure, precautions, and interpretation of results for this test must be followed strictly when testing.

- Failure to follow the Test Procedure as described above and in the package insert, may adversely affect test performance and/or invalidate the test result.
- The test should be used for the detection of SARS-CoV-2 antigen from human nasopharyngeal swab specimens.
- This test detects viable (live) and non-viable SARS-CoV **and** SARS-CoV-2 in the sample specimen. Test performance depends on the amount of virus (antigen) in the sample and may or may not correlate with viral culture results performed on the same sample.
- A negative test result may occur if the level of antigen in a specimen is below the limit of detection of the test, or if the sample was collected and/or transported improperly.
- Test results must be considered with other clinical data available to the clinician.
- Neither the quantitative value nor the rate of SARS-CoV-2 antigen concentration can be determined by this qualitative test.
- Negative results should be treated as presumptive and confirmed with a US FDA authorized molecular assay, if necessary, for clinical management, including infection control.
- If the differentiation of specific SARS viruses and strains is need, additional testing is required.
- Positive test results do not rule out co-infection with other pathogens.
- Positive test results do not differentiate between SARS-CoV and SARS-CoV-2.
- Children tend to shed virus for longer periods of time than adults, which may result in differences in sensitivity between adults and children.

Section References:

- Instructions for using STANDARD Q COVID-19 Ag Test http://sdbiosensor.com/xe/product/7672
- PIH Guide to Community and Clinical Management of COVID-19, https://partnersinhealth.sharepoint.com/:f:/r/sites/COVID19/PIH%20Clinical%20Guides%20Protocols%20%20Job%20Aids%20for%20COVID1/Guides%20for%20Clinical%20and%20Community%20Management%20of%20COVID-19?csf=1&web=1&e=lNXcsp
- STANDARD Q COVID-19 Ag Test, Package Insert. SD Biosensor.

Laboratory Procedure for External Quality Controls for Antibody and Antigen Rapid Tests

Standard operating procedure (SOP) for utilization of external quality controls for rapid antibody testing (Part A) and antigen testing (Part B) for COVID-19 testing performed at laboratories and medical facilities by health care personnel.

Control Test Procedure

Both the "STANDARD COVID-19 IgM/IgG Control" and the "STANDARD COVID-19 Ag Control" should be performed in the same manner as unknown specimens according to instructions of the STANDARD Q COVID-19 IgM/IgG Combo Test and the STANDARD Q COVID-19 Ag Test, respectively. It is recommended that these external positive and negative controls be run:

- Once for each new lot number
- Once for each untrained operator
- Once for each new shipment of test kits
- As required by test procedures in these instructions and in accordance with local, state and federal regulations of accreditation requirements.

Warnings and Precautions

- If there is evidence of microbial contamination in the reconstituted control, discard the control.
- Wear PPE such as gown, gloves, surgical mask and face shield when collecting or performing the test. Refer to procedure for the proper use of PPEs.
- Clean work surface with available disinfectant before starting work.
- Place absorbent bench liner on work surface to capture potential splatters and splashes.
- Store test kits at 2 - 30°C / 36 - 86°F.
- Kit materials are stable until the expiration date printed on the outer box.
- Do not use kit materials if the expiry date has passed.
- Handle all materials as though they contain infectious agents and dispose of all materials used for sample collection and test procedures in a biohazard container and/or sharps bin.

Limitation of Test

8. This product is provided for quality assurance purposes and must not be used for calibration or as primary reference preparations in any test procedure.
9. Adverse storage conditions or use of outdated reagents may produce erroneous results.
10. This product should not be used past the expiration date.
11. Alterations in physical appearance may indicate instability or deterioration of this product. If there is evidence of microbial contamination in this product, discard of it properly.

Part A: SD Biosensor STANDARD COVID-19 IgM/IgG Control

Intended Use and Test Principle

The STANDARD COVID-19 IgM/IgG Control ("antibody control") is intended for use as an external positive and negative quality control to monitor the performance of the STANDARD Q COVID-19 IgM/IgG Combo Test (and other IgM/IgG rapid diagnostic testing from SD Biosensor).

The antibody controls should be performed in the same manner as unknown specimens according to instructions of the STANDARD Q COVID-19 IgM/IgG Combo Test.

Requirements

Materials required but not provided:	• Proper PPE • Permanent marker • Distilled water • Micropipette and tips • STANDARD Q COVID-19 IgM/IgG Combo Test devices (3)
Materials provided:	• IgM positive control (tablet from violet colored tube) • IgG positive control (tablet from red colored tube) • Negative control (tablet from transparent tube)

IgM positive control (violet)

IgG positive control (red)

Negative control (transparent)

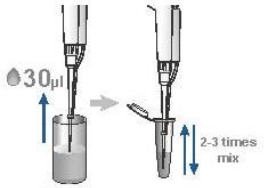
Test Procedure

NOTE: this product should be treated the same as patient specimens and run in accordance with instructions accompanying the STANDARD Q COVID-19 IgM/IgG Combo Test (section in the guide).

10. Allow 3 test devices from the STANDARD Q COVID-19 IgM/IgG Combo Test kit and the control tubes from the STANDARD Q COVID-19 IgM/IgG Control (one positive IgM, one positive IgG, and one negative) to rest at room temperature (15 - 30°C / 59 - 86°F) for at least 30 minutes prior to performing the test.
11. Carefully read the instructions included in the STANDARD COVID-19 IgM/IgG Control test package insert.
12. Label the three STANDARD Q COVID-19 IgM/IgG Combo test devices with "IgM positive control", "IgG positive control" and "negative control", respectively.
13. Check the expiration date of the control on the bottle and of the test device on the pouch. Do not use expired controls and test devices.

14. Open the bottle of the STANDARD COVID-19 IgM/IgG Control and take out one control tube from each. You should have three tubes (violet, red, and transparent).

15. Add 30µl of distilled water using the pipette and mix the distilled water and the control tablet in the control tube at least 2-3 times. **This serves as your "sample" to be loaded in the well of the STANDARD Q COVID-19 IgM/IgG Combo test device**. Repeat for the remaining two control tubes.



16. Continue to test in accordance with the instructions for use with the STANDARD Q COVID-19 IgM/IgG Combo Test.

17. Apply the prepared control mixture (10µl) into the well of the STANDARD Q COVID-19 IgM/IgG Combo test device (the same well you apply sample).
18. Apply 3 drops of buffer into the same well of the STANDARD Q COVID-19 IgM/IgG Combo test device.

Interpretation of test result

1. Interpret the test results in accordance with the instructions for use with the accompanying the STANDARD Q COVID-19 IgM/IgG Combo Test
2. Utilize the following tables as guidance for next steps for the STANDARD COVID-19 IgM/IgG Control:

IgM Positive		
Result	**Interpretation**	**Follow up**
Pass	Positive result for IgM	None
Fail	Negative result for IgM	Re-test*
Invalid	No Control (C) line	Re-test*

IgG Positive		
Result	**Interpretation**	**Follow up**
Pass	Positive result for IgG	None
Fail	Negative result for IgG	Re-test*
Invalid	No Control (C) line	Re-test*

Negative		
Result	**Interpretation**	**Follow up**
Pass	Negative result for IgM and/or IgG	None
Fail	Positive result for IgM and/or IgG	Re-test*
Invalid	No Control (C) line	Re-test*

*Use new test devices and new control for re-test.

3. Record all test results, as per Quality Management Program practices.
4. Dispose of the test devices as biohazard materials.
5. Clean work surface with disinfectant at the end of the work.

Section References:

3. Instructions for using STANDARD Q COVID-19 IgM/IgG Combo Test, http:sdbiosensor.com/xe/product/12509
4. PIH Guide to Community and Clinical Management of COVID-19, https://partnersinhealth.sharepoint.com/:f:/r/sites/COVID19/PIH%20Clinical%20Guides%20Protocols%20%20Job%20Aids%20for%20COVID1/Guides%20for%20Clinical%20and%20Community%20Management%20of%20COVID-19?csf=1&web=1&e=I3oPIb.

5. STANDARD COVID-19 IgM/IgG Control. Package Insert. SD Biosensor.

Part B: SD Biosensor STANDARD COVID-19 Ag Control

Intended Use and Test Principle

The STANDARD COVID-19 Ag Control ("Ag control") is intended for use as an external positive and negative quality control to monitor the performance of the STANDARD Q COVID-19 Ag Test (and other Ag-based diagnostic testing from SD Biosensor).

The antigen controls should be performed in the same manner as unknown specimens according to instructions of the STANDARD Q COVID-19 Ag Test.

Requirements

Materials required but not provided:	• Proper PPE • Permanent marker • Distilled water • STANDARD Q COVID-19 Ag Test devices (2) • STANDARD Q COVID-19 Ag buffer extraction tubes (2)
Materials provided:	• Positive control (tablet from red colored tube) • Negative control (tablet from transparent tube)

Positive control
(red)

Negative control
(transparent)

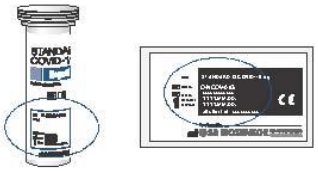
Test Procedure

NOTE: this product should be treated the same as patient specimens and run in accordance with instructions accompanying the STANDARD Q COVID-19 Ag Test (section 7.3 in the guide).

1. Allow 2 test devices from the STANDARD Q COVID-19 Ag Test and 2 tubes from STANDARD COVID-19 Ag Control (one positive and one negative) to rest at room temperature (15 - 30°C / 59 - 86°F) for at least 30 minutes prior to performing the test.

2. Carefully read the instructions included in the STANDARD COVID-19 Ag Control test package insert.

3. Label both STANDARD Q COVID-19 Ag test devices and extraction buffer tubes with “positive control” and “negative control”, respectively. Check the expiration date of the control on the bottle and of the test device on the pouch. Do not use expired controls and test devices.

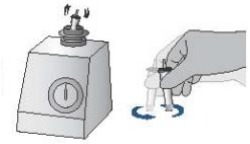


4. Open the bottle of the STANDARD COVID-19 Ag Control and take out one control tube, each. You should have two tubes, one positive and one negative (red and transparent).

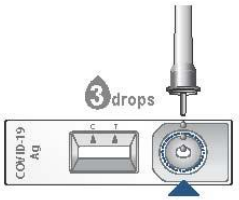
5. Insert the positive or negative control tablet into the correspondingly labeled extraction buffer tube (provided in the STANDARD Q COVID-19 Ag test).

6. Gently press the nozzle cap tightly onto the tube.

7. Mix the control tablet and the extraction buffer using a vortex or by hand swirling. **This mixture now serves as your "sample" to be loaded in the well of the STANDARD Q COVID-19 Ag test device (labeled "positive" or "negative" control)**.



8. Continue to test in accordance with the instructions for use with the STANDARD Q COVID-19 Ag Test.
9. Apply 3 drops of the prepared control mixture into the specimen well of the correspondingly labeled STANDARD Q COVID-19 Ag test device.



Interpretation of test result

1. Interpret the test results in accordance with the instructions for use with the accompanying the STANDARD Q COVID-19 Ag Test.
2. Utilize the following tables as guidance for next steps, for the STANDARD COVID-19 Ag Control:

Positive		
Result	**Interpretation**	**Follow up**
Pass	Positive result for Ag	None
Fail	Negative result for Ag	Re-test*
Invalid	No Control (C) line	Re-test*

Negative		
Result	**Interpretation**	**Follow up**
Pass	Negative result for Ag	None
Fail	Positive result for Ag	Re-test*
Invalid	No Control (C) line	Re-test*

*Use new test devices and new control for re-test.

3. Record all test results, as per Quality Management Program practices.
4. Dispose of the test devices as biohazard materials.
5. Clean work surface with disinfectant at the end of the work.

Section References:

1. Instructions for using STANDARD Q COVID-19 Ag Test,

http:sdbiosensor.com/xe/product/7672
2. PIH Guide to Community and Clinical Management of COVID-19, https://partnersinhealth.sharepoint.com/:f:/r/sites/COVID19/PIH%20Clinical%20Guides%20Protocols%20%20Job%20Aids%20for%20COVID1/Guides%20for%20Clinical%20and%20Community%20Management%20of%20COVID-19?csf=1&web=1&e=I3oPIb.
3. STANDARD COVID-19 Ag Control. Package Insert. SD Biosensor.

References and Additional Resources

1. BMJ Best Practices COVID-19. 2 March 2020 version.
2. Guan et al. Clinical characteristics of coronavirus disease 2019 in China. *NEJM*. Feb 2020.
3. Huang et al. Clinical features of patients infected with 2019 novel coronavirus in Wuhan, China. *Lancet*. Jan 2020.
4. Li Z, Yi Y, Luo X, Xiong N, Liu Y, et al. Development and clinical application of a rapid IgM-IgG combined antibody test for SARS-CoV-2 infection diagnosis. J Med Virol. 2020. doi: 10.1002/jmv.25727
5. Wang D, Hu B, Hu C, Zhu F, Liu X, Zhang J, Wang B, Xiang H, Cheng Z, Xiong Y, Zhao Y, Li Y, Wang X, Peng Z. Clinical Characteristics of 138 Hospitalized Patients With 2019 Novel Coronavirus-Infected Pneumonia in Wuhan, China. *JAMA*. 2020
6. World Health Organization. Advice on the use of masks in the community, during homecare and in health care settings in the context of the novel coronavirus (2019-nCoV) outbreak. January 2020.
7. World Health Organization. Report of the WHO-China Joint Mission on Coronavirus Disease 2019 (COVID-19). February 2020.
8. Zhou et al. Clinical course and risk factors for mortality of adult inpatients with COVID-19 in Wuhan, China: a retrospective cohort study. Lancet. March 2020.
9. Xie, C., et al., Comparison of different samples for 2019 novel coronavirus detection by nucleic acid amplification tests. Int J Infect Dis, 2020.
10. Ai, T., et al., Correlation of Chest CT and RT-PCR Testing in Coronavirus Disease 2019 (COVID-19) in China: A Report of 1014 Cases. Radiology, 2020: p. 200642.
11. Xie, X., et al., Chest CT for Typical 2019-nCoV Pneumonia: Relationship to Negative RT-PCR Testing. Radiology, 2020: p. 200343
12. Li, Y.Y., et al., [Comparison of the clinical characteristics between RNA positive and negative patients clinically diagnosed with 2019 novel coronavirus pneumonia]. Zhonghua Jie He He Hu Xi Za Zhi, 2020. **43**(0): p. E023.
13. Zhengtu Li et al., "*Development and Clinical Application of A Rapid IgM-IgG Combined Antibody Test for SARS-CoV-2 Infection Diagnosis" J. of Med. Virology, published on 2/20/2020*
14. Instructions for using STANDARD Q COVID-19 IgM/IgG Combo Test, http:sdbiosensor.com/xe/product/12509

COVID-19 Data Collection Tools Overview

Digital Data Collection Tools

1. Screening, Intake, and Contact Tracing in CommCare

Click here to view the COVID-19 CommCare Mobile Data Collection Application help documentation and demo videos. The application is available in each site's CommCare project space to be viewed. Please email BostonSIS@pih.org for further demonstrations and support on this application. This application is available in French and English.

2. COVID-19 Inpatient Care in OpenMRS EMR

Click here to view the COVID-19 OpenMRS module help documentation and demo videos. Please email BostonSIS@pih.org for further demonstrations and support implementing these modules. This module is available in French and English.

Printable Paper Forms

Printable forms are provided below and in the PIH COVID 19 Sharepoint folder. There are editable versions of each of these forms in Sharepoint so that sites can tailor them to their specific contexts.

Note: Click on the form areas below to be taken to form descriptions and the following printables:

1. Contact Tracing and Community-based Care
    A. Contact Tracing and Isolation Monitoring Register
    B. Case Monitoring in Community Register
    C. Suspected Case Testing Follow-Up Register

2. Intake, Symptoms Screening, Exposure, and Outcomes
    A. Intake and Symptom Screening for Cases or Contacts
    B. Exposure and Final Outcomes for Cases or Contacts

3. Lab Orders and Test Results
    A. Rapid Test Request and Result Form
    B. Lab Register

4. Facility-based care
    A. Facility Patient Register
    B. Facility Admission Form
    C. Facility Daily Progress Form
    D. Facility Discharge Form

Digital Data Collection Tools

CommCare Mobile Data Collection Application: Documentation and Demo Video for Contact Tracing and Suspect Follow-up Application

The following links will take you to documentation providing an overview of the application's functionality, and to a demo video which will walk you through the application.

Resource	**Links**
Application Overview Documentation	Click Here
Stream Demo Video	Click Here
Download Demo Video	Click Here

OpenMRS Electronic Medical Record System: COVID-19 Inpatient Care Modules

The following links will take you to documentation providing an overview of the OpenMRS module's functionality, and to a demo video which will walk you through the module.

Resource	**Links**
COVID-19 Inpatient Care Module Overview	Click Here
COVID-19 Lab Ordering and Results Entry Overview	Click Here
COVID-19 Patient Admission Demo Video	Click Here

Printable Paper Forms

1. Contact Tracing and Community Monitoring Registers

Find editable versions here.

A. Contact Tracing and Isolation Monitoring Register

What	A register to collect a COVID-19 case's recent contacts. This register allows any contact tracer to find and screen contacts. The register also allows contact tracer to follow up with contacts to monitor for symptom development, refer for testing, and close out contact record at the end of isolation period or upon conversion to a case.
Where	List of contacts can be filled in facility if case is admitted or in community if case is at home/isolation facility. Contact follow up happens in community wherever contact is.
Who	Contact Tracer
When	When a COVID-19 case gives a list of their contacts, then it is maintained at any follow up with contacts

B. Case Monitoring in Community Register

What	A register or patients who are positive but have mild symptoms and are isolating at home/isolation facility. Health workers will need to monitor these people for worsening symptoms and support home-based care.
Where	Community, either at home or an isolation facility where the case is.
Who	Any care team member following up with community-based cases of COVID-19
When	A new person is added to a team member's list when they become responsible for monitoring a case in the community.

C. Suspected Case Testing Follow-Up Register

What	A register for people who are still waiting for confirmatory testing and may not be COVID-19 cases despite symptoms or exposure. Suspected cases move off this list quickly when their diagnosis is presumed, confirmed or ruled-out at the end of the isolation time period.
Where	First filled at the laboratory where patient receives first rapid test. Intended for tracking at community level, but could be adapted for follow up of admitted patients who are also awaiting **confirmatory** test results.
Who	Community care team member who is assigned to follow up with patients who need confirmatory testing
When	When a symptomatic person requires confirmatory testing to determine diagnosis. Suspect is assigned to a community care team member, and moved from the list when it is determined that patient will be isolating in community, or admitted to facility, or is not a COVID-19 case.

COVID-19 Contact Tracing and Isolation Follow Up List

Case ID:	**Age:**	**Case Name:**	**Case phone number:**
Case Address:	**Gender:** □M □F	**Nearest health facility:**	**Date of interview :** (DD/MM/YY) ____/____/_____
Contact Tracer name:		**Contact Tracer phone:**	**Location of interview:** ☐ Facility ☐ Community

Line No.	Assigned Contact ID / Name of Contact	Phone Number / Address of Contact (Town/Village and Landmarks)	Age / Sex	Date of Last Contact with Case (DD/MM/YY)	Scheduled Date of Isolation End (DD/MM/YY)	Date Symptoms Develop (DD/MM/YY)	Referred for testing and results	Assigned Case ID[1]	Final Outcome[2]
1			□M □F	/ /	/ /	/ /	□ refer □ + □-		
2			□M □F	/ /	/ /	/ /	□ refer □ + □-		
3			□M □F	/ /	/ /	/ /	□ refer □ + □-		
4			□M □F	/ /	/ /	/ /	□ refer □ + □-		
5			□M □F	/ /	/ /	/ /	□ refer □ + □-		
6			□M □F	/ /	/ /	/ /	□ refer □ + □-		
7			□M □F	/ /	/ /	/ /	□ refer □ + □-		
8			□M □F	/ /	/ /	/ /	□ refer □ + □-		
9			□M □F	/ /	/ /	/ /	□ refer □ + □-		

1Received on positive test result or presumed positive.

