PROCEDURE

PET-HSE27-HH-PRD-00008
SARS-CoV-19 Testing

PART OF A BETTER FUTURE

Woodside Energy

Objective

To establish a process to manage the risk of exposure to employees and contractors in the workplace resulting from SARS-CoV-19 (COVID 19).

Audience

Petroleum Deepwater (Woodside Energy) employees, contractors, and visitors to Pet DW (WEL) owned and operated sites. Contractors working directly on behalf of Pet DW (WEL) and assessed as having an equivalent program are not required to use this procedure.

Owner

Annette Bisby, Head of Health and Safety - Corporate

Document Signatures (e-signatures are permissible)

	Business Role	Name	Signature
Approver	VP HSEQ Projects	Karelis Holuby	*Signature on file – refer to Memorandum: Heritage BHP Petroleum HSE MS Post-Merger Update*

Disclaimer:

This document has been updated to meet post-merger requirements. Updates have been restricted to rebranding of logo, company name and revision number and date. Updates have not impacted the design or functionality, or taken away from original intent, of the document.

Roles and Responsibilities

Role		Definition
Testing Coordinator	TC	The person responsible for managing the testing process from beginning to end within a specific region. This includes cross checks occur to ensure each personnel has all required test results and ensures no personnel is cleared to mobilize with a detect/positive/inconclusive test result. This is a process role not an organizational role. • **Mandatory Training: COVID Master Class**
Response Coordinator	RC	The person responsible for ensuring Testing Chain of Custody process is operational. Supports issue management between Testing Coordinator, Quarantine Coordinator, PET Health, HSE Managers, Supply and others as needed. This is a process role not an organizational role. • **Mandatory Training: COVID Master Class**
Quaratine Coordinator	QC	The person responsible for ensuring that quarantine locations operate in accordance with the HSE Standard requirements. Responsible managing the quarantine location (logistics) and ensuring all cross checks occur to ensure each personnel has all required test results and ensures no personnel is cleared to mobilize with a detect/positive/inconclusive test result. This is a process role not an organizational role. • **Mandatory Training: COVID Master Class**
HSE Manager	HM	The person responsible to ensure COVID-19 testing chain of custody is implemented at their location. The person responsible for liaising with PET Health, Pet DW (WEL) Health Contacts, Leaders, Human Resources and Contractor Representatives. • **Mandatory Training: COVID Master Class**
Healthcare Professional	HP	The person responsible to support on-site screening/swabbing process, and/or case management of person with suspected/actual COVID-19. The data would then be sent to and entered by Houston Health at health@petroleumdeepwater.com. • **Mandatory Training: COVID Master Class**
HSE Business Partner	HSE	The person responsible for supporting the Health, Safety and Environment (HSE) aspects of the process. • **Mandatory Training: COVID Master Class**
PET Principal Health	PH	The person responsible for establishing minimum requirements for this procedure. Supports management of issues/barriers that may be identified. • **Mandatory Training: COVID Master Class**
Medical Director/Team	MD	The person(s) responsible for supporting case management of detect/positive/inconclusive cases. • **Mandatory Training: COVID Master Class**
Contact Tracer	CT	The person responsible for performing contact tracing when a suspected/confirmed COVID-19 case is identified and ensuring all close/casual persons are identified. Additionally, responsible to notify the HSE Manager of close/casual contact(s) (Contact tracing documentation must be sent to Houston Health Services). This is a process role not an organizational role. • **Mandatory Training: COVID Master Class**
HR / Legal	HL	The person responsible for providing specialist advice to PET Health/ HSE Managers, Leaders, Testing Coordinators, etc. • **Mandatory Training: COVID Master Class**

Personnel	ALL	The person responsible to complete required screenings, testing and quarantine prior to mobilization.
Supply	SUP	The person responsible to support procurement of PPE, test kits, equipment and laboratories to support chain of custody process. • **Mandatory Training: COVID Master Class**
Requestor	REQ	The person making the request for testing and quarantine for personnel. This is a process role not an organizational role. • **Mandatory Training: COVID Master Class**

Introduction to the Pandemic Quarantine and Testing Framework

Key Principles

The testing and quarantine framework draws on three key principles:

- Reduce interactions between personnel to prevent the spreading of the virus
- Validate test results to ensure all personnel have the required number of negative/non-detect tests before mobilizing
- Reduction in the amount of time personnel spend in quarantine

General Accountabilities

The pandemic response risk is different compared to other similar risks; it is vital that all personnel involved understand:

- The risk
- The controls and control context
- Their responsibilities/accountabilities
- The expectation to contact health support in the event of outliers

Procedure

Phase 1: Strategy and Planning

Step	Description	Lead	Supporting Roles
1	Determine the type of test to be performed	PH	SUP MD
2	Quality control for lab and medical support	PH	SUP MD

Step 1. Determine the type of test to be performed

PET Health:

- Identify and validate test kits
  - Work with Supply to source test kits/equipment/laboratories to perform analysis of tests
  - Work with the Group medical team to evaluate test kits
  - Select kit based on outcome of evaluation (with consideration of cost, turn-around time, quarantine, availability)
  - Refer to Appendix 8. Approved Testing Protocols
  - Refer to Appendix 9: General Principles of Testing and Limitations
  - Refer to Appendix 12: Step Guide for Antigen Testing (pilot)