[2]NS=Never had symptoms REC=recovered RF=refuse D=died L=Lost A=admitted

Partners In Health

COVID-19 Case Community Monitoring List Page #_____

Data collector name:	Location:	Date (dd/mm/yyyy):

Line Number	Case Name Assigned Case ID Assigned Contact ID (if case started as a contact)	Address of contact (Town/Village &Landmark) OR (Location of isolation) Phone Number	Sex Age	Date of Symptom Onset (DD/MM/YY)	Date of Scheduled Isolation End (DD/MM/YY)	Develop Severe Symptoms? Refer to health facility?	Still symptomatic at end of Isolation? If Yes → New Date of Isolation End	Final Outcome[1] (See codes below)
1			□ M □ F	/ /	/ /	□ severe □ refer	□ still symptom / /	
2			□ M □ F	/ /	/ /	□ severe □ refer	□ still symptom / /	
3			□ M □ F	/ /	/ /	□ severe □ refer	□ still symptom / /	
4			□ M □ F	/ /	/ /	□ severe □ refer	□ still symptom / /	
5			□ M □ F	/ /	/ /	□ severe □ refer	□ still symptom / /	
6			□ M □ F	/ /	/ /	□ severe □ refer	□ still symptom / /	
7			□ M □ F	/ /	/ /	□ severe □ refer	□ still symptom / /	
8			□ M □ F	/ /	/ /	□ severe □ refer	□ still symptom / /	

[1]REC=Recovered D=Died RF=Refuse Follow up L=Lost A=Admitted

COVID-19 Suspected Case List (for patients who need confirmatory testing)

Name of date collector		Location of data collector	

#	Date of initial diagnostic test (DD/MM/YY)	Case ID or Contact ID	Full Name	Age	Address of Suspected Case (Town/Village and Landmarks)	Date of First Rapid Test (DD/MM/YY)	Scheduled Date of Second Rapid Test (+5 days from first) **OR** Actual Date of PCR Confirmatory Test (DD/MM/YY)	Results of Second Rapid Test or Confirmatory Test	Suspected Case Next Steps[1] (See codes below)
1						/ /	□ 2nd RDT □PCR / /	□ + □ -	
2						/ /	□ 2nd RDT □PCR / /	□ + □ -	
3						/ /	□ 2nd RDT □PCR / /	□ + □ -	
4						/ /	□ 2nd RDT □PCR / /	□ + □ -	
5						/ /	□ 2nd RDT □PCR / /	□ + □ -	
6						/ /	□ 2nd RDT □PCR / /	□ + □ -	
7						/ /	□ 2nd RDT □PCR / /	□ + □ -	
8						/ /	□ 2nd RDT □PCR / /	□ + □ -	
9						/ /	□ 2nd RDT □PCR / /	□ + □ -	
10						/ /	□ 2nd RDT □PCR / /	□ + □ -	
11						/ /	□ 2nd RDT □PCR / /	□ + □ -	
12						/ /	□ 2nd RDT □PCR / /	□ + □ -	
13						/ /	□ 2nd RDT □PCR / /	□ + □ -	
14						/ /	□ 2nd RDT □PCR / /	□ + □ -	

[1]**Next Step Codes :RF**=Case refuses follow up; **N**=Follow up not necessary; **A**=Admitted; **L**=Lost; **M**=Move case information to Case Community Monitoring List

2. Intake, Symptoms Screening, Exposure, and Outcomes

Find editable version here.

Note: these forms are combined into one document. If printed front and back the forms are combined into the below:

A. Intake and Symptom Screening for Cases or Contacts

What	• Demographics and Conditions (front of form):
	  ○ Demographic information
	  ○ Maternal, neonatal and child health information
	  ○ Pre-existing conditions
	• Symptom screening (back of form):
	  ○ History of illness and fever
	  ○ Danger signs
	  ○ Other symptoms

Where	Facility screening or Community. Stays with facility staff if patient is admitted to facility, community health worker if patient is isolating at home or in an isolation facility, or with patient if there is not community follow up available.
Who	Facility or Community frontline worker
When	Once – at first interaction with individual

B. Exposure and Final Outcomes for Cases or Contacts

What	• Exposure (front of form):
	  ○ General COVID-19 exposure information (travel, occupation, contact with known case)
	  ○ Contact with COVID-19 case information
	• Final Outcomes (back of form):
	  ○ Defines final outcomes for Cases (COVID-19 cases). **Note**: that discharge from a facility while the patient is not yet recovered is not a final outcome. Follow up will be required to get final outcome of these patients.
	  ○ Defines final outcome for Contacts (those who had contact with confirmed cases, but never were confirmed or presumed to be positive). **Note**: final outcome for Contacts includes being converted to a Case if Contact receives a confirmed or presumed COVID-19 diagnosis, a case outcome will be required for these people.

Where	Facility or Community. Stays with facility staff if patient is admitted to facility, community health worker if patient is isolating at home or in an isolation facility, or with patient if there is not community follow up available.
Who	Facility or Community frontline worker
When	Exposure is taken once at first interaction with individual. Final Outcomes is filled when a patient has a final outcome in either the facility or the community.

COVID-19 Patient Intake and Symptoms Screening

1. Patient Status at Intake ☐ Confirmed case ☐ Suspected case ☐ Contact
1.1 Case ID (if COVID-suspected or -confirmed):
1.2 Contact ID (if close contact of COVID case):

*a person may have a contact and case ID if they started as a contact and then were converted to a case

2. Contact Information and Demographics	
2.1 First name:	**2.2 Surname:**
2.3 Sex: ☐ Male ☐ Female	**2.4 Date of Birth:** _____/_____/_____ (DD/MM/YYY)
2.5 Age: _____Years _____Months (if <60 months)	**2.6 Nearest Health Centre**
2.7 Telephone number	**2.8 National social number/ identifier**
2.9 Other Electronic Number (HIV ID/NCD ID/EMR ID)	**2.10 Community Health Worker Name**
2.11 Province/Region if non-national, list country here	**2.12 District/Commune**
2.13 Town or Village	**2.14 Landmark/street name**

3. Visit Information **[pre-print country here]**	
3.1 Facility Name list community if not in facility	**3.3 Date of interview** _____/_____/_____ (DD/MM/YYY)
3.2 Data collector name	**3.4 Data collector phone number**

4. Symptoms	
4.1 Has the respondent experienced any respiratory symptoms (cough, shortness of breath, sore throat, running nose) in the last 14 days?	☐ No ☐ Yes
4.2 Fever (≥38 °C) or history of fever	☐ No ☐ Yes → Start date: _____/_____/_____ (DD/MM/YYYY) → Maximum temperature: _____
4.3 Dry cough	☐ No ☐ Yes → Start date: _____/_____/_____ (DD/MM/YYYY)

5. Danger Signs	
5.1 Rapid Breathing or Shortness of Breath	☐ No ☐ Yes → Start date: _____/_____/_____ (DD/MM/YYYY)
5.2 Altered consciousness	☐ No ☐ Yes → Start date: _____/_____/_____ (DD/MM/YYYY)
5.3 Inability to eat, drink, or walk	☐ No ☐ Yes → Start date: _____/_____/_____ (DD/MM/YYYY)
If yes to at least one danger sign, patient needs to be seen by clinician immediately	

COVID-19 Other Symptoms and Pre-existing Conditions

6. Other symptoms Check all that apply

□ Sore throat	□ Runny nose	If Yes to any →
□ Chest pain	□ Loss of appetite	Start date for first symptom:
□ Muscle aches (Myalgias)	□ Neurological signs	_____/_____/_____
□ Fatigue or general malaise	□ Seizures	(DD/MM/YYYY)
□ Vomiting or Nausea	□ Rash	
□ Diarrhoea	□ Conjunctivitis	
□ Headache	□ Other symptoms, specify: _____	

7. Pre-existing Condition(s) check all that apply

☐ Obesity	☐ Chronic lung disease (non-asthma)
☐ Underweight	☐ Chronic liver disease
☐ Hypertension	☐ Haematological disorder/Sickle cell disease
☐ Diabetes Type 1	☐ Chronic kidney disease
☐ Diabetes Type 2	☐ Epilepsy
☐ HIV	☐ Chronic neurological impairment/disease
☐ TB	☐ Cancer
☐ Heart disease	☐ Stroke
☐ Asthma (requiring medication)	☐ Other immune deficiency
☐ Mental health condition: _____	☐ Other pre-existing condition: _____

7.2 Smoking	☐ Current ☐ Former ☐ Never	
7.3 Vaccinated for influenza last 12 months	☐ No ☐ Yes → ☐ Unknown	Date:_____/_____/_____ (DD/MM/YYYY)
7.4 Received pneumococcal vaccine	☐ No ☐ Yes → ☐ Unknown	Date:_____/_____/_____ (DD/MM/YYYY)

8. Maternal and Child Health Information

8.1 Pregnant	☐ No ☐ Yes → → ☐ Unknown	Trimester: ☐ First ☐ Second ☐ Third ☐ Unknown Estimated delivery date: _____/_____/_____ (DD/MM/YYYY)
8.2 Post-partum Delivery in last 6 months	☐ No ☐ Yes → ☐ Unknown	Delivery date: _____/_____/_____ (DD/MM/YYYY)
8.3 Is patient <1 year old?	YES → **Breastfeeding?**	☐ Yes ☐ No ☐ Unknown
8.4 Is patient <5 years old?	YES → **Are vaccinations up to date?**	☐ Yes ☐ No ☐ Unknown

COVID-19 Patient Exposure Screening Form

1. Patient Status	☐ Confirmed case ☐ Suspected case ☐ Contact
1.1 Case ID (if COVID-suspected or -confirmed):	
1.2 Contact ID (if close contact of COVID case):	

*a person may have a contact and case ID if they started as a contact and then were converted to a case

2. Contact Information and Demographics (fill if separated from intake form)	
2.1 First name:	**2.2 Surname:**
2.3 Telephone number	**2.4 National social number/ identifier**
2.5 Province/Region	**2.6 District/Commune**
2.7 Town or Village	**2.8 Landmark/street name**

3. General Exposure Information

3.1 Have you travelled within the last 14 days?

☐ Yes → ☐ Domestically ☐ Internationally
☐ No
☐ Unknown

Start date: ____/____/____ (DD/MM/YYYY)

End date: ____/____/____ (DD/MM/YYYY)

If YES → Countries, Regions and Cities visited:

3.2 Have you been present in a healthcare facility in the last 14 days?

☐ Yes → Facility: _____
☐ No
☐ Unknown

3.3 Occupation

☐ Health worker
☐ Health laboratory worker
☐ Student
☐ Other, specify:_____

If YES to any → location of work or study: _____

4.4 In the past 14 days, have you had contact with anyone with suspected or confirmed COVID-19 infection?

☐ Yes → Go to **Primary Case Contact Information**
☐ No → Go to **Symptoms Form**
☐ Unknown → Go to **Symptoms Form**

5. Primary Case Contact Information

Complete if respondent had contact with a known/suspected COVID-19 Case

5.1 Name of primary COVID-19 case	**5.2 Case ID of primary COVID-19 case**
5.3 Relationship to primary COVID-19 case	**5.4 Date of last contact with case** ____/____/____ (DD/MM/YYY)

5.5 Does contact live with primary case?

☐ Yes →
☐ No
☐ Unknown

Number of days during the time the case was ill that were spent within 6 ft of case _____

Number of rooms in the home _____

Number of residents in the home _____

COVID-19 Patient Follow Up Form

1. Patient Status	☐ Confirmed case ☐ Suspected case ☐ Contact
1.1 Case ID (if COVID-suspected or confirmed):	
1.2 Contact ID (if close contact of COVID case):	

*a person may have a contact and case ID if they started as a contact and then were converted to a case

3. Close CONTACT Record Complete if respondent had contact with a known/suspected COVID-19 Case	
3.1 What was contact outcome?	☐ Completed isolation period **without** becoming a confirmed or presumed COVID-19 case ☐ Lost to follow up ☐ Died ☐ Refused follow up ☐ Became a confirmed or presumed COVID-19 case → Go to **Close CASE Record**

4. Close CASE Record Complete if respondent was a known/suspected COVID-19 Case	
4.1 What was case outcome?	☐ Recovered outside health facility (isolation period ended) ☐ Recovered at health facility (discharged) ☐ Lost to follow up ☐ Died ☐ Transferred out (Facility name: _____) ☐ Refused treatment or follow up

3. Lab Orders and Test Results

Find editable versions here.

A. Rapid Test Request and Result Form

What	• Submit orders and specimens to lab for testing • Record test results
Where	At screening location and in laboratory. Stays with facility staff if patient is admitted to facility, community health worker if patient is isolating at home or in an isolation facility, or with patient if there is not community follow up available.
Who	Orders: Completed by Clinical staff Results: Completed by Clinical or Laboratory Staff
When	When tests are ordered and completed

B. Lab Register

What	• Record basic patient information in one row per patient to easily tally number of each kind of test performed and the results
Where	In laboratory. Stays in laboratory.
Who	Clinical or Laboratory Staff
When	When tests are ordered and completed

COVID-19 TEST REQUEST FORM

1.Patient Status at Intake
1.1 Case ID (if COVID suspected):
1.2 Contact ID (if close contact of COVID case):

*a person may have a contact and case ID if they started as a contact and then were converted to a case

2. Contact Information and Demographics	
2.1 First name:	**2.2 Surname:**
2.3 Sex: ☐ Male ☐ Female	**2.4 Date of Birth:** _____/_____/_____ (DD/MM/YYY)
2.5 Age: _____Years _____Months (if <60 months)	**2.6 Telephone number**
Check if patient is a health worker: ☐	

3. Request Information	[pre-print country here]
3.1 Facility Name	**3.2 Date of request** _____/_____/_____ (DD/MM/YYY)
3.3 Type of test: ☐ Antibody test (IgM/IgG) ☐ Antigen test ☐ RT PCR test	**3.4 Type of specimen**: ☐ Nasal swab ☐ Oropharyngeal swab ☐ Venous blood ☐ Finger prick (blood)
3.5 Additional info/Comment:	
3.6 Requested by:	**3.7 Signature:**

To be completed in the laboratory

4. Specimen/Sample Information	
4.1 Sample ID:	**4.2 Collected by:**
4.3 Sample Collection Date and Time: _____/_____/_____ (DD/MM/YYY) _____:_____ HH:MM	

5. Test Information		
5.1 Test Performed by:	**5.2 Test Date and Time:**_____/_____/_____ (DD/MM/YYY) _____:_____ HH:MM	
5.3 Result Antibody test: ☐ Negative ☐ Positive IgM only ☐ Positive IgG only ☐ Positive IgM and IgG **If result is invalid re-do test**	**5.4 Result Antigen test:** ☐ Negative ☐ Positive **If result is invalid re-do test**	**5.5 Result RT PCR test:** ☐ Negative ☐ Positive ☐ Invalid
3.5 Additional info/Comment:		
Result communicated to:	**Date of result:** ____/____/_____ (DD/MM/YYY)	**Signature:**

Partners In Health

Form Version 2
31-Mar-2020

Date: ____________________ **COVID-19 Test Register** Facility Name: ____________________________

Case ID	Patient Name	Age	Reason			Date of 1st Rapid Test	1st Rapid Test							Date of 2nd Rapid Test (if applicable)	2st Rapid Test (if applicable)							Date of PCR Test (if applicable)	PCR Test			Notes
							Antibody Test				Antigen Test				Antibody Test				Antigen Test							
	Contact Info	Sex	Symptoms	Exposure	Contact		IgG Positive	IgM Positive	Negative	Invalid	Positive	Negative	Invalid		IgG Positive	IgM Positive	Negative	Invalid	Positive	Negative	Invalid	Sample ID	Positive	Negative	Invalid	
			☐	☐	☐		☐	☐	☐	☐	☐	☐	☐		☐	☐	☐	☐	☐	☐	☐		☐	☐	☐	
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4. Facility-based care for COVID-19 Cases

Find editable versions here. Editable versions of the Facility Admission, Daily Progress, and Discharge forms require a program called Balsamiq (email BostonSIS@pih.org for more information).

A. Facility Patient Register

What	Monitors the overall situation in the wards as a way to understand the status of currently and historically admitted cases. Collects information about admission date, basic demographics, COVID-19 and secondary diagnoses, intensive care needed, medications and outcomes
Where	Filled in facility ward. Stays in facility.
Who	Clinical staff
When	Patient information is entered on admission. Staff maintains register throughout treatment receives a **facility** outcome. (Facility outcome may not be a patient's final outcome if they are discharged before recovery.)

B. Facility Admission Form

What	Collects information at admission like symptoms, medications, secondary diagnoses
Where	Filled in facility ward. Stays in facility unless patient is discharged to recover in home/isolation facility, then forms transfer with patient to a community health worker, or isolation facility staff. If there is no community health worker or isolation facility staff available then forms should stay in facility.
Who	Clinical staff
When	Filled upon admission to health facility

C. Facility Daily Progress Form

What	Daily assessment of vitals and lab results and admission to intensive care
Where	Filled in facility ward. Stays in facility unless patient is discharged to recover in home/isolation facility, then forms transfer with patient to a community health worker, or isolation facility staff. If there is no community health worker or isolation facility staff available then forms should stay in facility.
Who	Clinical Staff
When	Filled daily for any number of days admitted to the facility

D. Facility Discharge Form

What	Discharge information for patients upon leaving the facility, includes secondary diagnoses and medications given to patient upon discharge
Where	Filled in facility ward. Stays in facility unless patient is discharged to recover in home/isolation facility, then forms transfer with patient to a community health worker, or isolation facility staff. If there is no community health worker or isolation facility staff available then forms should stay in facility.
Who	Clinical Staff
When	Filled at time of discharge from facility

Date: ______________________

COVID-19 Patient Treatment Register

Facility Name: ______________________________

Date of Admission D/M/Y	Case ID	Patient Name	Age / Sex	COVID-19 Suspected or Confirmed / Secondary Diagnosis	Admit to ICU	ICU Start Date / ICU End Date	Intensive Care: Oxygen Therapy	Intensive Care: Noninvasive Ventilation	Intensive Care: Inotrope/ Vasopresser	Medication: Antivirals	Medication: Antibiotics	Medication: Other	Discharge Date D/M/Y	Outcome Date D/M/Y	Outcome (see codes below)	Transfer Out Facility	Notes
			□ M □ F	□ susp □ conf	□		□ OT	□ NV	□ IN/VA	□ AV	□ AB	□ OT					
			□ M □ F	□ susp □ conf	□		□ OT	□ NV	□ IN/VA	□ AV	□ AB	□ OT					
			□ M □ F	□ susp □ conf	□		□ OT	□ NV	□ IN/VA	□ AV	□ AB	□ OT					
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OUTCOME CODES:
REC=Recovered at facility and discharged, **ISO**=Discharged to Isolation/unwell,
TO=Transfer Out, **REF**=Refused Care, **D**=Died

Admission Note

Date: _____ **Time:** _____

Patient Name:	Patient Id:
Age:	EMR Id:
Sex:	Hospital day #:

Patient Demographics

Employed as Healthcare Worker ☐ Yes ☐ No

Type: _____

Patient is pregnant? ☐ Yes ☐ No

Gestational Age: _____ weeks

Or Expected Due Date: _____

Post-partum patient? ☐ Yes ☐ No

Outcome: ☐ live birth ☐ still birth Delivery Date: _____

Patient is Infant? ☐ Yes ☐ No

Gestational Outcome: ☐ Term birth (≥37wk GA) ☐ Preterm birth (<37 wk GA)

Breastfeed: ☐ Yes ☐ No

If child, vaccinations up to date? ☐ Yes ☐ No

Home Medications

Allergies

Comorbidities ☐ None ☐ Unknown

Type 1 Diabetes	☐	Chronic kidney disease	☐
Type 2 Diabetes	☐	Asthma	☐
Hypertension	☐	Chronic pulmonary disease (not asthma)	☐
Epilepsy	☐	Tuberculosis	☐
Sickle Cell disease	☐	Cardiomyopathy	☐
Rheumatic Heart Disease	☐	Stroke	☐
HIV	☐	Malnutrition	☐

Other:

Mental Health Condition:

Smoking: ☐ Current ☐ Past ☐ Never

Onset/Admission

Transfer from other facility? ☐ Yes ☐ No

Transfer facility: _____ Admission Date: _____

Known contact with COVID-19 patient in 14 days prior to symptoms ☐ Yes ☐ No

Admission Condition Status: ☐ Mild ☐ Moderate ☐ Critical

First Line Medications

specify:

Second Line Medications

☐ Lopinavir/ritonavir 400mg/100mg PO q12h x 14 days

☐ Remdesivir

☐ Other: _____

Antibiotics

☐ Ceftriaxone ____ gm q ____ hours ☐ Amoxicillin _____ q ____ hours

☐ Doxycycline 100 mg BID

Signs and Symptom

Symptom start date: _____

Fever	☐	Chest pain	☐
Cough	☐	Muscles aches (Myalgias)	☐
With sputum production	☐	Fatigue/malaise	☐
Shortness of breath (Dyspnea)	☐	Nausea/vomiting	☐
Sore throat	☐	Diarrhea	☐
Runny nose	☐	Loss of taste/smell	☐
Headache	☐	Confusion	☐

Other, specify:

Vitals

Temp	°C °F	Cap refill time	☐ < 3 sec
Pulse	bpm		☐ ____ sec
RR	bpm	Pain:	☐ None ☐ Mild ☐ Moderate ☐ Intense
BP	/ mmHg		