Outputs	Test has been identified for use that meets/exceeds requirements

Step 2. Quality control for lab and medical support

PET Health:

- Work with Supply and Group Medical team and/or third-party auditor to evaluate the laboratory and staff.
  - Refer to Appendix 10: Quality Control – Test Kits and Laboratories
  - Refer to Appendix 11: Laboratory Verification Check List

Outputs	Laboratories and staff meet/exceed requirements to perform test analysis

Phase 2: Pre-Arrival Quarantine and Test Requisition

Step	Description	Lead	Supporting Roles
3	Ordering tests	TC	HP
4	Screening and swabbing logistic set up	TC	QC HP

Step 3. Ordering tests for on-site screening and swabbing

Testing Coordinator:

- Receives testing roster from Requestor
- Orders test labels from identified lab for personnel identified on the testing roster according to the lab protocol
  - Cross check ordered tests against testing roster to be sure a label is created for each person

NOTE: If testing only (no quarantine required) – refer to Appendix 7. Step Guide - Testing Only

Outputs	Tests ordered for each person on the testing roster

Step 4. Screening and swabbing logistic set-up

Testing Coordinator:

- Verify Testing Roster with site manager
- Schedule Healthcare Professionals for on-site screening and swabbing
  - Provide Healthcare Professionals with testing roster and screening materials (consent forms, screening forms)
  - Ensure Healthcare Professionals have swabbing kits and labels for each personnel
    - Provide extra swabs and blank labels for any changes that may occur on the test roster
  - Ensure Healthcare Professionals have appropriate transport equipment (cooler)
  - Ensure courier has been arranged to transport swab kits to the lab

NOTE: If performing antigen testing for modeling pilot, refer to Appendix 12. Antigen Testing Step Guide if performing Antigen Testing for Modelling Pilot and ensure antigen test kits are provided.

Outputs	On-site screening/swabbing arrangements are made Swab kits and labels are available for each personnel

Phase 4: Day of On-site Screening and Swabbing

Step	Description	Lead	Supporting Roles
5	Cross-check testing roster against personnel present for screening and swabbing	HP	TC QC
6	Pre-entry screening and swabbing occurs	HP	QC TC
7	Prepare swab kits for transport to lab	HP	TC
8	Manage personnel who are not cleared for pre-entry into quarantine	HP	HL MD HSE TC HM QC
9	Entry into quarantine	QC	HM HSE

Step 5. Cross check testing roster against personnel present for screening and swabbing

Healthcare Professional:

- Cross check testing roster to identify any changes that need to be made
  - If changes to testing roster are needed
    - Update testing roster
    - Create swabbing kit labels
    - Order tests from lab using lab protocol or use manual label process

Outputs	Updated testing roster Swabs are properly labeled

Step 6. Pre-entry screening and swabbing occurs

Healthcare Professional:

- Screen and swab all personnel on the testing roster
  - Ensure personnel complete screening form, consent to test form
  - Perform temperature check
  - Review screening form and identify any concerns
  - Identify personnel who are not cleared for pre-entry into quarantine
    - Discuss details with MD and make determination whether personnel are cleared for pre-entry based on the screening
    - If personnel are not cleared to enter, complete swabbing and notify Quarantine Coordinator and Testing Coordinator

NOTE: Refer to Appendix 12. Antigen Testing Step Guide if performing Antigen Testing for Modelling Pilot

Outputs	Screening and swabbing of all personnel occur

Step 7. Prepare swab kits for transport

Healthcare Professional:

- Prepare swab kits for transport to lab
  - Cross check testing roster to ensure there is a swab kit for all personnel
  - Cross check accuracy of swab kit labeling
  - Place swab kits in transport equipment (cooler) as outlined by swab kit instructions
- Ensure courier transports swab kits to identified lab
- Ensure lab receives swab kits
- Notify Testing Coordinator when lab receives swab kits

Outputs	All personnel have a swab kit Swab kits are packaged and transported to lab Identified lab receives swab kits

Step 8. Manage personnel who are not cleared for pre-entry into quarantine

- Quarantine Coordinator:
  - Support activities to remove persons who is not cleared to enter quarantine
  - Notify HSE Manager of persons who are not cleared to enter quarantine
- Testing Coordinator:
  - Support case management of personnel who are not cleared to enter quarantine
    - Work with the contractor company to support contract personnel

Outputs	Only cleared personnel enter quarantine Case management occurs for personnel who are not cleared to enter quarantine

Step 9. Entry into quarantine

- Personnel will be required to quarantine for the duration and at location specified by the local Operations Representative to facilitate testing. Pre- and post-testing quarantine duration and location will be determined in consultation with PET Health, Group Health Consultant, local regulations, and other pertinent factors
- Personnel will enter quarantine in an area isolated from the general public with decontaminated facilities, isolated food supplies and minimal access to others
- Personnel to remain in quarantine after the testing and up until the time of check in for helicopter departure
- Personnel are not to participate in the Prohibited Activities described in PET SARS-CoV Standard (PET-HSE27-HH-STD-00001) during the designated quarantine

Outputs	Personnel are aware of quarantine requirements Personnel are protected from exposure to COVID-19

Phase 5: Confirmation and Notification of Test Results

Step	Description	Lead	Supporting Roles
10	Monitor lab for results	TC	QC MD HP
11	Notify key stakeholders of test results	TC	HSE MD HM PH QC