O2 _____ % on _____ L/min ☐ room air

Physical Exam

System	Normal	Findings
General	☐ Yes ☐ No	
HEENT	☐ Yes ☐ No	
Neck	☐ Yes ☐ No	
Pulmonary	☐ Yes ☐ No	
Cardiovascular	☐ Yes ☐ No	
Abdominal	☐ Yes ☐ No	
Urogenital	☐ Yes ☐ No	
Rectal	☐ Yes ☐ No	
Musculoskeletal	☐ Yes ☐ No	
Lymph nodes	☐ Yes ☐ No	
Skin and mucosa	☐ Yes ☐ No	
Neurological	☐ Yes ☐ No	
	☐ Alert ☐ Verbal ☐ Pain ☐ Unresponsive	

Other, specify:

Supportive Care

☐ Oxygen _____ L/min ☐ Analgesic: _____

☐ Mechanical Ventilation ☐ Mask ☐ Mask with non-rebreather

☐ Nasal Cannula ☐ CPAP ☐ BiPAP ☐ FiO2

☐ IV Fluids _____ ml/hour specify: _____
☐ Central ☐ Peripheral

☐ IV Fluids _____ ml/hour specify: _____
☐ Central ☐ Peripheral

☐ IV Fluids _____ ml/hour specify: _____
☐ Central ☐ Peripheral

Other Medications

Admission Note

COVID-19 Testing

Specimen Date	Specimen Type	Test Type	Test Result
___/______/___	☐ Nasal swab ☐ Oropharyngeal swab ☐ Venous blood ☐ Finger prick (blood)	☐ Antibody test (IgM/IgG)	☐ Negative ☐ Positive IgM ☐ Positive IgG ☐ Invalid ☐ Positive IgM and IgG
		☐ Antigen test	☐ Negative ☐ Positive ☐ Invalid
		☐ RT PCR test	☐ Negative ☐ Positive ☐ Invalid
		☐ GeneXpert	☐ Negative ☐ Positive ☐ Invalid
___/______/___	☐ Nasal swab ☐ Oropharyngeal swab ☐ Venous blood ☐ Finger prick (blood)	☐ Antibody test (IgM/IgG)	☐ Negative ☐ Positive IgM ☐ Positive IgG ☐ Invalid ☐ Positive IgM and IgG
		☐ Antigen test	☐ Negative ☐ Positive ☐ Invalid
		☐ RT PCR test	☐ Negative ☐ Positive ☐ Invalid
		☐ GeneXpert	☐ Negative ☐ Positive ☐ Invalid
___/______/___	☐ Nasal swab ☐ Oropharyngeal swab ☐ Venous blood ☐ Finger prick (blood)	☐ Antibody test (IgM/IgG)	☐ Negative ☐ Positive IgM ☐ Positive IgG ☐ Invalid ☐ Positive IgM and IgG
		☐ Antigen test	☐ Negative ☐ Positive ☐ Invalid
		☐ RT PCR test	☐ Negative ☐ Positive ☐ Invalid
		☐ GeneXpert	☐ Negative ☐ Positive ☐ Invalid

Other testing

Test	result	Test	result	Test	result	Test	result
Haemoglobin	g/L or g/dL	Lymphocyte count	cells/µL	Sodium	mmol/L	Glucose	mmol/L or mg/dL
Haematocrit	%	Neutrophil count	cells/µL	Potassium	mEq/L	Total Bilirubin	µmol/L or mg/dL
WBC count	x109/L or x103/µL	Lactate	mmol/L or mg/dL	BUN	mmol/L or mg/dL	ALT/SGPT	U/L
Platelets	x109/L or x103/µL	CRP	mg/L	Creatinine	µmol/L or mg/dL	AST/SGOT	U/L

ABG Test:

pH	PO2 mmHg	HCO3 mmol/L	BE mmol/L
PCO2 mmHg	TCO2 mmol/L	SO2 %	Lactate mmol/L

☐ Chest X-Ray

Result:

☐ Abdominal Ultrasound ☐ Cardiac Ultrasound

Result:

Other findings:

Other diagnostic tests:

Diagnosis

COVID-19: ☐ Confirmed ☐ Suspected ☐ No

Secondary/Other Diagnoses:

Disposition

☐ Admit to ward ☐ Admit to COVID-19 Isolation
☐ Discharge ☐ Left against medical advice ☐ Death
☐ Quarantine at home ☐ Quarantine Facility
☐ Transfer to: ____________________________

Provider Clinical Plan

Nursing Admission Note

Signature: ______________________________

Name ______________________________ **Signature** ______________________________

Daily Progress Note

Patient Name:	Patient Id:
Age:	EMR Id:
Sex:	Days of Hospitalization:

Date: _____ **Time:** _____

Current Condition State: ☐ Mild ☐ Moderate ☐ Severe ☐ Critical

Transfer from: ☐ COVID-19 Isolation ☐ Hospital ☐ Other

Signs and Symptoms

Symptom				
Fever	☐ new	☐ improved	☐ unchanged	☐ worsened
Cough	☐ new	☐ improved	☐ unchanged	☐ worsened
With sputum production	☐ new	☐ improved	☐ unchanged	☐ worsened
Shortness of breath (Dyspnea)	☐ new	☐ improved	☐ unchanged	☐ worsened
Sore throat	☐ new	☐ improved	☐ unchanged	☐ worsened
Runny nose	☐ new	☐ improved	☐ unchanged	☐ worsened
Chest pain	☐ new	☐ improved	☐ unchanged	☐ worsened
Muscles aches (Myalgias)	☐ new	☐ improved	☐ unchanged	☐ worsened
Fatigue/malaise	☐ new	☐ improved	☐ unchanged	☐ worsened
Nausea/vomiting	☐ new	☐ improved	☐ unchanged	☐ worsened
Diarrhea	☐ new	☐ improved	☐ unchanged	☐ worsened
Confusion	☐ new	☐ improved	☐ unchanged	☐ worsened
Loss of taste/smell	☐ new	☐ improved	☐ unchanged	☐ worsened
Headache	☐ new	☐ improved	☐ unchanged	☐ worsened
Other, specify:				

First Line Medications

Specify:

Second Line Medications

☐ Lopinavir/ritonavir 400mg/100mg PO q12h x 14 days

☐ Remdesivir

Antibiotics

☐ Ceftriaxone ____ gm q ____ hours ☐ Amoxicillin _____ q ___ hours

☐ Doxycycline 100 mg BID ☐ Other: _____

Other Medications

Supportive Care

☐ Oxygen _____ L/min ☐ Analgesic: _____

☐ Mechanical Ventilation ☐ Mask ☐ Mask with non-rebreather

☐ Nasal Cannula ☐ CPAP ☐ BiPAP ☐ FiO2

☐ IV Fluids _____ ml/hour specify: _____
☐ Central ☐ Peripheral

☐ IV Fluids _____ ml/hour specify: _____
☐ Central ☐ Peripheral

☐ IV Fluids _____ ml/hour specify: _____
☐ Central ☐ Peripheral

Vitals

Temp	°C °F	Cap refill time	☐ < 3 sec
Pulse	bpm		☐ ____ sec
RR	bpm	Pain:	☐ None ☐ Mild ☐ Moderate ☐ Intense
BP	/ mmHg		

SpO2 _____ % on _____ L/min ☐ room air

Physical Exam

System	Normal	Findings
General	☐ Yes ☐ No	
HEENT	☐ Yes ☐ No	
Neck	☐ Yes ☐ No	
Pulmonary	☐ Yes ☐ No	
Cardiovascular	☐ Yes ☐ No	
Abdominal	☐ Yes ☐ No	
Urogenital	☐ Yes ☐ No	
Rectal	☐ Yes ☐ No	
Musculoskeletal	☐ Yes ☐ No	
Lymph nodes	☐ Yes ☐ No	
Skin and mucosa	☐ Yes ☐ No	
Neurological	☐ Yes ☐ No	
	☐ Alert ☐ Verbal ☐ Pain ☐ Unresponsive	
Other, specify:		

Primary Diagnoses:

COVID-19: ☐ Confirmed ☐ Suspected ☐ No

Other:

Secondary Diagnoses:

Pneumonia	☐	Congestive heart failure	☐
Acute Respiratory Distress Syndrome	☐	Myocarditis	☐
Pleural effusion	☐	Acute renal injury/ Acute renal failure ☐	Chronic: ☐
Anemia	☐	Liver dysfunction	☐
Meningitis/ Encephalitis	☐	Hyperglycemia	☐
Seizure	☐	Hypoglycemia	☐
Dehydration	☐	Cardiac arrest	☐
Metabolic disorders	☐	Meningoencephalitis	☐
Other:			

Daily Progress Note

Testing

SARS-CoV-2 Antibody	SARS-CoV-2 Antigen	SARS-CoV-2 RT-PCR	GeneXpert
☐ Negative Ab ☐ Invalid	☐ Negative	☐ Negative	☐ Negative
☐ Positive IgM only ☐ Positive IgG+IgM	☐ Positive	☐ Positive	☐ Positive
☐ Positive IgG on	☐ Invalid	☐ Invalid	☐ Invalid

Test	result	Test	result	Test	result	Test	result
Haemoglobin	g/L or g/dL	Lymphocyte count	cells/µL	Sodium	mmol/L	Glucose	mmol/L or mg/dL
Haematocrit	%	Neutrophil count	cells/µL	Potassium	mEq/L	Total Bilirubin	µmol/L or mg/dL
WBC count	x109/L or x103/µL	Lactate	mmol/L or mg/dL	BUN	mmol/L or mg/dL	ALT/SGPT	U/L
Platelets	x109/L or x103/µL	CRP	mg/L	Creatinine	µmol/L or mg/dL	AST/SGOT	U/L

ABG Test:

pH		PO2	mmHg	HCO3	mmol/L	BE	mmol/L
PCO2	mmHg	TCO2	mmol/L	SO2	%	Lactate	mmol/L

☐ Chest X-Ray Result:	☐ Abdominal Ultrasound ☐ Cardiac Ultrasound Result:
Other findings:	
Other diagnostic tests:	

Disposition

☐ Admit to ward ☐ Admit to COVID-19 Isolation ☐ Quarantine at home ☐ Left against medical advice

☐ Discharge ☐ Death ☐ Quarantine Facility ☐ Transfer to: _____

Provider Clinical Plan

Nursing Progress Note

Signature: _____

Name _____ **Signature** _____

Discharge Note

Date: _____ **Time:** _____

Patient Name:	Patient Id:
Age:	EMR Id:
Sex:	Hospital day #:

Primary Diagnoses:

COVID-19: ☐ Confirmed ☐ Suspected ☐ No

Other:

Secondary Diagnoses:

Pneumonia	☐	Congestive heart failure	☐
Acute Respiratory Distress Syndrome	☐	Myocarditis	☐
Pleural effusion	☐	Acute renal injury/ Acute renal failure ☐	Chronic: ☐
Anemia	☐	Liver dysfunction	☐
Meningitis/ Encephalitis	☐	Hyperglycemia	☐
Seizure	☐	Hypoglycemia	☐
Dehydration	☐	Cardiac arrest	☐
Metabolic disorders	☐	Meningoencephalitis	☐

Other:

ICU/Isolation

ICU or High Dependency Unit admission? ☐ Yes ☐ No

Total duration in ICU: _____

Date of ICU admission ___/___/___

Date of ICU discharge ___/___/___

Discharge Medications

☐ Amoxicillin _____ q___ hours

☐ Doxycycline 100 mg BID

☐ Other Antibiotic: _____

☐ Corticosteroids: Type _____ Route ____ Dose _____

☐ Antifungal agent

☐ Paracetamol _____ mg every _____ hour

Other medications:

Therapy given during hospital stay

Oxygen Therapy? ☐ Yes ☐ No

Non-invasive ventilation? (e.g. BIPAP, CPAP) ☐ Yes ☐ No

Inotropes/vasopressors? ☐ Yes ☐ No

Antibiotics? ☐ Yes ☐ No

Other intervention of Procedure:

Discharge Information

Discharge Date: _____/_____/_____

Disposition:

☐ Discharged to home

☐ Transfer to other facility

☐ Death

☐ Other (specify): _____

Discharge condition:

☐ Good/recovered

☐ Fair

☐ Poor

Follow up plan:

Other comments:

Name _____ **Signature** _____

PIH guide to extended use and reuse of masks and eye protection

During the COVID pandemic, extended use (when the mask or eye protection is worn continuously and not taken off between patients) or reuse (when the mask or eye protection is removed and then replaced) of personal protective equipment may be required.

In general:

- ***Keep your mask on continuously as much as possible!*** Extended use is preferred over reuse because there is less risk of spreading the virus.
- ***You can never do hand hygiene enough!*** Remember hand hygiene before and after removing or replacing any PPE item
- ***If you need to take your mask off, take it all the way off***. For example, do not pull a mask down under your chin to take a drink of water. This keeps your face from being accidently contaminated by the outside of the mask.

How to remove a mask:

- Perform hand hygiene
- Remove mask carefully by the straps. Do not touch the outside surface (dirty surface).
- Place the mask in your designated storage container – ensure you always place the dirty side (the outside of the mask) in the same direction
- Perform hand hygiene

How to put a used mask back on:

- Perform hand hygiene and put on gloves
- Carefully pick the mask up by the straps, and ensuring the outside does not touch your nose or mouth, replace it on your face
- Remove gloves and perform hand hygiene
- Only re-use your own mask

When to replace a mask for a new one:

- If it is wet or dirty
- If it is damaged
- If it has been used in an aerosol generating procedure, such as intubation, nebulization, or suctioning (for N95s)

When do I need an N95 instead of a surgical mask:

- When swabbing a patient for a COVID test (extended use or reuse ok)

- When performing an aerosol generating procedure, such as intubation, nebulization, or suctioning (discard after the procedure)

How to remove and reuse eye protection:

- Remove eye protection by the handles of the goggles or strap of the face shield. Carefully place outside down (dirty side down) in a 'dirty bin.'
- Perform hand hygiene. Then either:
    - Option 1: Put on new gloves. Clean all sides of the eye protection with the cleaning solution. Place the eye protection into your own designated storage container (separate from your mask), dirty side (outside down). Remove gloves and perform hand hygiene.
    - Option 2: Reusable eye protection may be soaked in sodium hypochlorite 0.5% for 1 hour and left in a clean, open space to dry for at least 1 hour.

Extended Use PPE – Donning

Updated 27 March 2020

1. Don PPE outside of patients room. Ensure hair is pulled back away from face.

2. Perform hand hygiene
   - Alcohol-based sanitizer OR soap and water

3. Put on gown
   - Ensure gown fully covers entire body when closed or tied

4. Put on mask/respirator
   - If new mask/respirator, hold mask/respirator in one hand and bring to face
     - Pull lower elastic band over head and below ears
     - Pull upper elastic band over head and above ears
     - Press nose clip to ensure a tight seal of mask
   - If re-using mask/respirator, hold by straps only, taking care not to touch the outside (dirty) side of the mask

5. Perform Hand Hygiene
   - Alcohol based hand sanitizer

6. Put on gloves
   - Ensure gloves go over cuff of gown
   - If using same gown between patients, put 2 pairs of gloves on. Change external pair between each patient

Extended Use PPE – Doffing

Updated 27 March 2020

1. Doff PPE, except for mask/respirator in patient's room/ward. Remember gloves, face shield, front of gown and sleeves are CONTAMINATED. Wash hands immediately if you touch any of these surfaces with your bare hands

2. Remove gown
- Avoid touching outside contaminated surface of gown
- Pull gown from head and away from body
- If possible, remove gloves at same time as gown, ensuring you only touch the inside of gown and gloves
- Wrap gown into a ball with contaminated surface (outside of gown) inside
- Discard gown in appropriate receptacle

3.If gloves removed, perform hand hygiene
- Alcohol-based hand sanitizer

4. If not already done, remove gloves
- Grasp gloves in palm of hand and pull glove off
- Discard glove in waste container
- Slowly and gently slide finger under other glove between glove and cuff of gown. Avoid touching contaminated side of glove

5. Perform hand hygiene
- Alcohol-based hand sanitizer

6. Remove eye protection
- If using face shield, tilt head forward, grasp strap and gently pull strap over head, pulling the face shield away from face
- If using googles, grasp ear pieces behind ears and pull googles and away from face
- Carefully place outside down (dirty side down) in a 'dirty bin' until they can be cleaned for re-use (see instructions on re-using PPE)

7. Perform hand hygiene
- Alcohol-based hand sanitizer

8. With mask/respirator in place, leave patients room and enter anteroom or hallway

9. Remove mask/respirator
- Pull lower elastic band over head
- Pull upper elastic band over head and pull mask away from face
- If re-using, place mask/respirator in an appropriate storage container (plastic container recommended). Ensure dirty side of mask/respirator is face down

10. Perform hand hygiene
- Alcohol-based hand sanitizer

Guidance on Non-Standard PPE for COVID-19

The global COVID-19 pandemic has led to worldwide shortages of personal protective equipment (PPE). This document discusses alternative non-standard PPE that can be considered. **It is important to note that, at present, none of the options below have sufficient evidence to recommend their routine use. First steps to expand PPE availability should be PPE conservation which includes extended use, re-use, and limiting the number of people and procedures that would require PPE. Please see PPE conservation guidance.**
The use of non-standard PPE should be used as a 'last resort' strategy. The strategies below are unproven and their ability to protect a healthcare worker is unknown.

Non-standard Mask Options

- Locally made cloth masks
    - Should be worn with face shield that extends to the chin or below for added protection
    - To increase effectiveness, masks should be made with tightly-woven, fluid-resistant fabric and fit closely to the face, over both the nose and mouth. Multiple layers are preferred. WHO has guidance on fabric types and shape
    - Effectiveness may decrease when wet; should be replaced if sweaty or damp
    - It should be noted multiple studies show these do not provide as much protection as official surgical masks and in a clinical setting they should only be worn as last resort. One study suggests an increased infection risk and a false sense of protection for clinicians.
    - During this time of global shortage there are some institutions that are prioritizing the use of cloth masks in low-risk areas to conserve the use of surgical masks and N95s to higher risk and known risk patient areas.
- Makeshift 'respirators' from surgical masks and viral filters are being researched as alternate N95s in aerosolizing procedures
    - https://www.childrenshospital.org/research/departments-divisions-programs/departments/surgery/surgical-innovation-fellowship
- Evidence exists on ways to safely decontaminate N95 masks using hydrogen peroxide vapor and UV light. Care must be taken with any decontamination method to ensure masks are safely collected and redistributed, and that sterilization protocols are correctly followed to achieve the desired result. Information on types of decontamination methods is available at www.n95decon.org.

Non-standard gown options

- Locally made gowns can be considered in the absence of certified gowns. There is limited data on these.
    - Should be made of cloth with small pore size: non-woven, spun bound fabric, or tightly-woven, fluid-resistant fabric (such as polyester)
    - Certified re-usable gowns are typically coated with a fluorocarbon-based repellant finish to prevent liquid and microbial penetration. This may not be possible with

locally made gowns, so particular care should be taken to avoid getting gowns wet and to change when wet.
    - Design:
        - Extends to knees; fully covers arms and torso (front as one piece and back with ties)
        - Cuffs at end of arms (consider thumb loops to prevent gap between gown and gloves)
        - Higher neck to protect against splashes
        - Tight-seams or sealed seems
    - Inspect with each use to ensure no visible holes
    - Clothes worn underneath a locally made gown should be inspected after doffing – if soiled, they must be properly sterilized or discarded
- Other gown alternatives include lab coats, patient gowns, aprons, combinations of clothing (sleeve covers + coats) and should be used as a last resort.

Updated 17 June 2020 | Annex

Introduction: Below describes PIH's approach to PPE usage throughout the COVID-19 pandemic. Please do not hesitate to reach out with questions to the COVID-19@pih.org

1. *PPE conservation*
2. *PPE Conservation posters (English, French, Spanish)*
3. *Extended use and reuse of masks and eye protection*
4. *Extended Use PPE – donning and doffing*
5. *Nonstandard PPE Memo*

PIH Guide to PPE Conservation

Our priority is the safety of our patients and healthcare workers. It is CRITICAL that as triage and isolation systems are rapidly planned and implemented, early efforts are made to conserve PPE as global stock is limited. Conserving PPE now will ensure enough supplies to keep providers safe throughout the pandemic

Strategically Reduce Individual PPE Use

- Extend Use & Re-Use: Extended use is preferred over reuse. Extended use of respiratory protection is defined as the wearing of a disposable mask without removal or re-donning of the mask. Due to the rapidly evolving epidemic and to ensure protection for the frontline health workers many organizations, including the CDC is recommending re-use when necessary. See below for safe re-use procedures.
- Concentrate Care Delivery: Develop Strategies to complete multiple task utilizing the same set of PPE. For example: taking vital signs and giving medication at the same time.
- Appropriate use of PPE: WHO recommends the use of a surgical mask for the routine care of suspected COVID patients, and the use of N95 in COIVD patients during aerosolizing procedures like intubation or nebulization. When able N95 masks should be replaced after any aerosolizing procedure however, re-use of N95 masks may be necessary. N95 masks should be used according to PIH protocols for TB treatment

Reuse PPE:

Face Shields: Reusable face shields can be soaked in sodium hypochlorite 0.5% for 1 hour and left in a clean, open space to dry for at least 1 hour

Gowns: In some wards, gowns may need to be worn continuously as a provider moves between patients. In these cases, the provider should double glove and change outer gloves between patients. If gowns are in short supply, re-usable gowns can be considered. (see PIH guidelines on alternative PPE). If reusable gowns are used they should be machine washed with 60-90° C water and laundry detergent

Surgical and Procedural Masks: Given current supply global levels, most hospitals will need extended use of masks between patients (meaning that the mask is not removed between

patients but stays on a provider's face continuously). At many hospitals, masks will need to be re-used (meaning removed from the face and then put back on in between patients). PIH has a job aid to assist with safe re-use of mask. Key tenants of this include:

- Surgical and procedural masks must be worn by a single wearer.
- The removed mask should be placed in a designated receptacle for reuse.
- Perform hand hygiene immediately before and after putting on or otherwise touching a reused mask.
- Masks must be replaced when dirty or contaminated

Our priority is the safety of our patients and healthcare workers. It is CRITICAL that as triage and isolation systems are rapidly planned and implemented, early efforts are made to conserve PPE as stock is limited globally. Conserving PPE now will ensure enough supplies to keep providers safe throughout the epidemic – how to safely conserve and re-use PPE?