Step 10. Monitor lab for results

- Testing Coordinator:
  - Monitor lab portal for test results – once results are in:
    - Download test results
    - Cross check test results with testing roster for that group to ensure there is a test result for each person
    - If a test is missing, contact lab to inquire reason for missing test result
    - Identify detect/positive/inconclusive test results

Outputs	
	Cross check is completed to ensure all results are received Al test results are received for each person Confirmed/inconclusive case is identified

Step 11. Notify key stakeholders of test results

- Testing Coordinator to notify:
  - Quarantine Coordinator via phone call, text and email
  - PET Principal Health – detect/positive/inconclusive by text/email
  - Pet DW Health (Houston Health Services) – send test result documentation and testing roster for input into Cority (Health@petroleumdeepwater.com)
- Quarantine Coordinator:
  - Cross check test results with testing roster for that group to ensure there is a test result for each person
  - Contact Testing Coordinator if a test result is missing
  - If missing test is second test for mobilization clearance, DO NOT RELEASE PERSONNEL FROM QUARANTINE HOTEL
  - Once second test result is received and is non-detect/negative, the person may be released for mobilization with 2 non-detect/negative test results for the quarantine period
  - Notify HSE Manager of detect/positive/inconclusive test result
  - Notify personnel of results
  - If detect/positive/inconclusive result, notify person to stay in their room until further instruction
- HSE Manager:
  - Notify pre-identified key stakeholders of detect/positive/inconclusive case (Ops Mgr., VP HSE)
  - Notify pre-identified contact tracer to begin contact tracing

Outputs	Notifications are made to key stakeholders Documentation is provided to Pet DW for data entry Cross check is completed to ensure all results are received Personnel are notified of test results Detect/Positive/Inconclusive cases are isolated

Phase 6: Case Management

Step	Description	Lead	Supporting Roles
12	Management of suspected (inconclusive) or confirmed case	QC	HM MD PH TC
13	Contact tracing for close and casual contacts	CT	HSE PH HM
14	Ongoing case management until released to return to work (RTW)	TC	HL HSE MD PH

Step 12. Management of suspected (inconclusive) or confirmed case

Quarantine Coordinator:

- Ensure personnel is isolated to room until plan for transport from quarantine hotel is developed and contact tracing has been completed
- Facilitate cleaning/disinfection following identified protocols for facility

HSE Manager:

- Support Quarantine Coordinator with developing plan for transporting personnel from quarantine hotel after contact tracing has been completed

Testing Coordinator:

- Support case management of personnel
- If contractor, liaise with contractor company to follow their protocols (if no protocols, follow Pet DW protocols)
- Once return to work requirements (RTW) have been met, support RTW process

Outputs	Person remains in isolation until plan in place to remove from quarantine location Initial Cleaning/Disinfection occurs Key stakeholders are notified Contact tracing is started

Step 13. Contact Tracing for Close and Casual Contacts

Contact Tracer:

- Use Pet DW contact tracing template (PET-HSE27-FRM-00029) and references PET Guidance Document - COVID-19 Contact Tracing Process (PET-HSE27-FRM-00028)
- Request C-19 Tracer data (if available)
- Interview identified case for close/casual contacts
- Notify HSE Manager/Quarantine Coordinator of close/casual contacts of potential exposure

- Notify Quarantine Coordinator of additional areas that may need to be cleaned disinfected
- Send contact tracing documentation to Houston Health Services (Health@petroleumdeepwater.com)

Outputs	Close and casual contacts are identified Additional cleaning/disinfection measures are taken Contact tracing documentation is managed

Step 14. Ongoing case management until released to return to work (RTW)

- Personnel may return to work after meeting all requirements outlined in the Petroleum: COVID-19 Return to Work Requirements (PET-HSE27-HH-MAN-00014)
- Contact Local Medical Director, PET Health or Pet DW Health Contact with questions concerning RTW.

Outputs	Personnel are cleared to return to work

Appendices

Appendix 1. Quarantine Coordinator Check List

Petroleum Deepwater (WEL)	
Quarantine Coordinator	
Activity	**Completion Date**
1. Obtain test roster and verify all required fields are completed (name must be the same as on government issued ID)	
2. Provide testing roster to Testing Coordinator	
3. Ensure hotel is ready for personnel	
4. Post flight schedule in the common areas	
5. Provide support to the Testing Coordinator and screening/swabbing team	
6. Once test results are received from Testing Coordinator, perform second cross check to ensure results are received for each personnel on testing roster and results are cross checked to ensure detect/positive/inconclusive are identified	
7. Notify HSE Manager of all results	
8. Notify personnel of all results (provides a copy of the test where able)	
9. If detected/positive or inconclusive: Place N95 on personnel's doorknob, follow protocols for managing detected/positive/inconclusive case	
10. Facilitate the removal of detected/positive personnel and work with Testing Coordinator to manage inconclusive result	
11. If first test is not detected/negative, personnel continues to quarantine	
13. Update internal system with results (Trackit/SharePoint)	
14. Provide support for second test (or third, if required) 96 hours from last swab	
15. Once test results are received from Testing Coordinator, perform second cross check to ensure results are received for each personnel on testing roster and results are cross checked to ensure detect/positive/inconclusive are identified	