Minimize Number of People using PPE

- On Patient Rounds: Consider only having direct caregivers interact with the patient rather than members of the team responsible for the care of other patients
- On Shift: Designate a subset of caregivers to operate in the isolation area, rather than more providers in both areas. All caregivers can adhere to the above strategies to reduce PPE usage
- In the Operating Room: Limit surgeries to only essential surgeries and limit the number of observes and non-essential personnel, reducing the number of PPE sets used.
- In General: No visitors for patients suspected or confirmed to have COVID-19 (with the exception of parents for children). Visitors cannot enter COVID-19 isolation ward.

Role for hospital administrators:

Hospital administration should actively enforce PPE conservation measures. Some strategies used include:

- Removing or limiting PPE on wards less likely to require them
- Centralized PPE distribution instead of PPE stored on wards
- PPE monitors who can correct individuals when PPE is overused (for example, if an N95 mask is used in a situation where a surgical mask would have been sufficient)

PIH GUIDELINES FOR PERSONAL PROTECTIVE EQUIPMENT (PPE) CONSERVATION

Our priority is the safety of our patients and healthcare workers. It is **CRITICAL** that as triage and isolation systems are rapidly planned and implemented, early efforts are made to **conserve PPE** as global stock is limited. Conserving PPE now will ensure enough supplies to keep providers safe throughout the pandemic.

STRATEGICALLY REDUCE INDIVIDUAL PPE USE

Extend Use & Re-Use	Extended use is preferred over reuse. Extended use of respiratory protection is defined as the wearing of a disposable mask without removal or re-donning of the mask. Due to the rapidly evolving epidemic and to ensure protection for the frontline health workers many organizations, including the CDC is recommending re-use when necessary and safe. See below for safe re-use procedures.
Concentrate Care Delivery	Develop Strategies to complete multiple task utilizing the same set of PPE. For example: taking vital signs and giving medication at the same time.
Appropriate use of PPE	WHO recommends the use of a surgical mask for the routine care of suspected COVID patients, and the use of N95 in COVID patients during aerosolizing procedures like intubation or nebulization. When able N95 masks should be replaced after any aerosolizing procedure however, re-use of N95 masks may be necessary. N95 masks should be used according to PIH protocols for TB treatment.

REUSE PPE

Face Shields. Reusable face shields can be soaked in sodium hypochlorite 0.5% for 1 hour and left in a clean, open space to dry for at least 1 hour.

Gowns. In some wards, gowns may need to be worn continuously as a provider moves between patients. In these cases, the provider should double glove and change outer gloves between patients. If gowns are in short supply, re-usable gowns can be considered. (see PIH guidelines on alternative PPE). If reusable gowns are used they should be machine washed with 60-90° C water and laundry detergent

Surgical and procedural masks. Given current supply global levels, most hospitals will need extended use of masks between patients (meaning that the mask is not removed between patients but stays on a provider's face continuously). At many hospitals, masks will need to be re-used (meaning removed from the face and then put back on in between patients). PIH has a job aid to assist with safe re-use of mask. Key tenants of this include:

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On Shift	Designate a subset of caregivers to operate in the isolation area, rather than more providers in both areas. All caregivers can adhere to the above strategies to reduce PPE usage.
In the Operating Room	Limit surgeries to only essential surgeries and limit the number of observes and non-essential personnel, reducing the number of PPE sets used.
In General	No visitors for patients suspected or confirmed to have COVID-19 (with the exception of parents for children). Visitors cannot enter COVID-19 isolation ward.

ROLE FOR HOSPITAL ADMINISTRATORS

Hospital administration should actively enforce PPE conservation measures.

Some strategies used include:

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- Centralized PPE distribution instead of PPE stored on wards
- PPE monitors who can correct individuals when PPE is overused (for example, if an N95 mask is used in a situation where a surgical mask would have been sufficient)

Notre priorité est la sécurité de nos patients et du personnel soignant. En planifiant et instaurant rapidement des procédures de triage et d'isolement, il est PRIMORDIAL de s'efforcer de préserver les stocks d'EPI dès le départ, l'approvisionnement étant limité mondialement. Préserver dès maintenant les EPI permettra d'assurer la disponibilité de suffisamment d'équipements pour assurer la sécurité des soignants tout au long de la pandémie.

RÉDUIRE STRATÉGIQUEMENT L'UTILISATION INDIVIDUELLE DES EPI

Prolongez l'utilisation & la réutilisation

Une utilisation prolongée est préférable à une réutilisation. L'utilisation prolongée d'une protection respiratoire est définie comme le port d'un masque jetable sans qu'il ne soit retiré ni ré-enfilé. En raison de l'évolution rapide de l'épidémie et pour assurer la protection des agents de santé de première ligne, de nombreuses organisations, y compris le CDC, recommandent la réutilisation, si nécessaire. Voir les procédures sûres de réutilisation ci-dessous.

Regroupez la prestation des soins

Mettez en place des stratégies pour effectuer plusieurs tâches en utilisant les mêmes EPI. Exemple : prenez les signes vitaux et administrez les médicaments en même temps.

Utilisez correctement les EPI

L'OMS recommande l'utilisation d'un masque chirurgical pour les soins de routine aux patients susceptibles d'avoir le COVID, et l'utilisation de masques N95 pour les patients confirmés COVID pendant les procédures à risque de générer une aérosolisation, comme l'intubation ou la nébulisation. Dans la mesure du possible, les masques N95 doivent être remplacés après toute procédure susceptible de générer une aérosolisation, mais il peut s'avérer nécessaire de les réutiliser. Les masques N95 doivent être utilisés conformément aux protocoles PIH pour le traitement de la tuberculose.

RÉUTILISATION DES EPI

Masques faciaux: Les masques faciaux réutilisables peuvent être trempés dans une solution d'hypochlorite de sodium à 0,5 % pendant 1 heure, puis laissés à sécher dans un espace propre et ouvert pendant au moins 1 heure

Blouses: Dans certains services, les blouses doivent parfois être portées en continu pendant qu'un soignant s'occupe de plusieurs patients. Dans ces cas-là, le soignant doit superposer deux paires de gants et changer ceux du dessus entre les patients. Si peu de blouses sont disponibles, des blouses réutilisables peuvent être envisagées (voir les directives PIH sur les EPI alternatifs). Si des blouses réutilisables sont utilisées, elles doivent être lavées en machine à 60-90 °C avec un produit détergent.

Masques chirurgicaux et procéduraux: Compte tenu des niveaux mondiaux actuels d'approvisionnement, dans la plupart des hôpitaux une utilisation prolongée des masques sera nécessaire entre les patients (le masque n'est pas retiré d'un patient à l'autre, mais reste en permanence sur le visage du soignant). Dans de nombreux hôpitaux, les masques devront être réutilisés, c'est-à-dire qu'ils seront retirés du visage, puis remis entre les patients. PIH a mis à disposition un outil de travail expliquant comment réutiliser le masque en toute sécurité. Les principaux éléments de cet outil indiquent que:

- Chaque masque chirurgical et procédural doit être porté par une seule personne.
- Le masque retiré doit être placé dans un récipient désigné pour sa réutilisation.
- Procédez à l'hygiène des mains immédiatement avant et après avoir mis ou touché un masque réutilisé.
- Les masques doivent être remplacés lorsqu'ils sont sales ou contaminés

Notre priorité est la sécurité de nos patients et du personnel soignant. En planifiant et instaurant rapidement des procédures de triage et d'isolement, il est PRIMORDIAL de s'efforcer de préserver les stocks d'EPI dès le départ, l'approvisionnement étant limité mondialement. Préserver dès maintenant les EPI permettra d'assurer la disponibilité de suffisamment d'équipements pour assurer la sécurité des soignants tout au long de la pandémie.

LIMITEZ AU MAXIMUM LE NOMBRE DE PERSONNES QUI UTILISENT DES EPI

Lors des tournées de patients	Faites en sorte que seuls les soignants directs interagissent avec le patient, plutôt que les membres de l'équipe chargée des soins à d'autres patients.
Pendant les quarts de travail	Désignez un sous-groupe de soignants qui travailleront dans la zone d'isolement, plutôt qu'avoir un plus grand nombre de soignants circulant dans les deux zones. Tous les soignants peuvent adhérer aux stratégies précisées ci-dessus afin de réduire l'utilisation des EPI.
En salle d'opération	Limitez les opérations aux seules interventions essentielles et limitez le nombre d'observateurs et de personnel non essentiel, ce qui permettra de réduire le nombre d'EPI utilisés.
En général	Aucun visiteur n'est autorisé pour les patients soupçonnés d'avoir le COVID-19 ou confirmés COVID-19 (à l'exception des parents pour les patients enfants). Les visiteurs ne sont pas autorisés à entrer dans la zone d'isolement du COVID-19.

RÔLE DE L'ADMINISTRATION DES HÔPITAUX

L'administration hospitalière doit faire activement respecter les mesures de préservation des stocks d'EPI.

Les stratégies utilisées comprennent:

- Supprimer ou limiter les EPI dans les services moins susceptibles d'en avoir besoin.
- Organiser la distribution centralisée des EPI au lieu de les stocker dans les différents services.
- Un personnel dédié au contrôle des EPI afin de réajuster les procédures utilisées par certains soignants en cas de sur-utilisation des EPI (par exemple, si un masque N95 est utilisé dans une situation où un masque chirurgical aurait suffi).

Nuestra prioridad es la seguridad de nuestros pacientes y trabajadores de la salud. Es **IMPRESCINDIBLE** que a medida que los sistemas de triaje y aislamiento se planifican e implementan rápidamente, se realicen esfuerzos iniciales para **conservar el EPP** ya que el abastecimiento global es limitado. Conservar el EPP ahora garantizará suficientes suministros para mantener a los proveedores a salvo durante toda la pandemia.

REDUZCA ESTRATÉGICAMENTE EL USO INDIVIDUAL DE EPP

Uso extendido y reutilización

Se prefiere el uso extendido sobre la reutilización. El uso extendido de protección respiratoria se define como el uso de una máscara desechable sin quitarse o volver a ponerse la máscara. Debido a la epidemia que evoluciona rápidamente y para garantizar la protección de los trabajadores de salud de primera línea, muchas organizaciones, incluidos los CDC, recomiendan su reutilización cuando sea necesario. Vea a continuación los procedimientos de reutilización segura.

Entrega de atención concentrada

Desarrolle estrategias para completar múltiples tareas utilizando el mismo conjunto de PPE. Por ejemplo: tomar signos vitales y administrar medicamentos al mismo tiempo.

Uso apropiado de PPE

La OMS recomienda el uso de una máscara quirúrgica para la atención rutinaria de pacientes con sospecha de COVID, y el uso de N95 en pacientes con COVID durante procedimientos de aerosolización como intubación o nebulización. Sin embargo, cuando se puedan reemplazar las máscaras N95 después de cualquier procedimiento de aerosolización, puede ser necesario reutilizar las máscaras N95. Las máscaras N95 deben usarse de acuerdo con los protocolos de PIH para el tratamiento de la TB+G2.

REUTILICE LOS EPP

Caretas: Los protectores faciales reutilizables pueden empaparse en hipoclorito de sodio al 0,5% durante 1 hora y dejarse secar en un espacio limpio y abierto durante al menos 1 hora.

Batas: En algunas salas, es posible que sea necesario usar batas de manera continua a medida que el proveedor se mueve entre pacientes. En estos casos, el proveedor debe doblar los guantes y cambiar los guantes externos entre los pacientes. Si escasean las batas, se pueden considerar batas reutilizables. (Consulte las pautas de PIH sobre EPP alternativo). Si se usan batas reutilizables, se deben lavar a máquina con agua a 60-90° C y detergente para la ropa.

Máscaras quirúrgicas y de procedimiento: Dados los niveles globales de suministro actuales, la mayoría de los hospitales necesitarán un uso extendido de máscaras entre pacientes (lo que significa que la máscara no se quita entre pacientes sino que permanece en la cara de un proveedor continuamente). En muchos hospitales, las máscaras deberán reutilizarse (es decir, quitarla de la cara y luego volver a colocarla entre paciente y paciente). PIH tiene una ayuda laboral para ayudar con la reutilización segura de la máscara. Entre los usuarios y elementos clave incluimos:

- Las máscaras quirúrgicas y de procedimiento deben ser usadas por un solo usuario.
- La máscara retirada debe colocarse en un recipiente designado para su reutilización.
- Higienícese de las manos inmediatamente antes y después de ponerse o tocar una máscara reutilizada.
- Las máscaras deben reemplazarse cuando estén sucias o contaminadas.

Nuestra prioridad es la seguridad de nuestros pacientes y trabajadores de la salud. Es **IMPRESCINDIBLE** que a medida que los sistemas de triaje y aislamiento se planifican e implementan rápidamente, se realicen esfuerzos iniciales para **conservar el EPP** ya que el abastecimiento global es limitado. Conservar el EPP ahora garantizará suficientes suministros para mantener a los proveedores a salvo durante toda la pandemia.

MINIMIZAR EL NÚMERO DE PERSONAS QUE USAN EPP

En rondas de pacientes	Considere solo que los cuidadores directos interactúen con el paciente en lugar de los miembros del equipo responsable del cuidado de otros pacientes
En el turno	Designe un subconjunto de cuidadores para operar en el área de aislamiento, en lugar de más proveedores en ambas áreas. Todos los cuidadores pueden adherirse a las estrategias anteriores para reducir el uso de EPP
En la sala de operaciones	Limite las cirugías a solo cirugías esenciales y limite el número de observadores y personal no esencial, reduciendo el número de conjuntos de EPP utilizados.
En general	No permitir visitas para pacientes sospechosos o confirmados de tener COVID-19 (con la excepción de los padres para los niños). Los visitantes no pueden ingresar a la sala de aislamiento COVID-19.

PAPEL DE LOS ADMINISTRADORES DEL HOSPITAL

La administración del hospital debe hacer cumplir activamente las medidas de conservación del EPP.

Algunas estrategias pueden ser:

- Removing or limiting PPE on wards less likely to require them
- Centralized PPE distribution instead of PPE stored on wards
- PPE monitors who can correct individuals when PPE is overused (for example, if an N95 mask is used in a situation where a surgical mask would have been sufficient)

Updated 17 June 2020 | Annex

COVID-19 Transport Guidelines

Updated: 24 March 2020

1. General Hygiene Guidelines for Drivers and Transport Staff
    a. If possible, wear new disposable gloves for every journey
    b. If not wearing gloves: Before, during, and after each trip, wash your hands with soap and water for at least 20 seconds. Use an alcohol-based hand sanitizer that contains at least 60 percent alcohol if soap and water are not available.
    c. Avoid touching your face, eyes, nose, or mouth with unwashed hands.
    d. Avoid close contact with passengers
    e. If possible, ask passengers to sit in the back to create physical distance.
    f. Have hand sanitizer available for both driver and passengers
    g. Please reference JOB AID Rwanda Evac for evacuating positive patients to treatment centers

2. Vehicle Disinfection
    a. Routine Cleaning/Disinfection – *Before and After each trip and at the end of each shift/day*
        1. *Use a 70% alcohol-based solution (or soap and water if not available) to wipe down all high-touch surfaces:* steering wheel, shifter, door handles, windows, any other area that has been touched by passengers or driver
        2. Deep cleaning – *After each trip carrying symptomatic patients, follow routine cleaning plus:* Full cleaning of all passenger areas, including: floor, passenger seat, back of front seat, door, window, etc.
    b. If proper cleaning/disinfection cannot be performed, leave vehicle unused for minimum 48 hours

Recommended Minimum Cleaning and Disinfecting Frequencies

Type of Surface	Examples	Soap and Water	Disinfect
Minimally Touched Surfaces	Exterior, Headliner, Trunk	When Dirty	Only after Human Contact
Frequently Touched Surfaces	Door Handles, Switches, Dashboard, Carpet, Seats Steering Wheel, Shifter, Keys, Interior Windows	Routinely	High Touch Areas

Choosing the Right Disinfectant (please see below for acceptable disinfectants)

- Use an Alcohol-based cleaner for cars.
- Avoid: Chlorine Bleach as it can damage plastic, fabric and metal
- DO NOT MIX SOLUTIONS

a. Trip Guidelines

Low-Risk Trips	*Medium-Risk Trips*	*High-Risk Trips*
As many carriers of COVID-19 are asymptomatic, the only no-risk journey is by yourself. a. PPE (Mask and Gloves) Recommendations: follow general hygiene guidelines b. Follow routine cleaning instructions above c. Maximum capacity: 1 (driver only)	Non-medical trips, including carrying asymptomatic close contacts, Medical trips carrying patients with other conditions (trauma, obstetric), No high-risk passengers (pre-existing health conditions, elderly, etc.) b. PPE (Mask and Gloves) Recommendations a. Masks and gloves highly recommended for passengers and driver b. Follow routine cleaning instructions above. c. Maximum Capacity: 4 d. Keep windows open during trip	Symptomatic patients, Patients in high-risk categories (pre-existing health conditions, elderly, etc.) **Symptomatic and high-risk passengers should only travel for purposes of medical treatment** d. PPE (Mask and Gloves) Recommendations: **Masks and gloves must be worn by all occupants in the vehicle** e. For moving patients, wear appropriate full PPE, including eye protection, gown and gloves f. After helping a medical passenger out of the car, you should remove all protective equipment and wash your hands or use hand sanitizer before getting back into your vehicle. g. Follow routine and deep cleaning instructions above h. Maximum Capacity:4 i. Keep windows open during trip

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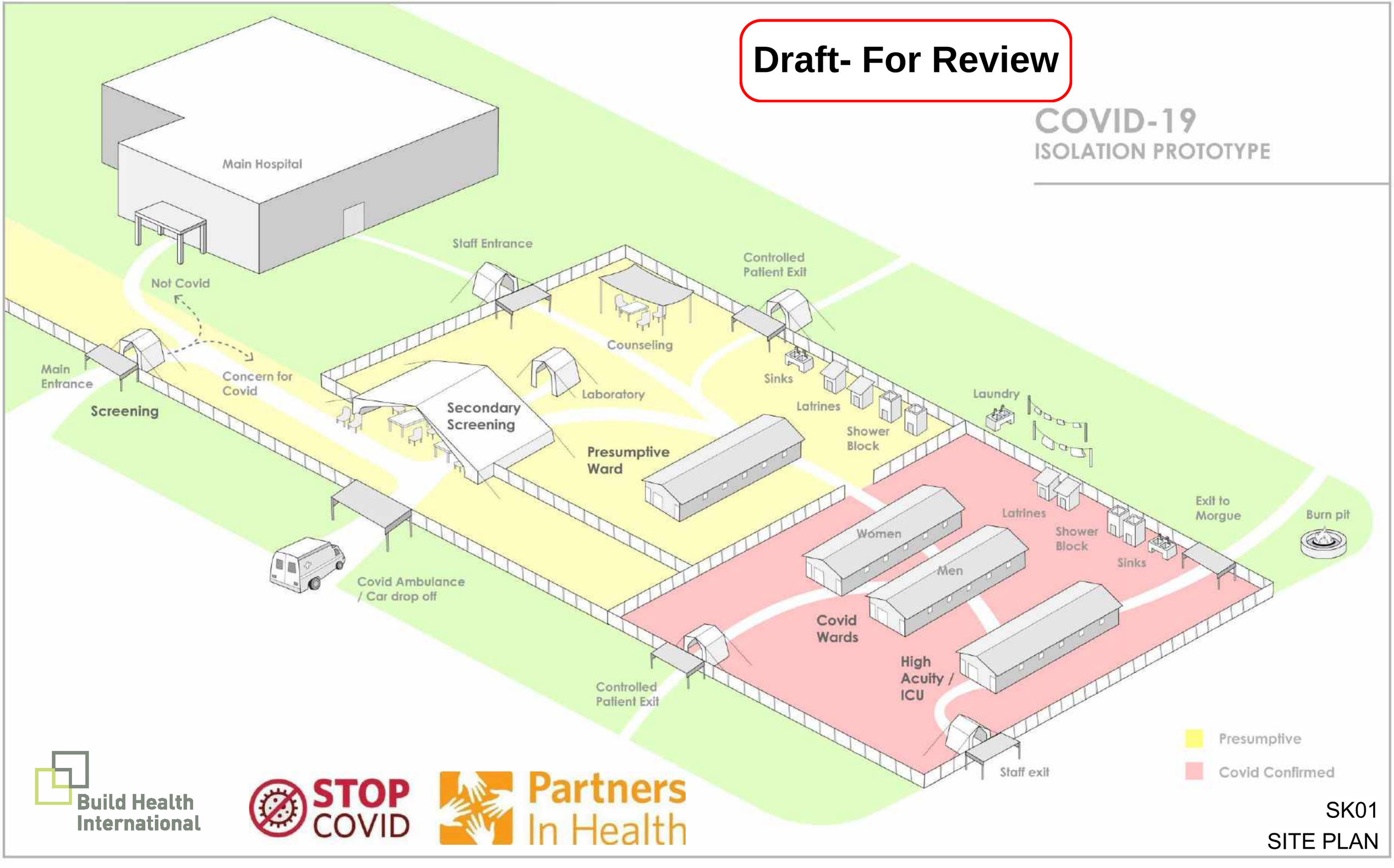
COVID-19
ISOLATION PROTOTYPE



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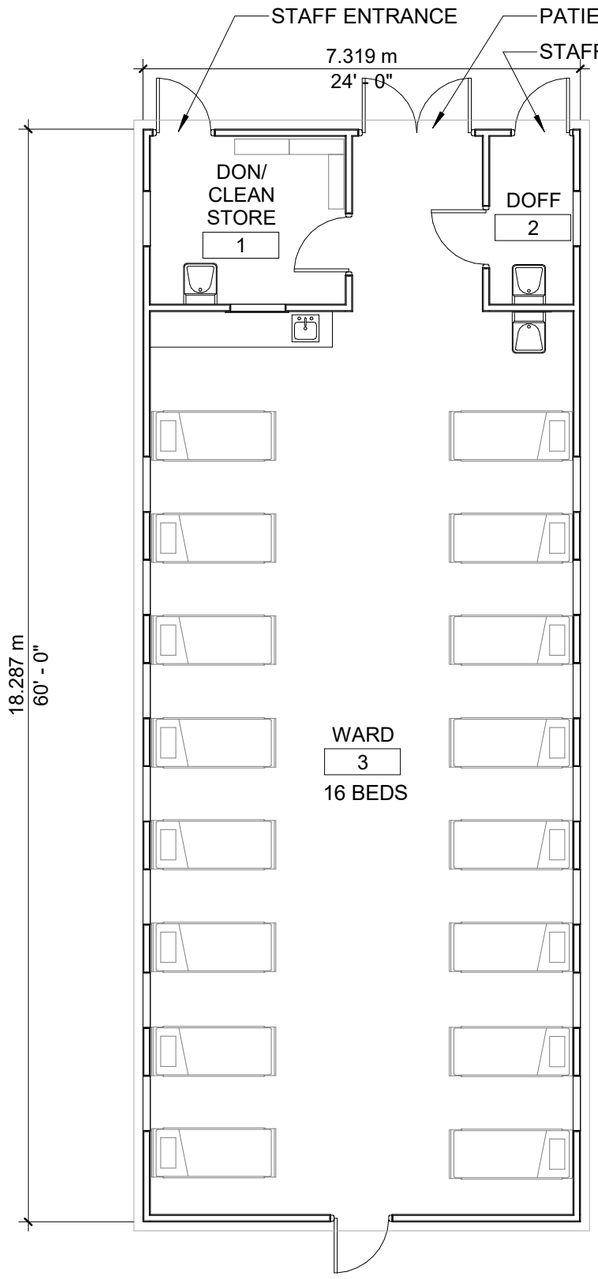
SITE PLAN



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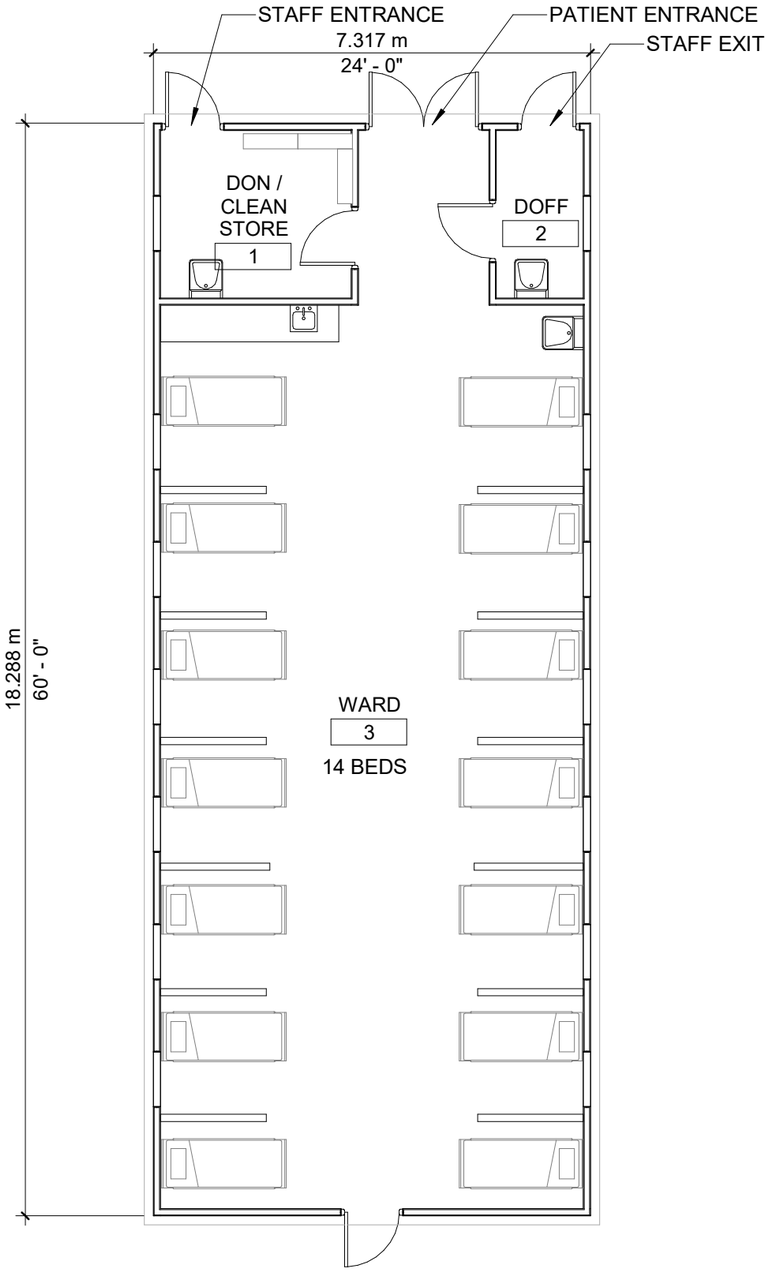

1 CONFIRMED WARD - EQUIPMENT

SCALE 1 : 100

2 PRESUMPTIVE WARD - EQUIPMENT

SCALE 1 : 100

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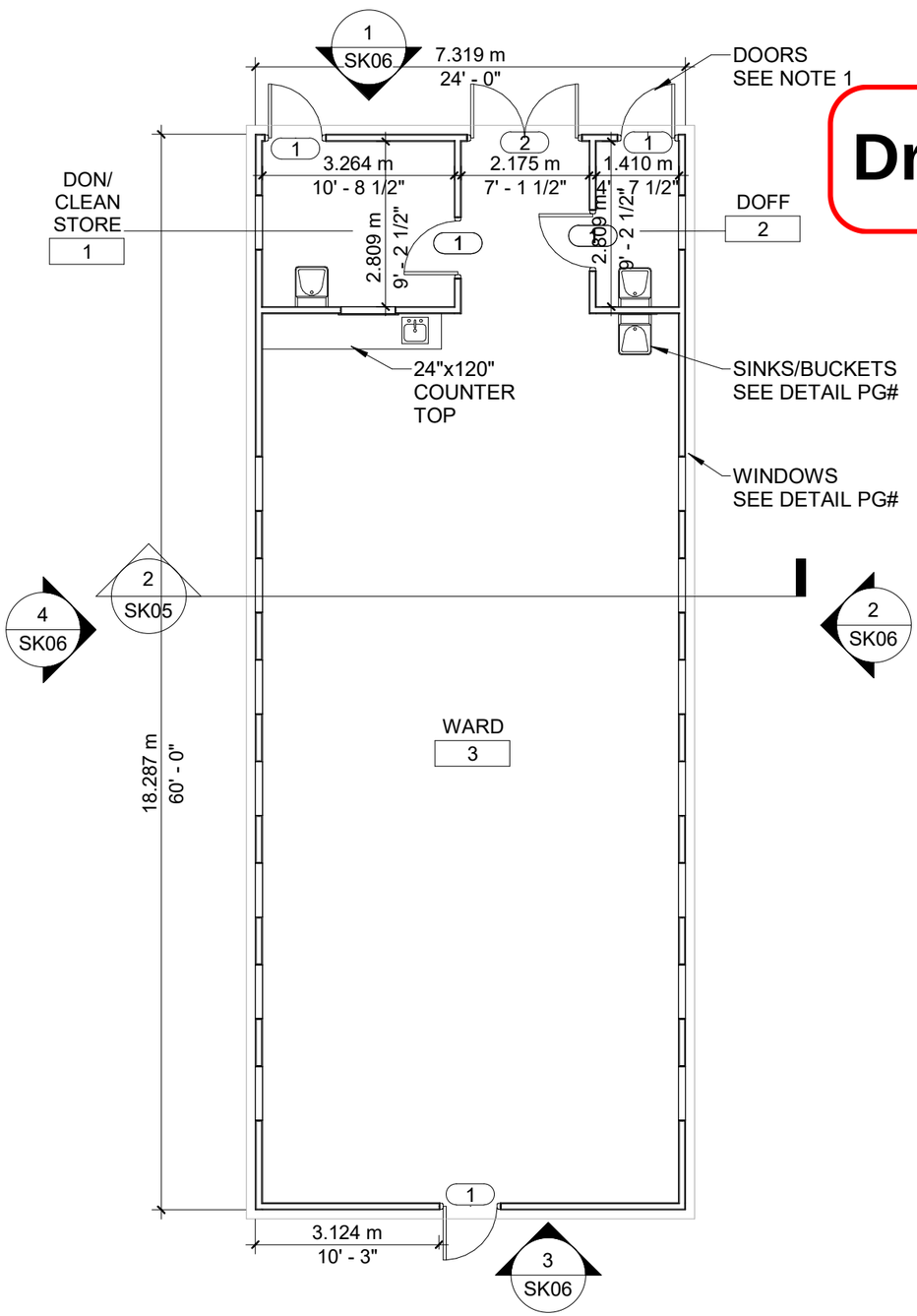
FLOOR PLANS



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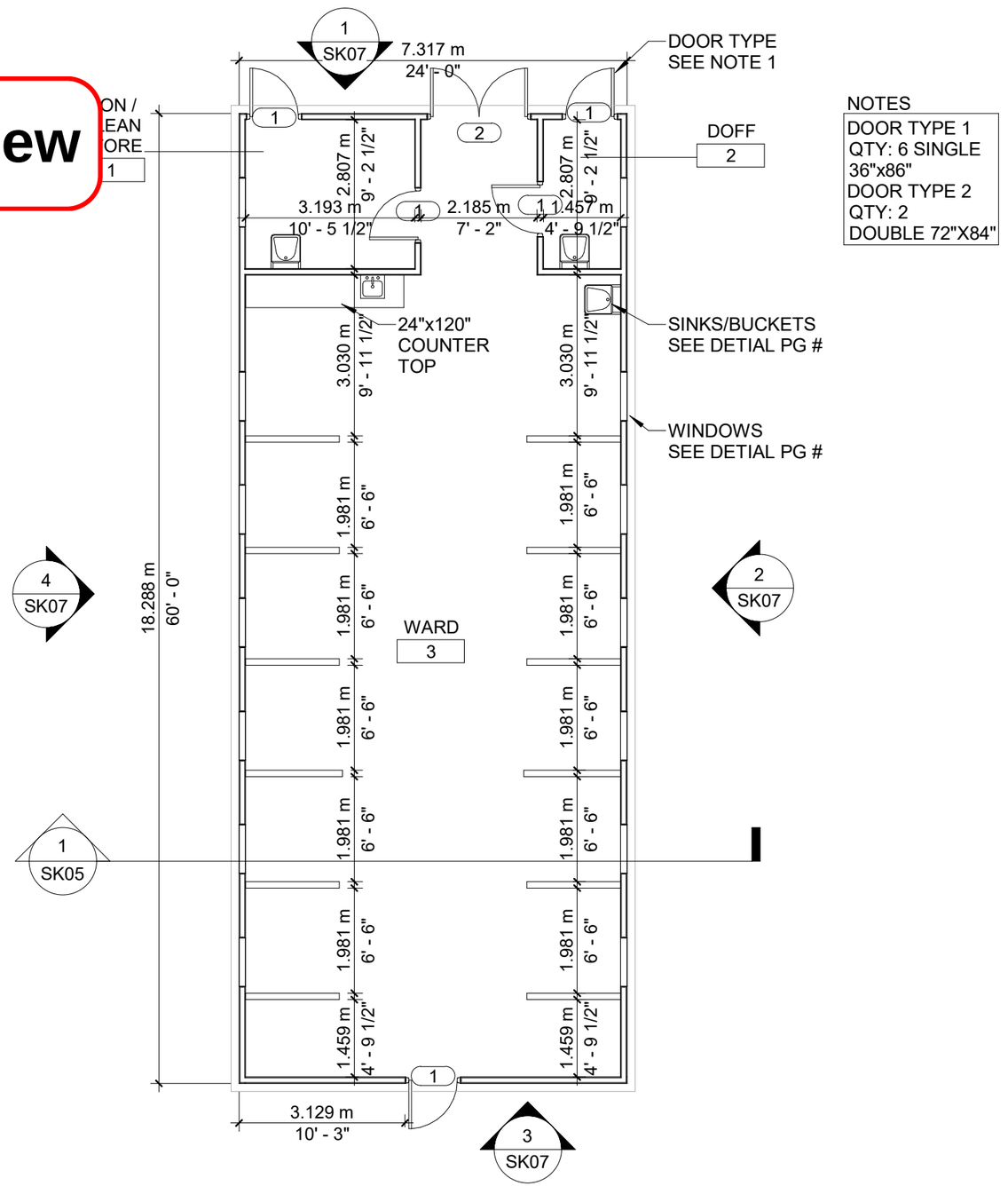

1 CONFIRMED WARD - DIM + TAGS

SCALE 1 : 100

2 PRESUMPTIVE WARD - DIM + TAGS

SCALE 1 : 100

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SK03

FLOOR PLAN D&P

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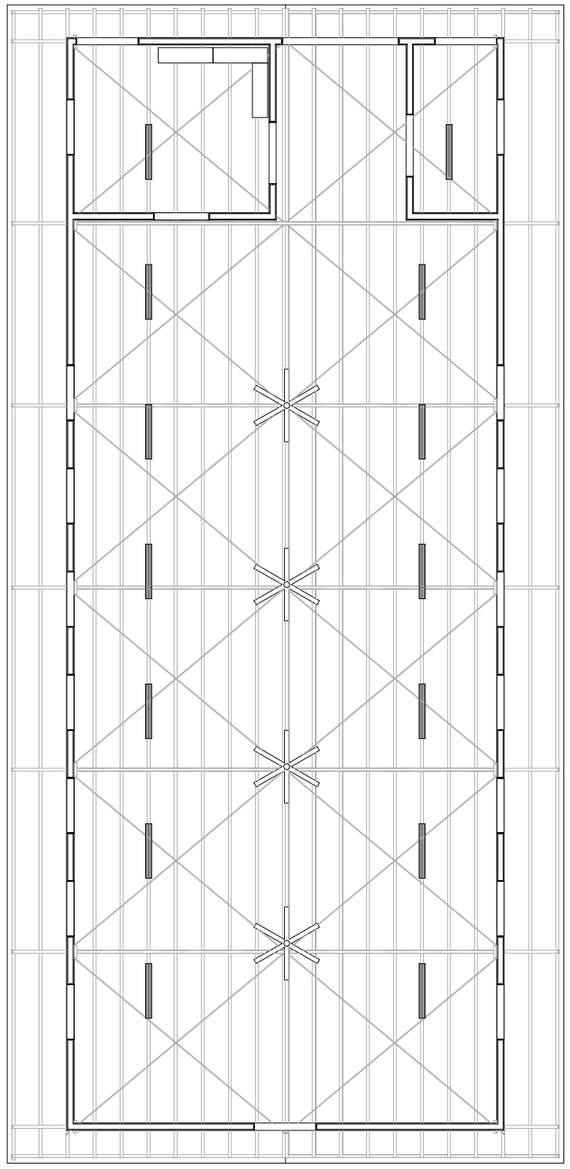
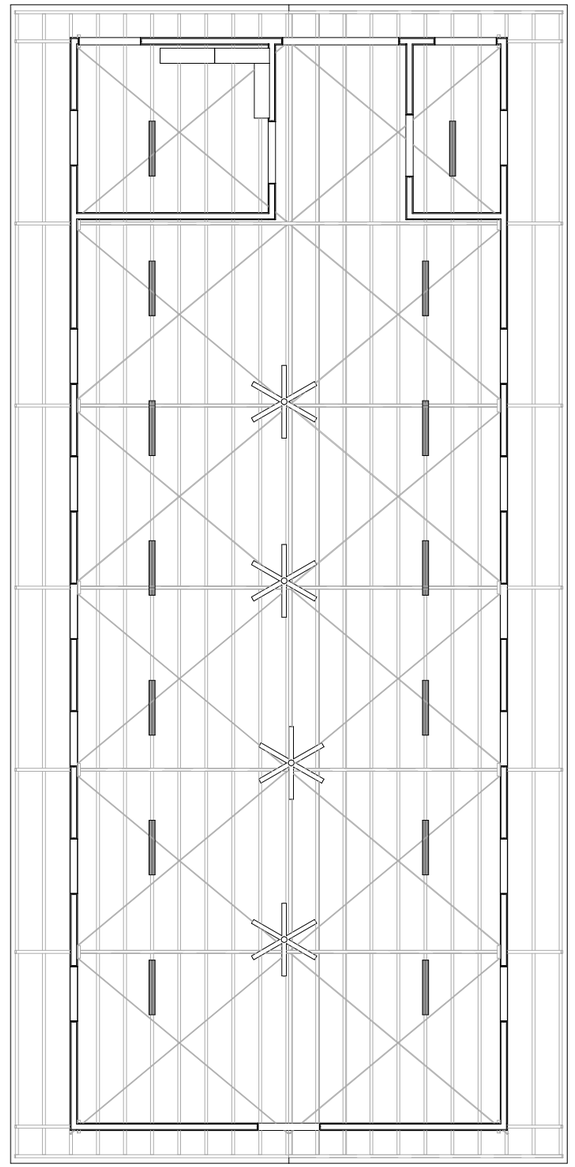