16. Notify personnel of all results (provides a copy of the test where able)	
17. Not detected/negative: Cleared to mobilize Cross-check bracelets, roster and last health screen for symptoms/temperature prior to departure	
18. Detected/positive: Not cleared to mobilize Places N95 on personnel's doorknob Inconclusive: Inform personnel to stay in room and await further instructions	
19. Update internal system with results (Trackit/SharePoint) if available	
20. Obtain crew roster and verify all required fields are completed	
21. Ensure cleaning protocols are followed at quarantine hotel	

Appendix 2. Testing Coordinator Check List

Petroleum Deepwater (WEL)	
Testing Coordinator	
Activity	**Completion Date**
1. Review testing roster template (~48 hours prior to onsite screening/swabbing) and any screening forms that may be received (Address any concerns identified)	
2. Order PCR tests orders tests from lab via portal and cross check tests ordered for all personnel on testing roster	
3. Pre-populate test kit labels	
4. Schedule health care professional for site screening and swabbing	
5. Ensure Healthcare professionals have screening forms (and equipment), consent forms and swab kits	
6. Ensure health care professionals are mobilized at the hotel for screening	
7. Monitor lab portal (12-24 hours after samples are run for results and pulls test results from lab portal)	
8. Ensure all results are received, downloaded and cross checked with testing roster	
9. Notify Quarantine Coordinator of all results via phone/text/email (text/email to PET Health all detected/inconclusive results)	
10. If inconclusive: Testing Coordinator works with local Medical Director and lab to retest or rerun test personnel who are not cleared to enter quarantine are case managed	
11. Provide Pet DW Health (Houston Health Services) with all test results	
NOTE: If performing antigen testing as a part of the Modelling Pilot – refer to Appendix 12. Antigen Testing Step Guide and Appendix 13. Antigen Test Result Form	

Appendix 3. Testing Roster Template

	BHP		Location	Testing Data										Reporting to Health Agency
	Ascession #	Last Name	First Name	Date of Birth	Sex	Test Category Day of Testing	Company	Location	Date of Collection	Collection Time	Result Time	Test Type (PCR Lab or Antigen)	Result	Antigen Test
1														
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Appendix 4. Contact Tracer Check List

Petroleum Deepwater (WEL)	
Contact Tracer	
Activity	**Completion Date**
1. Obtain name of suspected/confirmed case	
2. Request C-19 Tracer data (or similar) if available	
3. Complete COVID-19 Contact Tracing Template (PET-HSE27-FRM-00029) References PET Guidance Document - COVID-19 Contact Tracing Process (PET-HSE27-FRM-00028)	
4. Identify close/casual contacts, areas for decontamination/cleaning/disinfection	
5. Provide data to Quarantine Coordinator and HSE Manager/Business Partner	
6. Send contact tracing data to Pet DW Health (Houston Health Services) for inclusion into Cority	
7. Notify HSE Manager of all close and casual contact	

Appendix 5. Healthcare Professional – Screening and Swabbing Checklist

Petroleum Deepwater (WEL)	
Healthcare Professional – Screening and Swabbing	
Activity	**Completion Date**
1. Arrive at site and set up for screening/swabbing	
2. Cross check testing roster and identify any changes - create kit labels for swabs for any new person's added	
3. Collect forms, conducts screening, and administers PCR test/swabbing (refer to Appendix 9: Step Guide for Antigen Testing if piloting at location)	
4. Clear personnel if screening test is passed	
5. Notify Quarantine Coordinator and Test Coordinator of personnel who are not cleared to enter quarantine	
6. Cross check testing roster against each kit to ensure there is a kit for each person and accurate information is on each kit	
7. Package samples in transportation cooler and ensure courier (if not transported by Healthcare professional) picks up samples and transports them to the lab	
8. Verify lab receives samples and notify Testing Coordinator	
NOTE: If performing antigen testing as a part of the Modelling Pilot – refer to Appendix 12. Antigen Testing Step Guide and Appendix 13. Antigen Test Result Form	

Appendix 6. Prohibited Activities

The following activities are prohibited because they are not consistent with providing and maintaining the quarantined environment. Individuals engaging in the following activities will be subject to discipline up to, and including, termination of employment for employees and removal from the site for all other employees and contractors:

- Attending public or private gatherings in excess of two people from different households or in a place where social distancing (6 ft. or 2 m.) cannot be maintained for the duration of the activity
- Leaving the Company provided quarantine facility once tested
- Inviting others to the quarantined facility provided by the Company
- Refusal to social distance during stay at Company provided facility
- Other activities as outlined by quarantine location coordinators

Appendix 8. Approved Testing Protocols

Molecular Test (RT-PCR)

- Ensure the screening form, consents to test form, and temperature screenings have been completed and reviewed
- All Healthcare Professionals shall don a respirator, face shield, gloves, and an apron prior to administering the test
- Prepare the collection swab, transport media, and transport tube
- Prepare the donor by sitting them in a chair and explaining the process
- Collect the sample from the back of the nasal passage using a soft tipped swab
- Return the swab to the collection tube and transport media
- Secure the tube and apply the appropriate label (cross-check for accuracy)
- Package the specimen for transport
- Ensure transport occurs