1 CONFIRMED WARD
SCALE 1 : 100



2 PRESUMPTIVE WARD
SCALE 1 : 100

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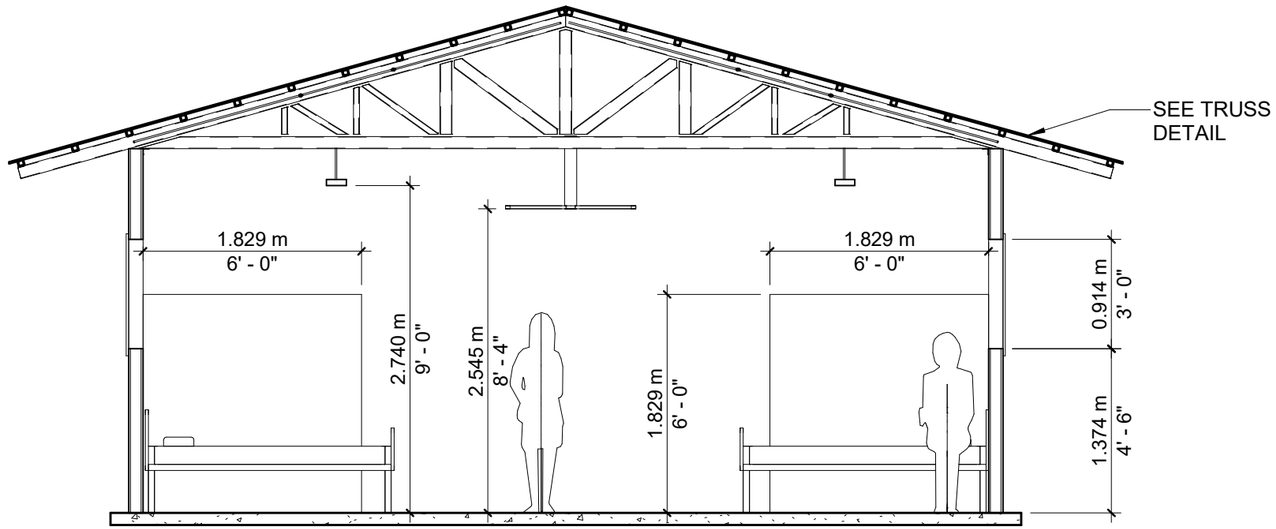
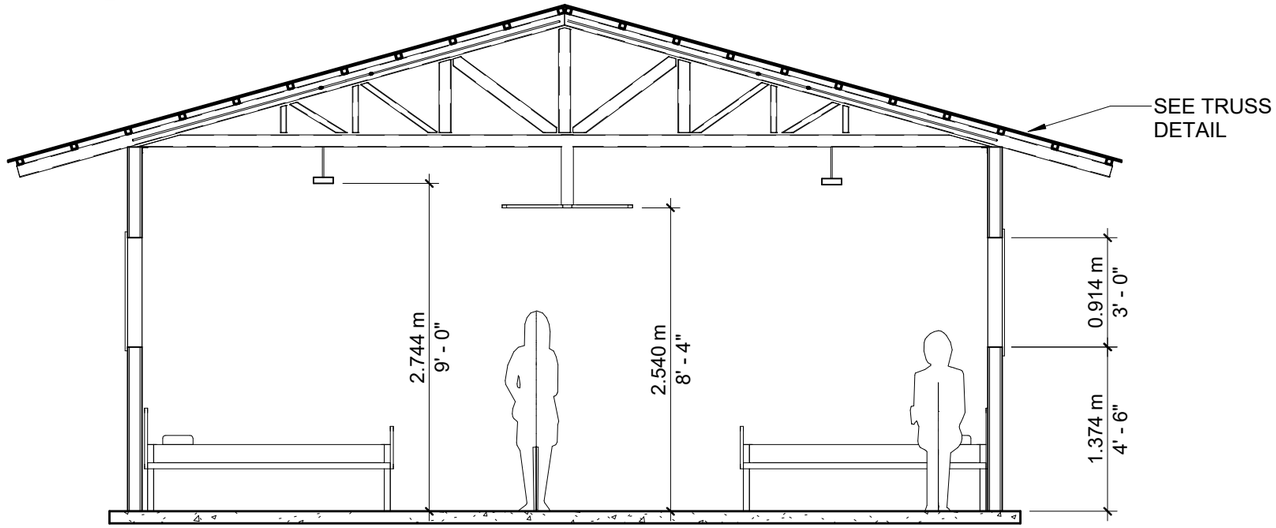
REFLECTED CEILING PLANS



1 PRESUMPTIVE WARD

SCALE 1 : 50



2 CONFIRMED WARD

SCALE 1 : 50

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BUILDING SECTIONS

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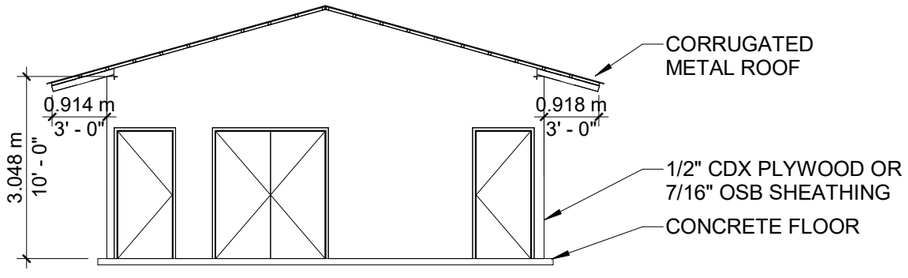
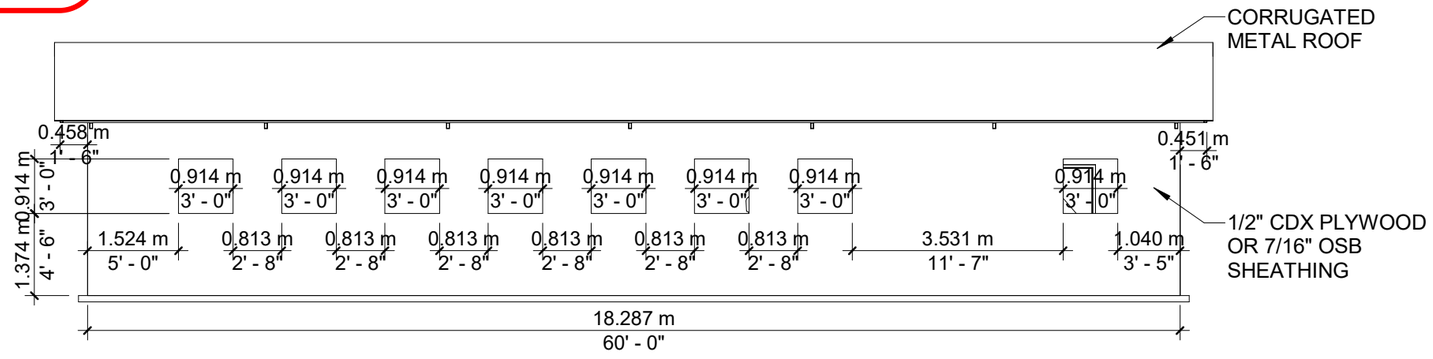


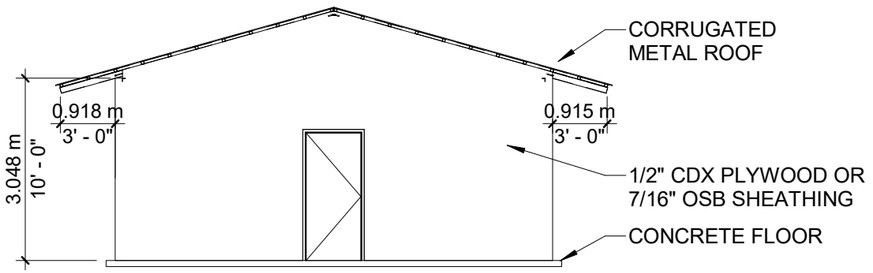
1 CONFIRMED WARD NORTH

SCALE 1 : 100



2 CONFIRMED WARD EAST

SCALE 1 : 100



3 CONFIRMED WARD SOUTH

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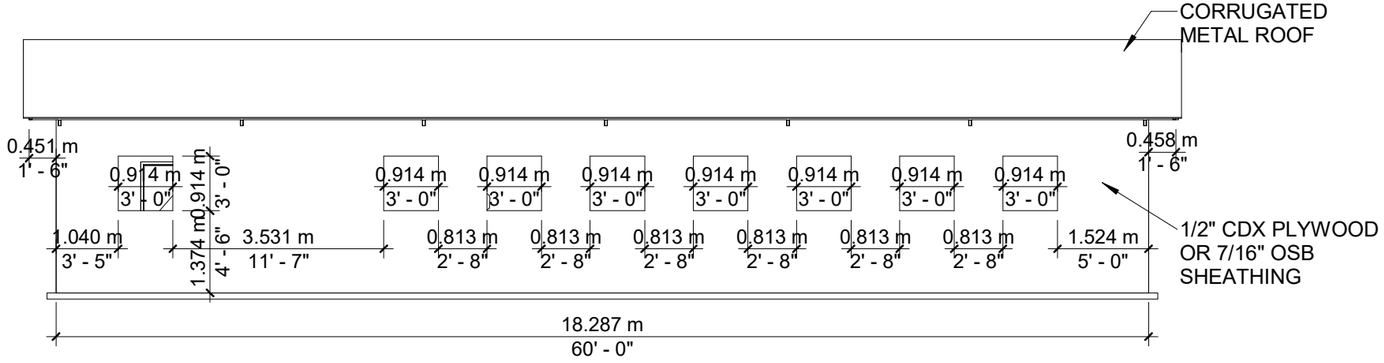

4 CONFIRMED WARD WEST

SCALE 1 : 100

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ELEVATIONS CONFIRMED WARD

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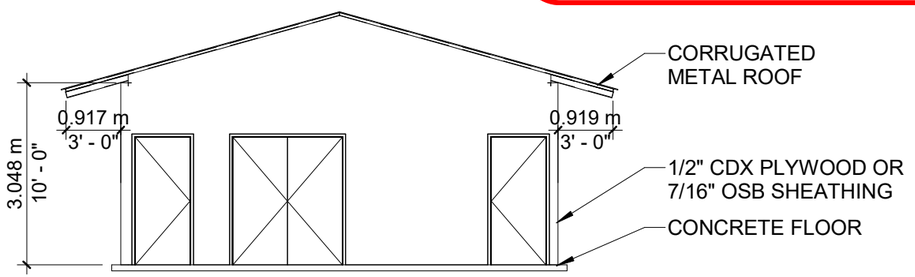
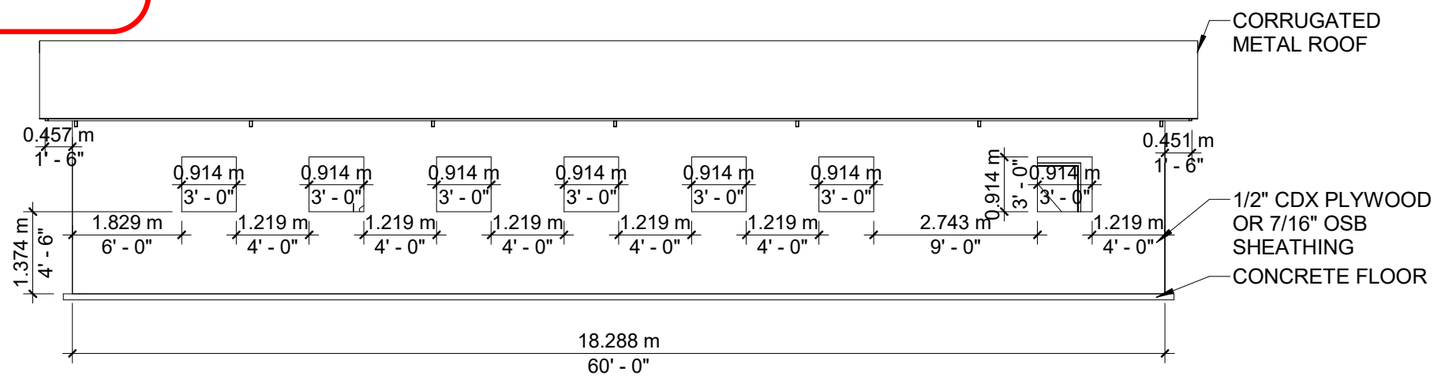


1 PRESUMPTIVE WARD NORTH

SCALE 1 : 100



2 PRESUMPTIVE WARD EAST

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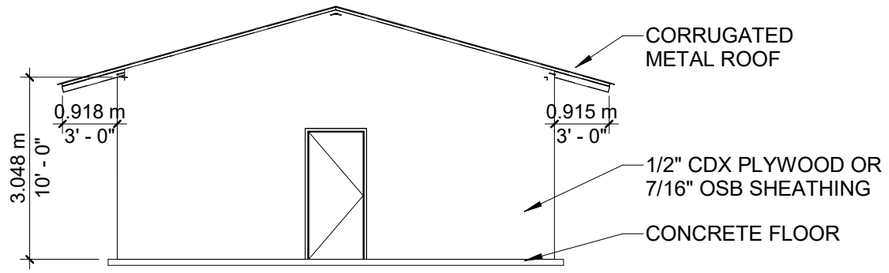

3 PRESUMPTIVE WARD SOUTH

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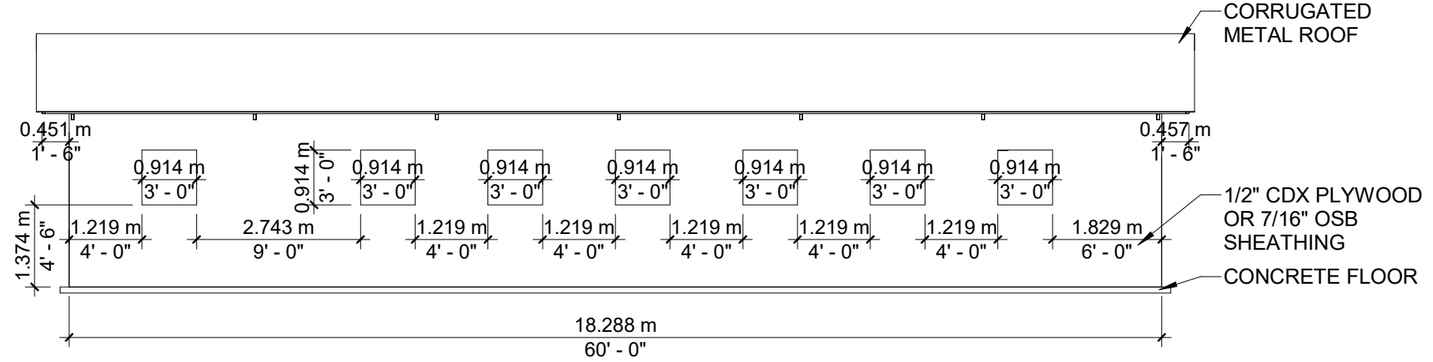

4 PRESUMPTIVE WARD WEST

SCALE 1 : 100

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ELEVATIONS PRESUMPTIVE WARD

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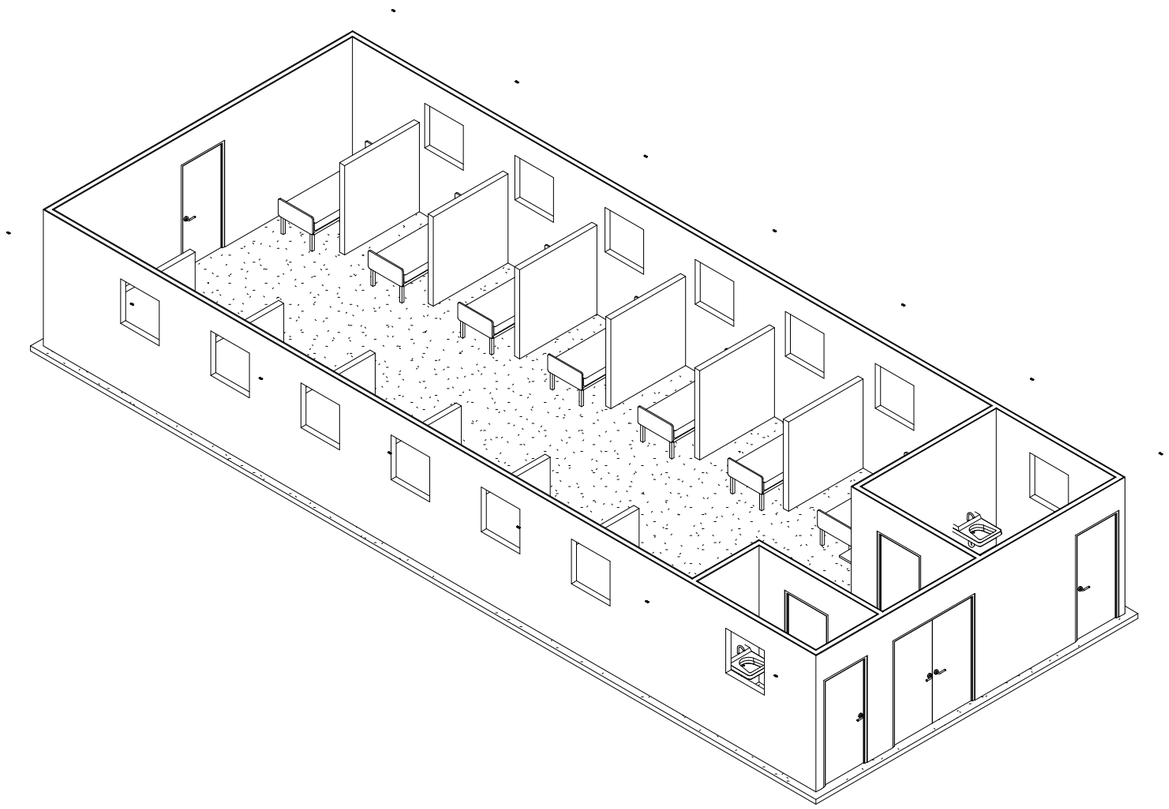
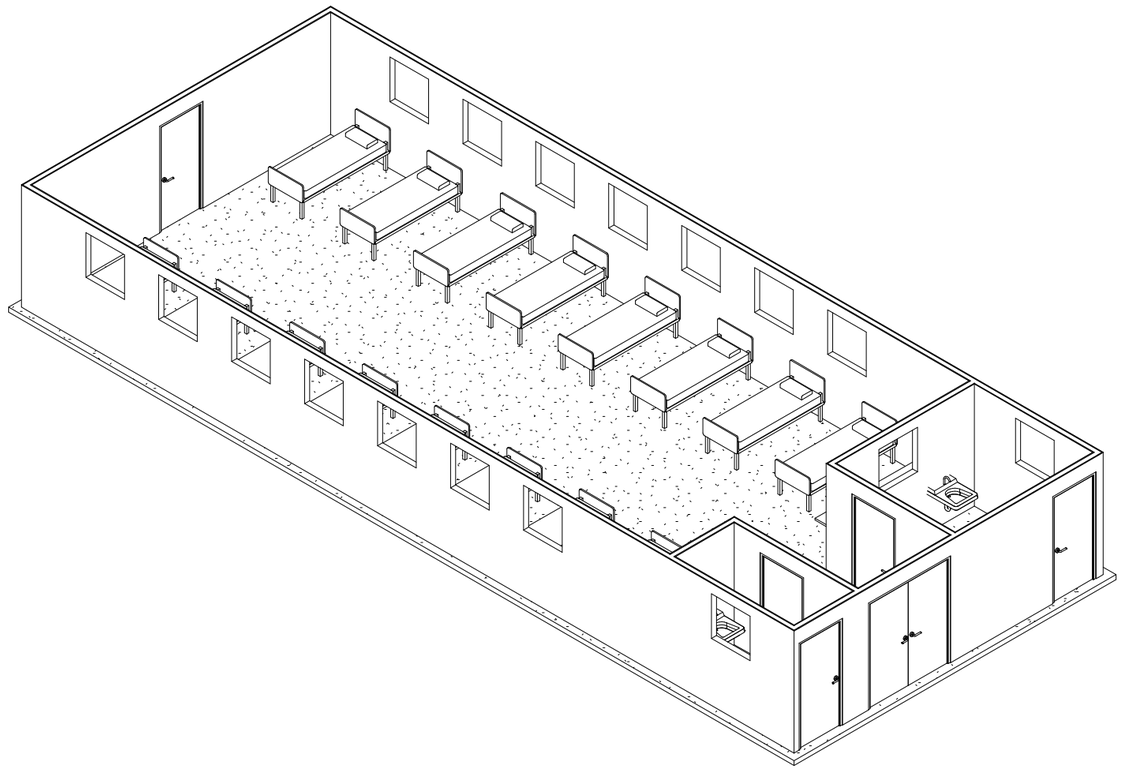


1 3D AXON PRESUMPTIVE WARD
SCALE



2 3D AXON CONFIRMED WARD
SCALE

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AXONS

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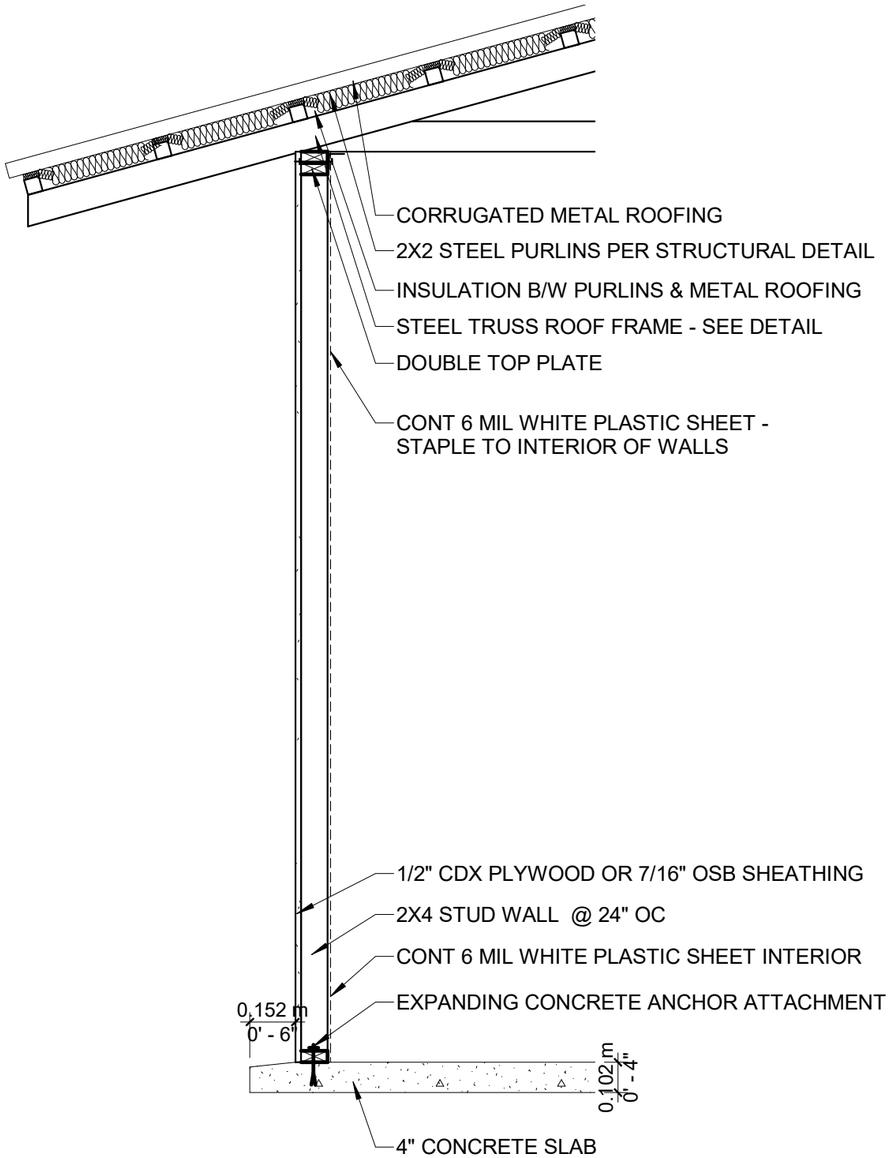
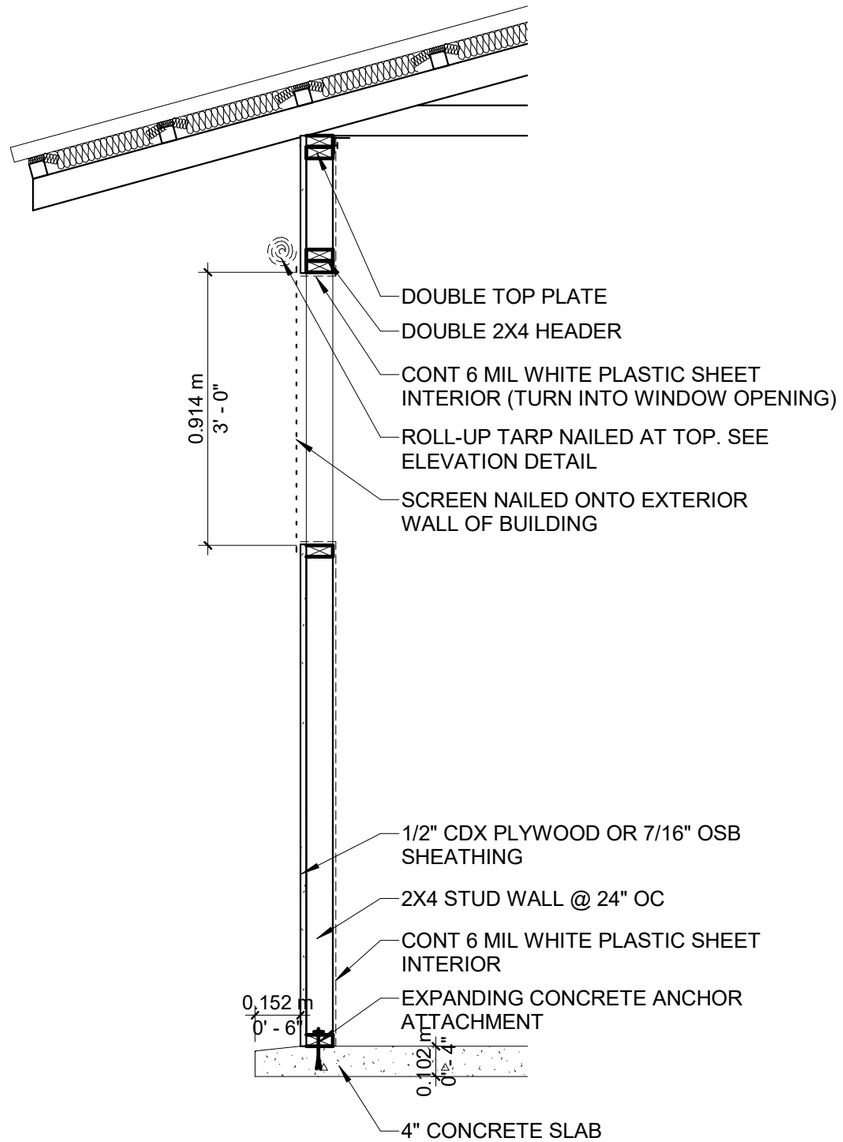
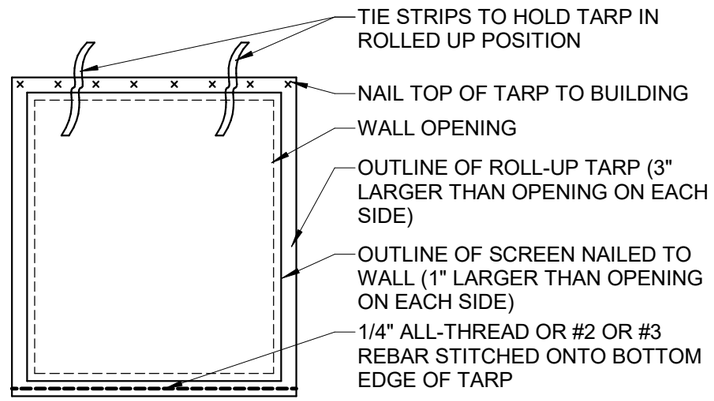


FRAMED PLYWOOD WALLS



FRAMED PLYWOOD WALLS @ WINDOWS



WINDOW COVERING ELEVATION

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WALL SECTIONS

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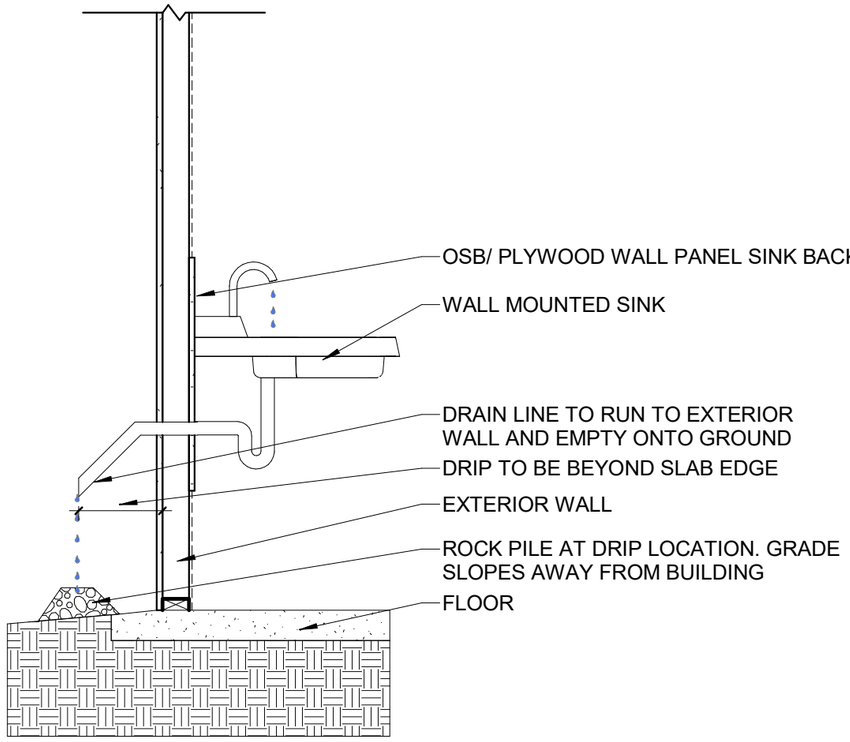
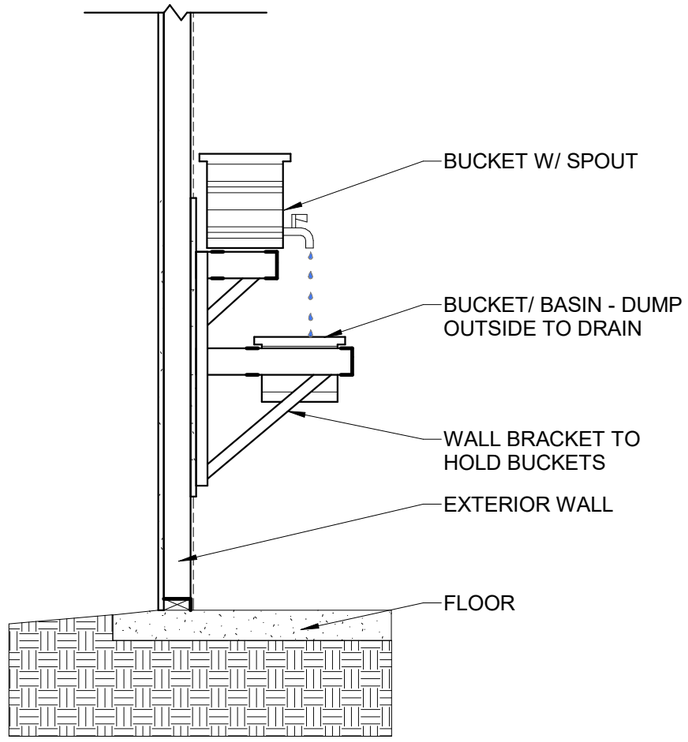


OPTION A: PLUMBED SINK



OPTION B: BUCKET SINK

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SINK OPTION DETAILS

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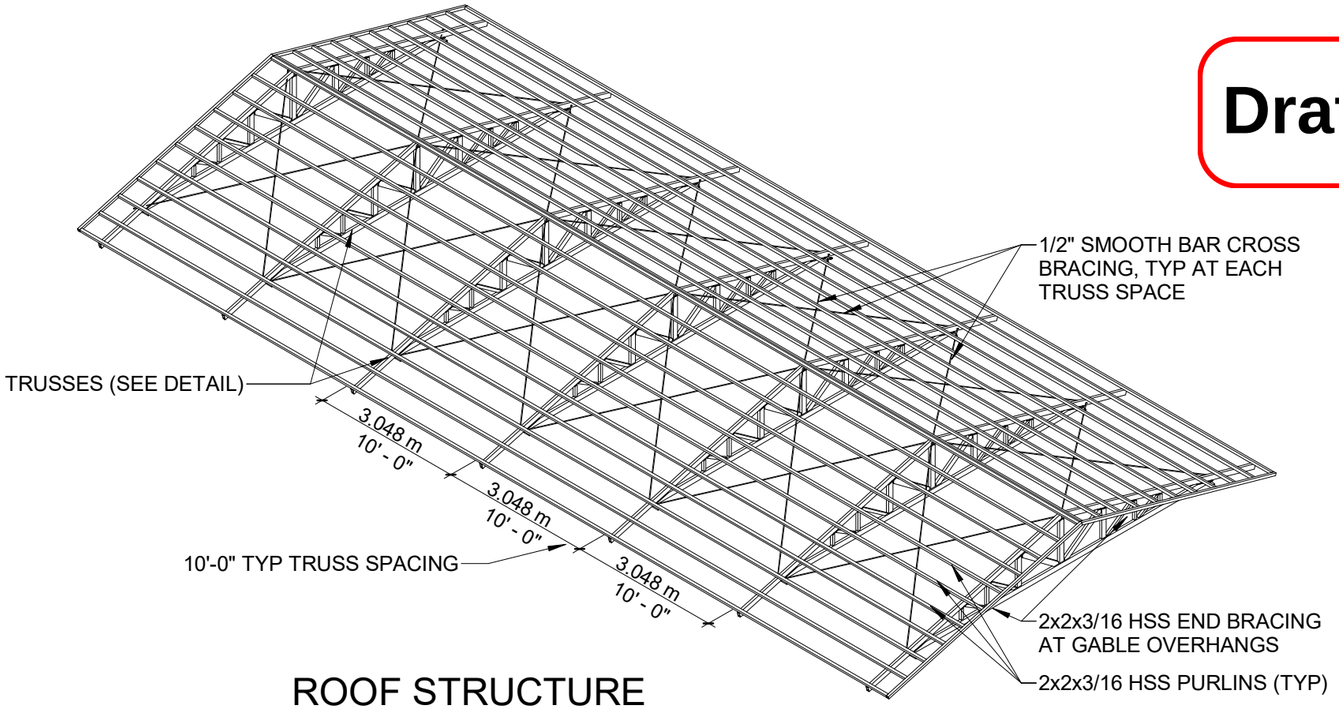
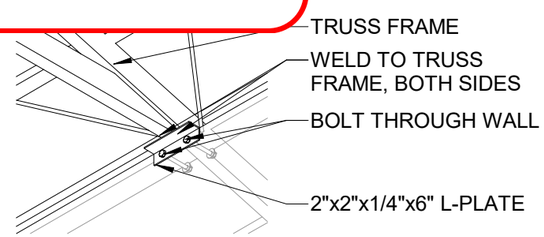
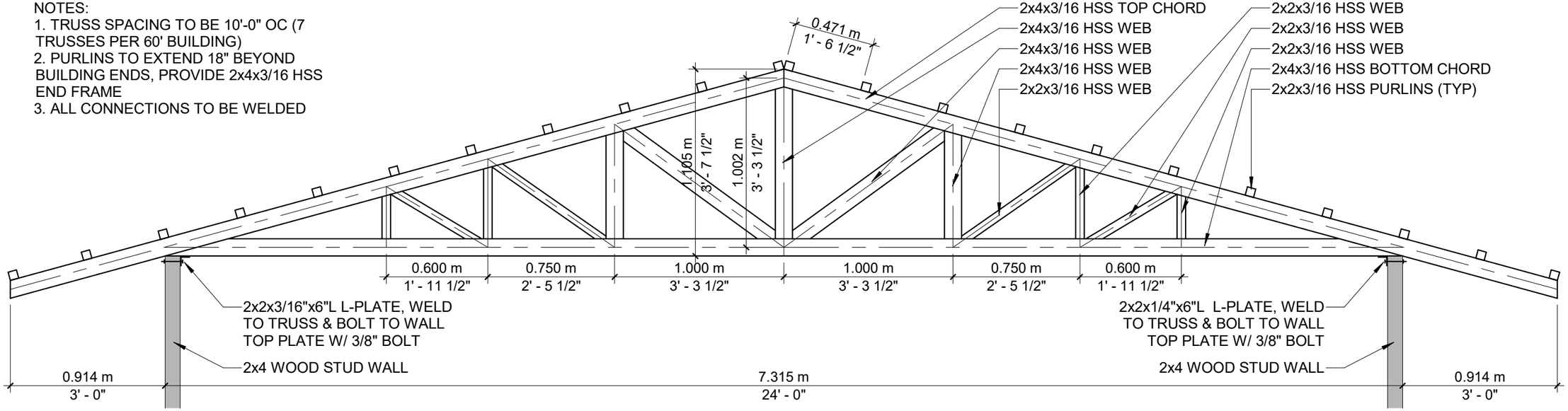


ROOF STRUCTURE



ROOF ATTACHMENT

NOTES:
1. TRUSS SPACING TO BE 10'-0" OC (7 TRUSSES PER 60' BUILDING)
2. PURLINS TO EXTEND 18" BEYOND BUILDING ENDS, PROVIDE 2x4x3/16 HSS END FRAME
3. ALL CONNECTIONS TO BE WELDED



STEEL TRUSS

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STEEL TRUSS DETAILS

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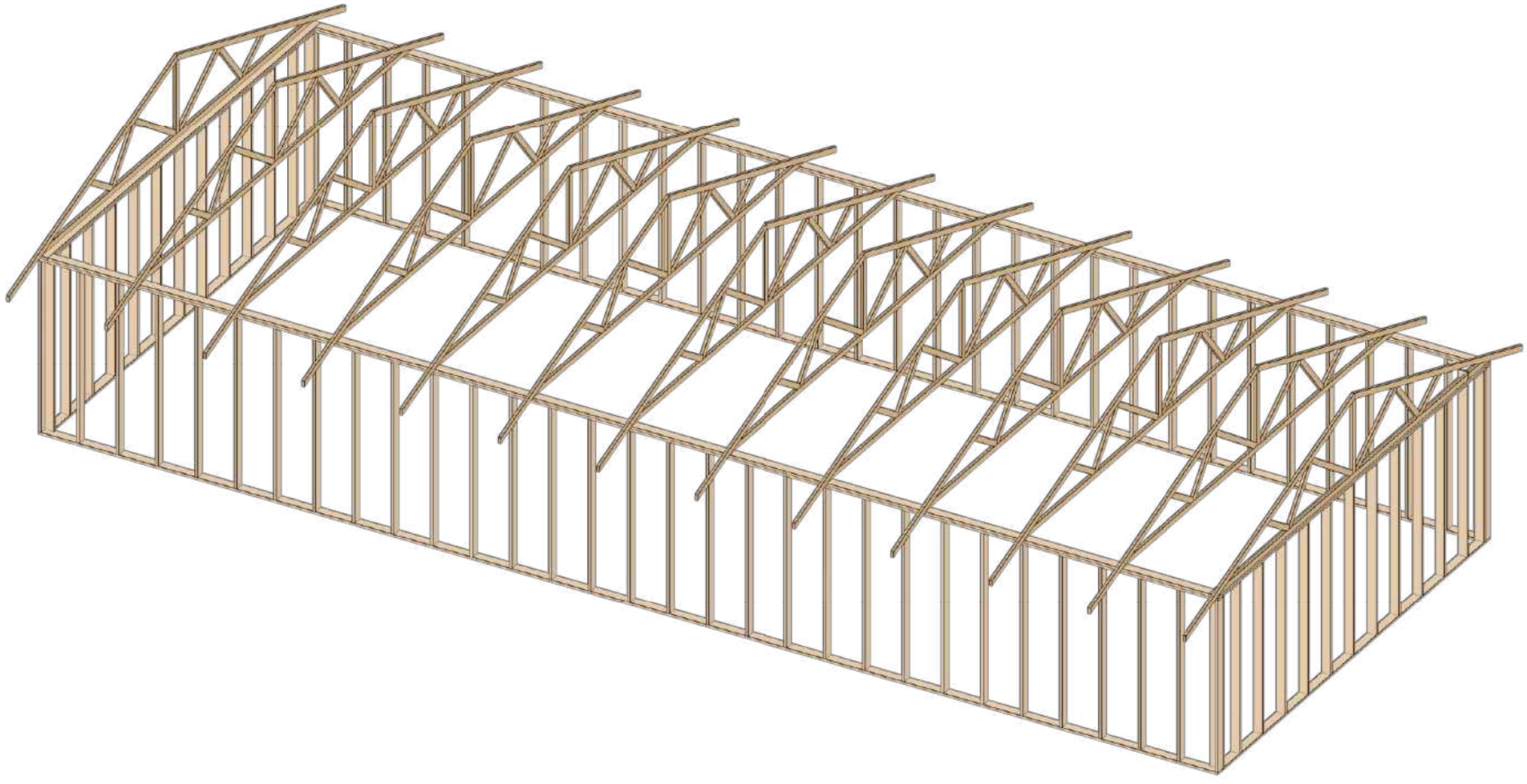

FLOOR PLAN

1/2" = 1'

A NAME ELEVATION OR SECTION

1/2" = 1'