Antigen Test (Modelling Pilot only) - refer to Appendix 13 and 14 below

Outputs	Forms and screenings have been completed
	Swabs/tests completed
	Cross check is completed to ensure all kits are labeled for RT-PCR tests
	Personnel are notified of rapid test results
	Swab kits are packaged and sent to lab

Appendix 7. Step Guide - Testing Only

Pre-work for screening/swabbing on-site

1. Identify personnel quarantining and/or testing

Requestor to notify the Quarantine Coordinator and Quarantine Coordinator with:

- Mobilization dates
- Personnel names (must be name on government issued document)
- Passport specifics (if required)
- Any quarantine considerations (i.e., food allergies, special considerations, etc.)
- Identify back-ups (if required)

2. Screening and swabbing logistic set-up

Testing Coordinator:

- Schedule Healthcare Professionals for on-site screening and swabbing
  - Provide Healthcare Professionals with testing roster and screening materials (consent forms, screening forms)
  - Ensure Healthcare Professionals have swabbing kits and labels for each personnel
    - Provide extra swabs and blank labels for any changes that may occur on the test roster
  - Ensure Healthcare Professionals have appropriate transport equipment (cooler)
  - Ensure courier has been arranged to transport swab kits to the lab

Day of Screening/Swabbing:

Healthcare Professional:

- Cross check testing roster to identify any changes that need to be made
  - If changes to testing roster are needed
  - Update testing roster
  - Create swabbing kit labels
  - Order tests from lab using lab protocol or use manual label process
- Screen and swab all personnel on the testing roster
  - Ensure personnel complete screening form, consent to test form
  - Perform temperature check
  - Review screening form and identify any concerns
  - Identify personnel who are not cleared for pre-entry into quarantine
    - Discuss details with MD and make determination whether personnel are cleared for pre-entry based on the screening
    - If personnel are not cleared to enter, complete swabbing and notify Quarantine Coordinator and Testing Coordinator
- Prepare swab kits for transport to lab
  - Cross check testing roster to ensure there is a swab kit for all personnel
  - Cross check accuracy of swab kit labeling
  - Place swab kits in transport equipment (cooler) as outlined by swab kit instructions
- Ensure courier transports swab kits to identified lab
- Ensure lab receives swab kits
- Notify Testing Coordinator when lab receives swab kits

Outputs	Notifications are made to key stakeholders
	Documentation is provided to Pet DW for data entry
	Cross check is completed to ensure all results are received
	Personnel are notified of test results
	Detect/Positive/Inconclusive cases are isolated

Appendix 9. General Principles of Testing and Limitations

There are some general principles that must be considered when undertaking screening of this kind, particularly because these tests have been developed very quickly in response to the COVID-19 threat and have therefore not undergone the scientific evaluation process that is normally required for such tests.

Informed Consent	Tests should not be performed on any person without their informed consent. This means the person must be informed of how the test is done, how results of the test are described (e.g., positive or negative), the limitations of the test, the risk of false positive and false negative, and the actions that will be taken as a result of the outcome of the test. Any questions they have should be answered prior to the request for their consent to perform the test. The person should also be informed of the actions that will be taken if they do not consent to the test.
Clinical Governance	The test process must be performed under careful clinical governance, with a suitably qualified person responsible for, and overseeing the process, including setting up of the test facilities, execution of the test, identification of samples, provision of results to the person being tested, documentation, and disposal of medical waste.
Health and Safety of Testing Personnel and Persons being tested	The test process must include controls designed to protect the health and safety of the testing personnel and the persons being tested. Protection against contamination from specimens, and risk of transmission of infection from one person to another must be in place throughout the testing process. This is particularly so in the collection of nasal swabs, as this collection method often provokes coughing or sneezing in the person being tested, so measures to reduce transmission to the testing personnel, and other persons going through the testing process must be in place.
Risk Communication	POC testing has limitations in that it will not pick-up early infection (due to the test methodology), and it is not considered a confirmatory diagnostic test. Therefore, the testing process using POC testing should not be described as a measure to fully exclude the disease from workplaces, and a test result of “negative” does not give license to ignore other measures of disease transmission prevention such as washing hands and social distancing. To be clear, all individuals—regardless of test result—are required to adhere to all applicable Pet DW COVID-19 protocols and procedures.
Evaluate the Testing Process	The test process should be evaluated to assure that clinical governance processes are working, health and safety measures are in place and working, and that informed consent is being given. The process should also be evaluated for efficacy of the test.
Limitations	• This takes significantly longer to perform than Point of Care testing, there is potentially increased risk to the health care professional from the taking of a nasal swab, and it is significantly more expensive than Point of Care testing

	• The test has the potential to provide a false negative due to inadequate swab collection, improper storage, or early/late stages of the virus • Research on the Sensitivity (false negative) of the RT-PCR for COVID-19 vary being the virus and testing is still relatively new, though early reports show a high sensitivity between 95% to 75% depending on the variables in testing • False positive can occur, though, the current view of specificity (false positive) is as high as 99%