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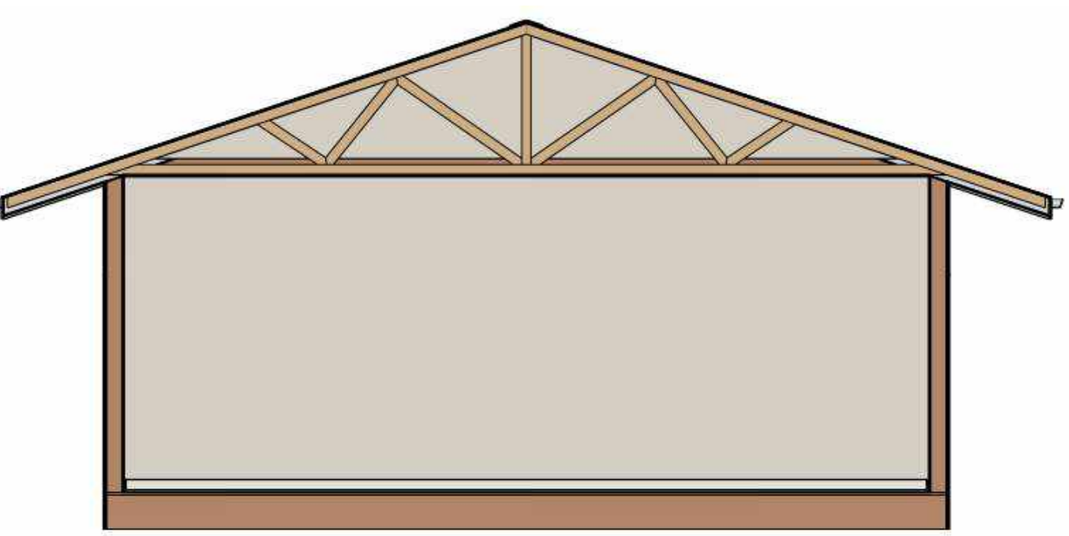
WOOD TRUSS DETAILS



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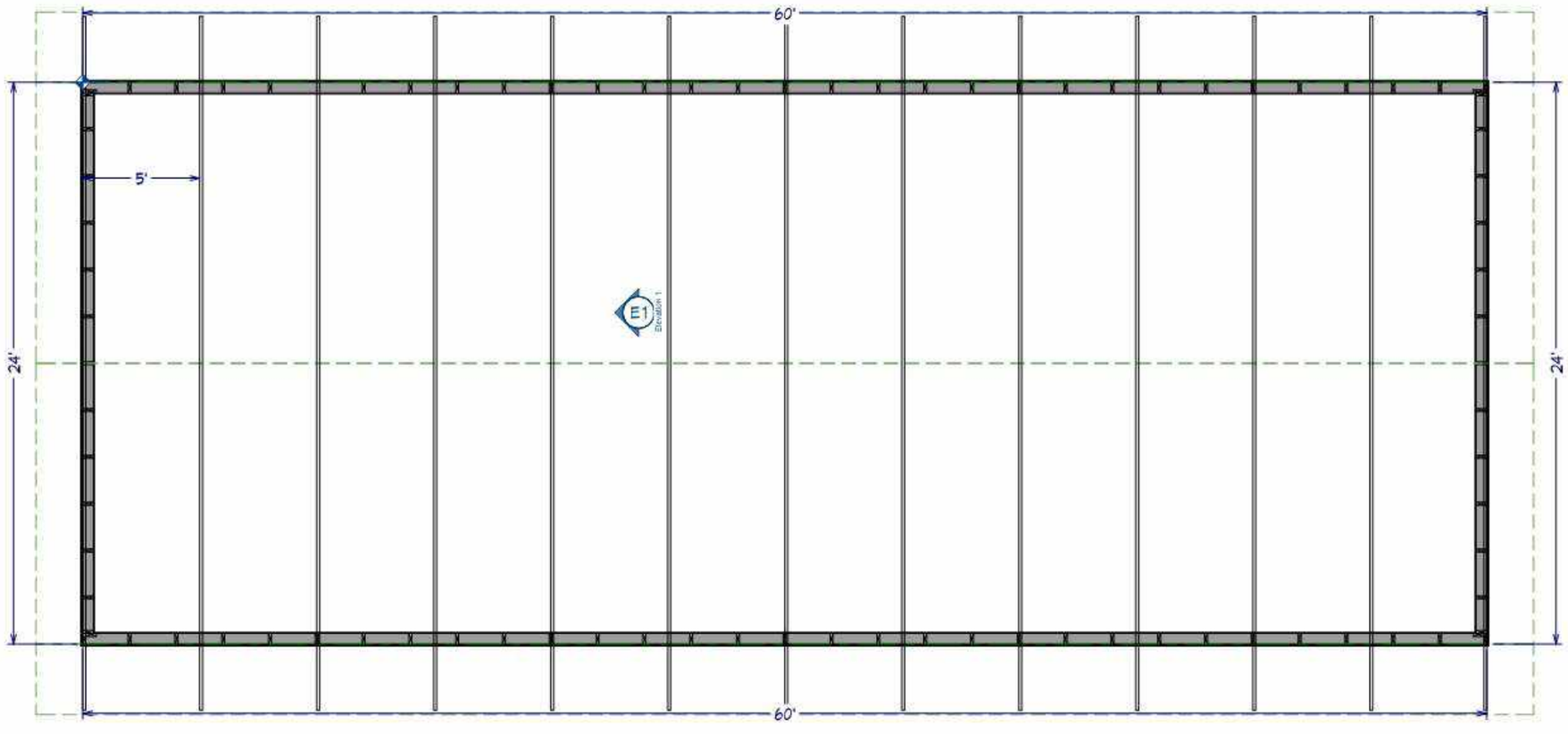

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WOOD TRUSS DETAILS

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PENDING STRUCTURAL DESIGN

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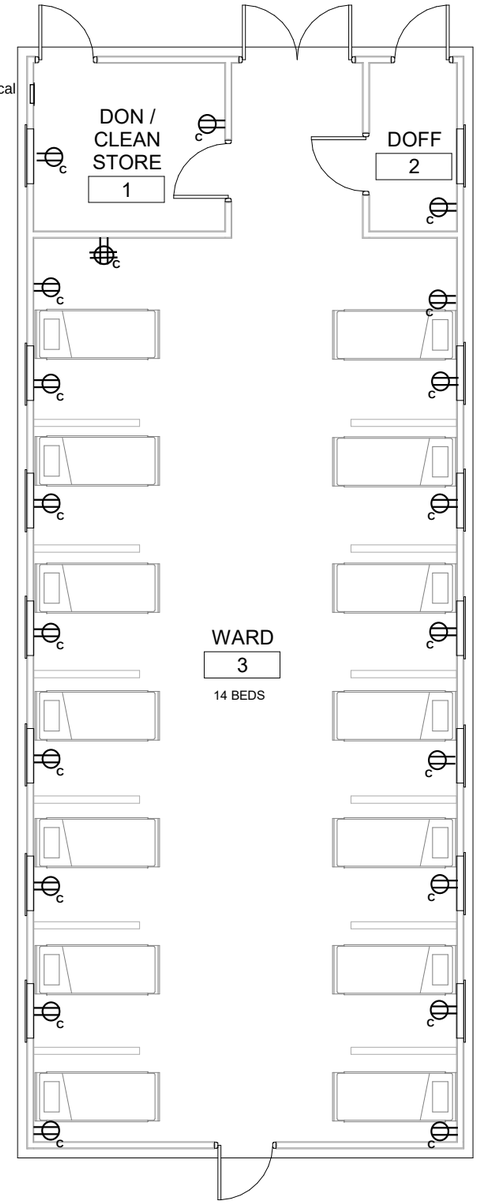
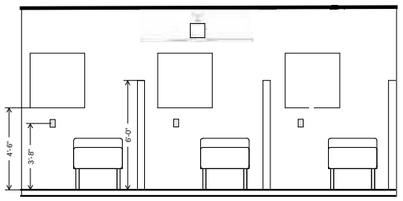
WOOD TRUSS DETAILS

Flush Mounted 8 Circuit Electrical Breaker Panel in Outside Wall



PRESUMPTIVE WARD TYPICAL POWER PLAN



RECEPTACLE LOCATION TYPICAL

C	Receptacle Mounted 1.12m A.F.F.
C	Quad Mounted 1.12m A.F.F.
$	Light Switch Mounted 1.12m A.F.F.
$FC	Fan Control Mounted 1.12m A.F.F.
L-1	LED Linear Ceiling Hung Strip Light
CF-1	56" Variable Speed Ceiling Fan
WS-1	LED Weatherproof Wall Sconce

LEGEND

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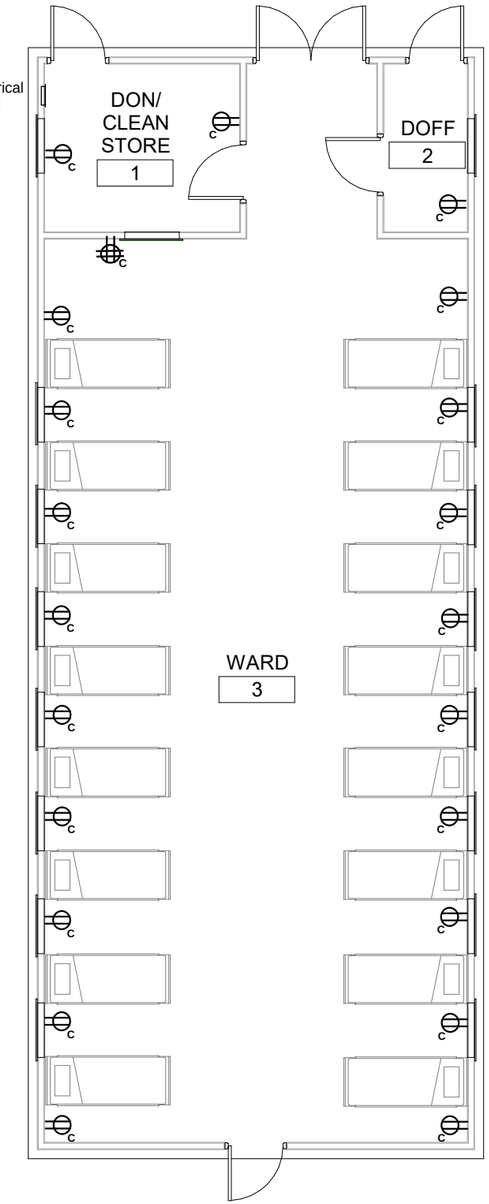
Flush Mounted 8 Circuit Electrical Breaker Panel in Outside Wall



CONFIRMED WARD TYPICAL POWER PLAN

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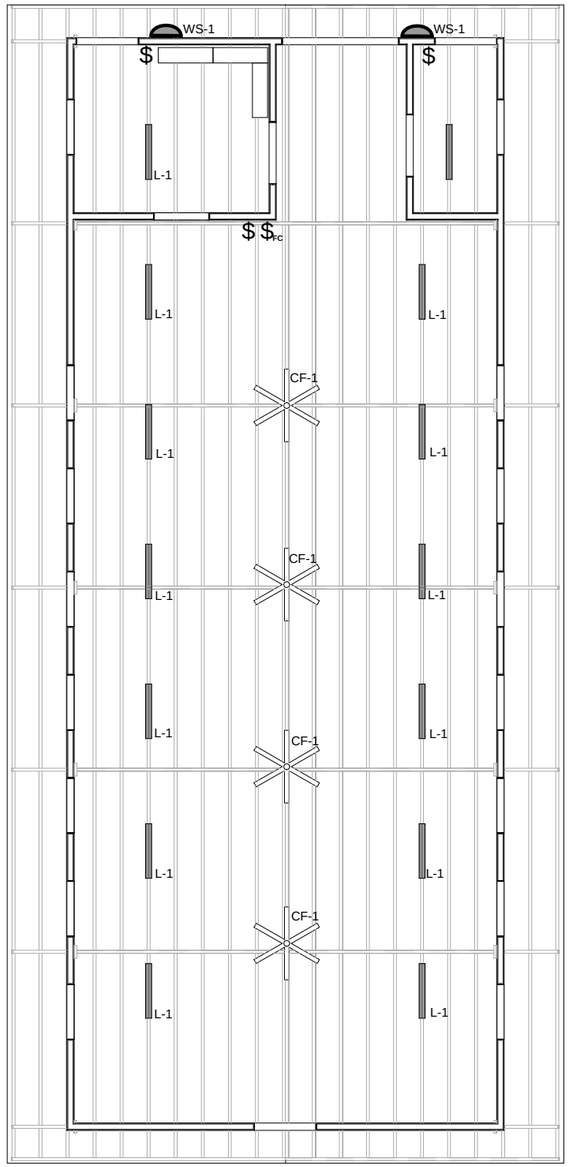
Version 1.02-IEC

SK-16

Typical Ward Electrical Power Plan



Receptacle Mounted 1.12m A.F.F.	
Quad Mounted 1.12m A.F.F.	
$	Light Switch Mounted 1.12m A.F.F.
$rc	Fan Control Mounted 1.12m A.F.F.
L-1	LED Linear Ceiling Hung Strip Light
CF-1	56" Variable Speed Ceiling Fan
WS-1	LED Weatherproof Wall Sconce

LEGEND

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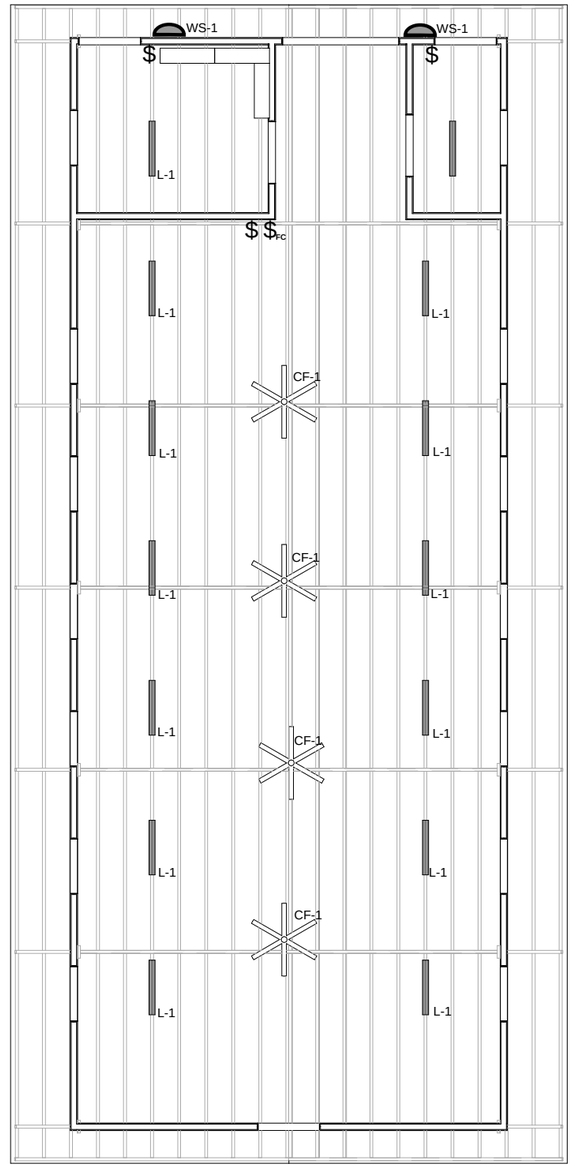

1 CONFIRMED WARD
SCALE 1 : 100

2 PRESUMPTIVE WARD
SCALE 1 : 100

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REFLECTED CEILING PLANS

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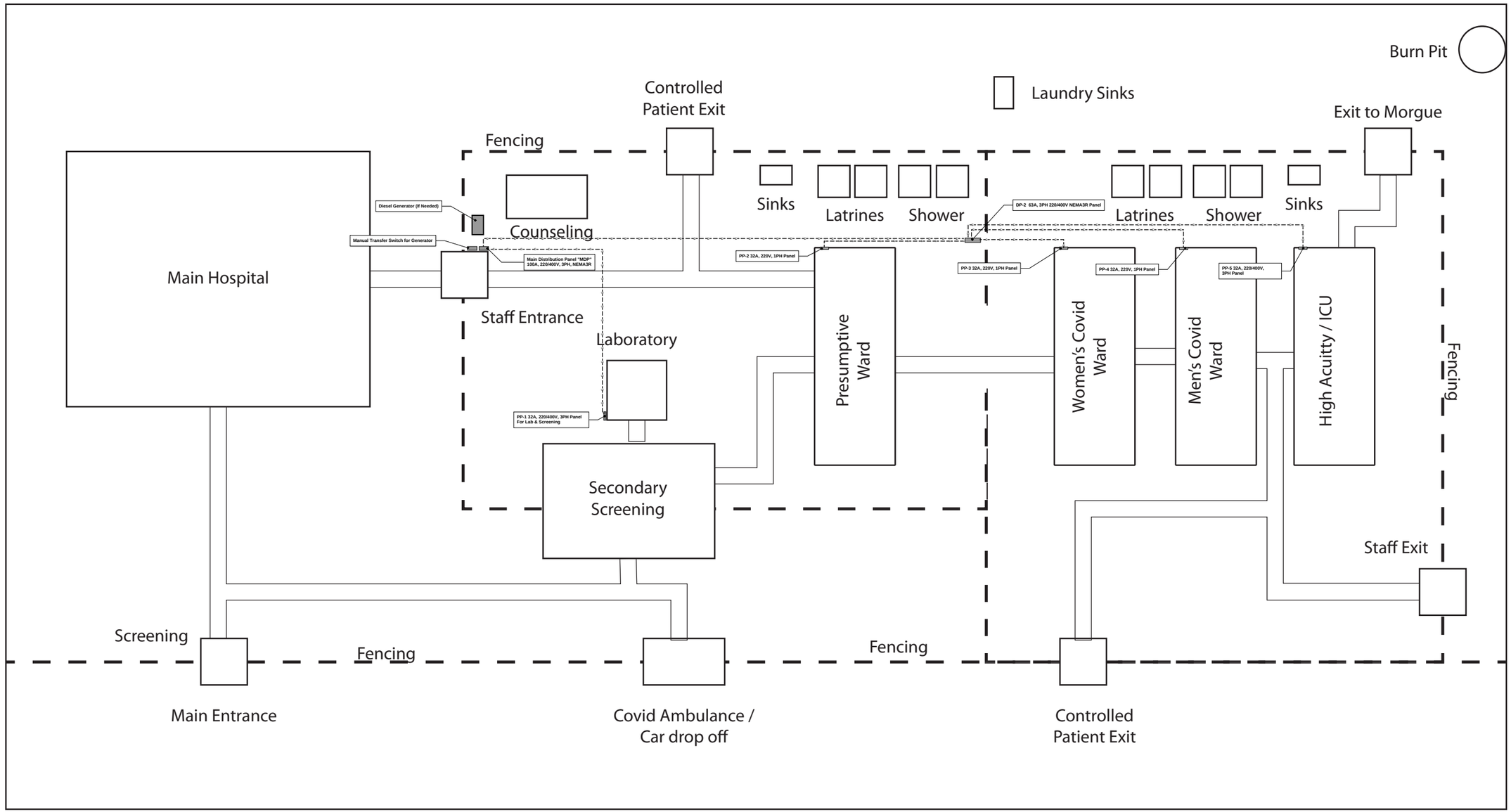

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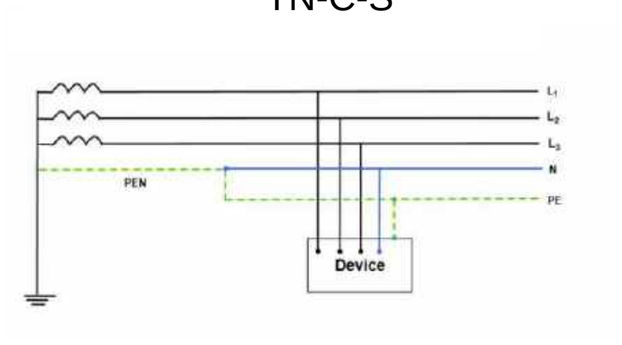
Example of Electrical Distribution Plan

Typical Ward Panel Schedule

	PROJECT: PIH COVID	PANEL		PP-1			
	LOCATION:	Presumptive Ward					
	VOLTAGE:	230 PH: 1		WIRE: 2 KAIC 10			
	MAIN BUS:	62 AMPS		NEUTRAL BUS: 100%			
	MAIN BREAKER:	32 A FRAME		62 A TRIP			
	MOUNTING:	Flush		GROUND BUS: FULL			
	TOTAL VA			FEEDER: COVID MDP			
	DIRECTORY	L1	L2	CKT.	AMPS	L1	Y
R	Clean Receptacles Bldg #2	720		1	10/1 RCBO		
R	Bed Receptacles Bldg #1		720	2	10/1 RCBO		
R	Bed Receptacles Bldg #1	720		3	10/1 RCBO		
R	Bed Receptacles Bldg #1		720	4	10/1 RCBO		
R	Bed Receptacles Bldg #1	720		5	10/1 RCBO		
R	Bed Receptacles Bldg #1		720	6	10/1		
L	Lights & Fans Bldg #1	916		7	10/1		
L	Spare		0	8	6/1		
E	Spare	0		9	10/1		
E	Spare		0	10	12/1		
	SUBTOTAL	3,076	2,160				

RCPT: 1ST 10KVA @ 100% =	4,320	VA
Remaining KVA @ 50% =	0	VA
LIGHTING: KVA @ 100% =	916	VA
EQUIP.: KVA @ 100% =	0	
TOTAL DEMAND =	5,236	VA
TOTAL AMPS	23.8	AMPS

Recommended Earthing System
TN-C-S



ELECTRICAL INSTALLATION GENERAL NOTES

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