Appendix 10. Quality and Control – Test kits and Laboratories

QUALITY CONTROL MEASURES

- Test kits must be FDA/EUA approved molecular PCR test kits.
- Regulatory agency approved laboratory and equipment (i.e., CLIA) to analyze test kits.
- Controls should be included (both positive and negative controls and a blank, lacking nucleic acid template), as appropriate for each assay. Quantitative assays should include negative, low-positive, high-positive controls and a blank.
- The positive control should have a clinically relevant amount of analyte.
- The negative control should contain other nucleic acid targets that would be expected to be present in the patient sample.
- Controls should be present in a biologically matrix that simulate clinical samples.
- Controls should be processed in the same manner as patient samples.
- It is important to consider controlling each step from primary sample to result.
- Failure of any of the controls invalidates the run and repeating the entire run should be considered in this case.
- The blank should contain the complete reaction mixture EXCEPT nucleic acids or for assays that start with RNA that is processed to cDNA, use RNA that is processed without reverse transcriptase added as the blank.
- Amplification of an internal nucleic acid target (either endogenous or spiked) is recommended to ensure that inhibitors are not interfering with the assay.
- Standards (e.g., size markers) should be used in each run that involves size separation.
- Proper calibration of the instruments used in the assay should be maintained.
- Routine preventive maintenance of all instruments (e.g., thermocyclers, pipettes, etc.).
- Testing of new lots of reagents - New lots of all reagents should be tested side-by-side with the old reagent, prior to implementation.
- Proficiency Testing
- Labs should participate in national testing programs (e.g., CAP) for all tests they perform.
- If no proficiency test is offered, labs should participate in an alternative assessment at least twice per year (per CLSI). An inter-laboratory exchange is preferable. CAP has a sample exchange registry for assays not offered in its commercially available proficiency testing.
- Assessment of continued technologist competency.
- Documentation - the laboratory must keep results of validation studies as long as the protocol is in use, and for at least two years after the protocol is retired.
- Reporting/Laboratory Information System
- The test report should reflect the reason for the patient's referral.
- If pre-written interpretations ("canned comments") are used, the laboratory director should ensure that the correct test interpretation is issued.

ONGOING QUALITY ASSURANCE MEASURES FOR LABORITORIES

- Regular review of normal and abnormal results (e.g., review of percentage of positive reactions, by virus or another analyte)
- Review of turnaround times
- Review of rejected specimens
- Annual Quality Improvement project(s)

Appendix 11. Laboratory Verification Check List

Petroleum Deepwater (WEL)

Laboratory Testing and Validation Checklist

This checklist should be completed as a part of the supply process to identify laboratories for molecular PCR COVID-19 Testing.

It is understood that in some countries, there may not be the same requirements as outlined by the American Society Microbiology, American Molecular Pathology Guidelines/Standards and US Federal Drug Administration. Please note the country specific information in each section as appropriate and provide documentation/verification evidence as required in the country the lab is located.

General Questions	**Response**	**Completion Date**
What is the current and anticipated testing capacity - # of molecular COVID-19 assay/day?		
What is the testing turn-around time - including result reporting back to the client?		
How does the lab source kits/reagents, etc.? Any shortages or anticipated shortages?		
Verification (Unmodified FDA approved or FDA cleared tests)	**Response**	**Documentation Required?**
Accuracy - The amount of agreement between the information from the test under evaluation (the index test) and the reference standard (the best available method for establishing the presence or absence of the condition of interest.		
Precision- The closeness of agreement between independent test/measurement results obtained under stipulated conditions, Getting the same results with repetition of the assay		
Reportable range- The span of test result values over which the laboratory can establish or verify the accuracy of the instrument or test system		

measurement response (this will be presence or absence within a given C(t)		
Linear range (for quantitative assays)- The range where the test values are proportional to the concentration of the analyte in the sample		
Reference intervals (normal values) for laboratory patient population; C(t) reporting		
Analytic Sensitivity (the ability of a test to detect a mutation when that mutation is present o Sensitivity = True positive ÷ (True positive + False negative; Also used to refer to the lower limit of detection (LLOD) for the analyte of interest (i.e., the lowest concentration of analyte that the assay can consistently detect with acceptable precision); Or the lowest amount of starting material (nucleic acid) for an assay that will provide consistent results with acceptable precision?		
Analytic Specificity (The ability of a test to give a normal (negative) result in specimens that do not have the mutation being tested; Specificity = True negative ÷ (True negative + False positive); The ability of a test to detect only the intended analyte without cross-reacting with closely related analytes or potentially interfering substances)		
Reference Materials and Controls (Reference materials (RM) are substances whose properties are sufficiently homogeneous and well established to be used for the calibration of the measuring system, the assessment of a measurement method, for assigning values to materials, or for quality control)		

Verification Questions	Response	Documentation/Verification Required?
Are the tests done as batches under a high complexity FDA authorization, e.g., under FDA EUA?		
What instrumentation is being used? Is it an “all-in one” assay like GeneXpert or a multi-stage involving RNA extraction/purification, etc.?		
All commercial EUA tests should be verified for accuracy and precision in a similar fashion to FDA-cleared diagnostic assays—provide verification example.		**Yes**
Does the lab have biosafety and protective equipment for sample processing—biosafety cabinets etc.? Provide safety control plan (or like).		**Yes**
Frequency of QC- External QC must be run every day of patient testing or no less then manufacturer’s instructions. Provide verification example.		**Yes**
Verification procedures- Verification procedure for batched and non-batched (i.e., random access, sample to answer) assays should be similar in approach. Testing to assess carryover by alternating positive and negative specimens during verification is recommended for batched testing. Similarly, alternating the testing of positive and negative specimens throughout the verification is recommended for non-batched testing. Provide verification sample of all steps. • Step 1. Perform one positive and one negative QC • Step 2. Option 1: Verification panel with commercial synthetic material • Step 2. Option 2: Verification panel with residual patient samples		**Yes**

What is the determination of detection limit (usually this is from the manufacturer)?		
ONGOING QUALITY CONTROL MEASURES	**Response**	**Documentation/Verification Required?**
Controls should be included (both positive and negative controls and a blank, lacking nucleic acid template), as appropriate for each assay. Quantitative assays should include negative, low-positive, high-positive controls and a blank.		**Yes - QC Process/Procedure**
The positive control should have a clinically relevant amount of analyte.		
The negative control should contain other nucleic acid targets that would be expected to be present in the patient sample.		
Controls should be present in a biologically matrix that simulate clinical samples.		
Controls should be processed in the same manner as patient samples.		
It is important to consider controlling each step from primary sample to result.		
Failure of any of the controls invalidates the run and repeating the entire run should be considered in this case.		
The blank should contain the complete reaction mixture EXCEPT nucleic acids or for assays that start with RNA that is processed to cDNA, use RNA that is processed without reverse transcriptase added as the blank.		
Amplification of an internal nucleic acid target (either endogenous or spiked) is recommended to ensure that inhibitors are not interfering with the assay.		
Standards (e.g., size markers) should be used in each run that involves size separation.		

Proper calibration of the instruments used in the assay should be maintained.		**Yes - Calibration records**
Routine preventive maintenance of all instruments (e.g., thermocyclers, pipettes, etc.).		**Yes - Maintenance records**
Testing of new lots of reagents - New lots of all reagents should be tested side-by-side with the old reagent, prior to implementation.		**Yes - Test results**
Proficiency Testing	**Response**	**Documentation/Verification Required?**
Labs should participate in national testing programs (e.g., CAP) for all tests they perform.		**Yes - Example**
If no proficiency test is offered, labs should participate in an alternative assessment at least twice per year (per CLSI). An inter-laboratory exchange is preferable. CAP has a sample exchange registry for assays not offered in its commercially available proficiency testing.		**Yes - Example**
Assessment of continued technologist competency.		**Yes - Continuing education/training records**
The laboratory must keep results of validation studies if the protocol is in use, and for at least two years after the protocol is retired.		**Yes - Validation records**
Reporting/Laboratory Information System in place		**Yes - Test reporting records**
The test report should reflect the reason for the patient's referral.		**Yes - Test report sample**
If pre-written interpretations ("canned comments") are used, the laboratory director should ensure that the correct test interpretation is issued		**Yes - Interpretation records**
Laboratory Management	**Response**	**Documentation/Verification Required?**

Refer to CLIA Personnel Qualification Requirements		**Yes - CV, Resume, Course work**

Appendix 12. Step Guide for Antigen Testing (Modelling Pilot Project)

BD Veritor System – Rapid Detection of SARS-CoV-2

Link to complete instructions: Test Instructions

PRECAUTIONS

1. For in vitro diagnostic use. In the USA, only for use under an Emergency Use Authorization.

2. In the USA, this test has not been FDA cleared or approved; this test has been authorized by FDA under an EUA for use by authorized laboratories, use by laboratories certified under the CLIA, 42 U.S.C. §263a, that meet requirements to perform moderate, high, or waived complexity tests and at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

3. This test has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens: and, in the USA, this test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of the virus that causes COVID-19 under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

4. Do not use this kit beyond the expiration date printed on the outside carton.

5. Do not use the kit to evaluate patient specimens if either the positive control swab or negative control swab fail to give expected results.

6. Test results are not meant to be visually determined. All test results must be determined using the BD Veritor Plus Analyzer.

7. To avoid erroneous results, specimens must be processed as indicated in the assay procedure section.

8. Do not reuse any BD Veritor System test device or kit components.

9. When collecting a nasal swab sample, use the nasal swab supplied in the kit.

10. Proper specimen collection, storage and transport are critical to the performance of this test.

11. Specific training or guidance is recommended if operators are not experienced with specimen collection and handling procedures. Wear protective clothing such as laboratory coats, disposable gloves, and eye protection when specimens are collected and evaluated.

12. Pathogenic microorganisms, including hepatitis viruses and Human Immunodeficiency Virus, may be present in clinical specimens. Standard precautions and institutional guidelines should always be followed in handling, storing, and disposing of all specimens and all items contaminated with blood or other body fluids.

13. The SARS-CoV-2 positive control swabs have been prepared from recombinant viral proteins and do not contain infectious material.

14. Dispose of used BD Veritor System test devices as biohazardous waste in accordance with federal, state and local requirements.

15. Reagents contain sodium azide, which is harmful if inhaled, swallowed or exposed to skin. Contact with acids produces very toxic gas. If there is contact with skin, wash immediately with plenty of water. Sodium azide may react with lead and copper plumbing to form highly explosive metal azides. On disposal, flush with a large volume of water to prevent azide build-up.

16. Test devices used in a laminar flow hood or in areas with high air flow should be covered during test development to ensure proper sample flow.

17. For additional information on hazard symbols, safety, handling and disposal of the components within this kit, please refer to the Safety Data Sheet (SDS) located at bd.com.

Storage

Kits may be stored at 2–30 °C. DO NOT FREEZE. Reagents and devices must be at room temperature (15–30 °C) when used for testing.

Notification and case management of detect/positive antigen test result:

1. Personnel who have a detect/positive antigen test result **WILL NOT BE ALLOWED INTO QUARANTINE OR TO REMAIN IN QUARANTINE.**
2. Healthcare Professional will notify personnel, Quarantine Coordinator and Test Coordinator.
3. Quarantine Coordinator will notify and work with HSE Manager to transport person off site.
4. Testing Coordinator will assist with case management of person until released to return to work (RTW).
5. Documentation will be sent to Pet DW Health (Houston Health Services) by Testing Coordinator.
6. Testing Coordinator must report all antigen test results to the governmental agency (as required).

Outputs	Notifications are made to key stakeholders Documentation is provided to Pet DW for data entry Cross check is completed to ensure all results are received Personnel are notified of test results Detect/Positive/Inconclusive cases are isolated Governmental agency reports are made if required

Appendix 13. Antigen Test Result Form

LABORATORY REPORT - BD Veritor

Requesting Physician: PEARSON, JOSEPH MD

Patient Name: _____

Date of Birth: _____

Male / Female: _____

Test Date: _____

Test Time: _____

Test Name	Result	Control	Reference Range
SARS CoV-2 Antigen	SARS-CoV-2 ☐ DETECTED ☐ NOT DETECTED	☐ PRESENT	NOT DETECTED

This is a chromatographic digital immunoassay that is used with the BD Veritor Plus Analyzer Instrument intended for the direct and qualitative detection of SARS-CoV-2 nucleocapsid antigens. Not for any other viruses or pathogens. This test has not been FDA cleared or approved. This test has been authorized by FDA under an Emergency Use Authorization (EUA) for use by laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C.§ 263a, to perform moderate complexity/high complexity tests and at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

Appendix 14. Step Guide for Xpert Xpress SARS-CoV-2

Click here for test instructions

Principle of the Procedure

The Xpert Xpress SARS-CoV-2 test is an automated *in vitro* diagnostic test for qualitative

detection of nucleic acid from SARS-CoV-2. The Xpert Xpress SARS-CoV-2 test is performed on GeneXpert Instrument Systems.

The GeneXpert Instrument Systems automate and integrate sample preparation, nucleic acid extraction and amplification, and detection of the target sequences in simple or complex samples using real-time PCR assays. The systems consist of an instrument, computer, and preloaded software for running tests and viewing the results. The systems require the use of single-use disposable cartridges that hold the RT-PCR reagents and host the RT-PCR process. Because the cartridges are self-contained, cross-contamination between samples is minimized. For a full description of the systems, see the *GeneXpert Dx System Operator Manual* or the *GeneXpert Infinity System Operator Manual*.

The Xpert Xpress SARS-CoV-2 test includes reagents for the detection of RNA from SARS-CoV-2 in nasopharyngeal swab specimens. A Sample Processing Control (SPC) and a Probe Check Control (PCC) are also included in the cartridge utilized by the GeneXpert instrument. The SPC is present to control for adequate processing of the sample and to monitor for the presence of

potential inhibitor(s) in the RT-PCR reaction. The SPC also ensures that the RT-PCR reaction conditions (temperature and time) are appropriate for the amplification reaction and that the RT-PCR reagents are functional. The PCC verifies reagent rehydration, PCR tube filling, and

confirms that all reaction components are present in the cartridge including monitoring for probe integrity and dye stability.

The nasopharyngeal swab specimen and/or nasal wash/aspirate specimen is collected and placed into a viral transport tube containing 3 mL transport medium. The specimen is briefly mixed by rapidly inverting the collection tube 5 times. Using the supplied transfer pipette, the sample is transferred to the sample chamber of the Xpert Xpress SARS-CoV-2 cartridge. The GeneXpert cartridge is loaded onto the GeneXpert Instrument System platform, which performs hands-off, automated sample processing, and real-time RT-PCR for detection of viral RNA.

Note Safety Data Sheets (SDS) are available at www.cepheid.com or www.cepheidinternational.com under the **SUPPORT** tab.

Storage and Handling

Store the Xpert Xpress SARS-CoV-2 cartridges at 2-28°C.

Do not open a cartridge lid until you are ready to perform testing.
Do not use a cartridge that is wet or has leaked.

Notification and case management of detect/positive test result:

1. Personnel who have a detect/positive antigen test result **WILL NOT BE ALLOWED INTO QUARANTINE OR TO REMAIN IN QUARANTINE.**
2. Healthcare Professional will notify personnel, Quarantine Coordinator and Test Coordinator.
3. Quarantine Coordinator will notify and work with HSE Manager to transport person off site.

4. Testing Coordinator will assist with case management of person until released to return to work (RTW).
5. Documentation will be sent to Pet DW Health (Houston Health Services) by Testing Coordinator.
6. Testing Coordinator must report all antigen test results to the governmental agency (as required).

Appendix 15. Disclaimer

The analysis of risks and/or issues contained in this document has been developed for internal management purposes and is based on preliminary internal assessments, which may change materially as they remain subject to ongoing analysis, review and approval by internal and external subject matter experts and management. Amongst other factors, COVID-19 modelling and data is evolving rapidly, and this document is based upon data, information and/or analytical techniques available to the author(s) at the time of preparation.

