COVID-19 TESTING: ABBOTT ID NOW COVID-19 POINT OF CARE TESTING
5/19/2020

The following guidance is for institutions that have an Abbott ID NOW instrument and test kits for performing CLIA-waived rapid, point of care COVID-19 testing.

- **Allocation and distribution of instruments and test kits will be determined by Central Office Health Services Division based on institutional needs and agency priorities.**

- Limitations in the number of tests that can be performed may require prioritization of testing with the Abbott ID Now instrument. If institutions require additional testing supplies they should consult with their Regional Infection, Prevention and Control Consultant and the Regional Medical Director and then send the request to (b)(7)(C). The following are BOP-recommended priorities for COVID-19 testing.

GENERAL MANAGEMENT BASED ON SYMPTOMS AND TEST RESULTS

Please see the BOP guidance on Isolation and Quarantine for hosing of inmates based upon results of testing.

TECHNICAL GUIDANCE

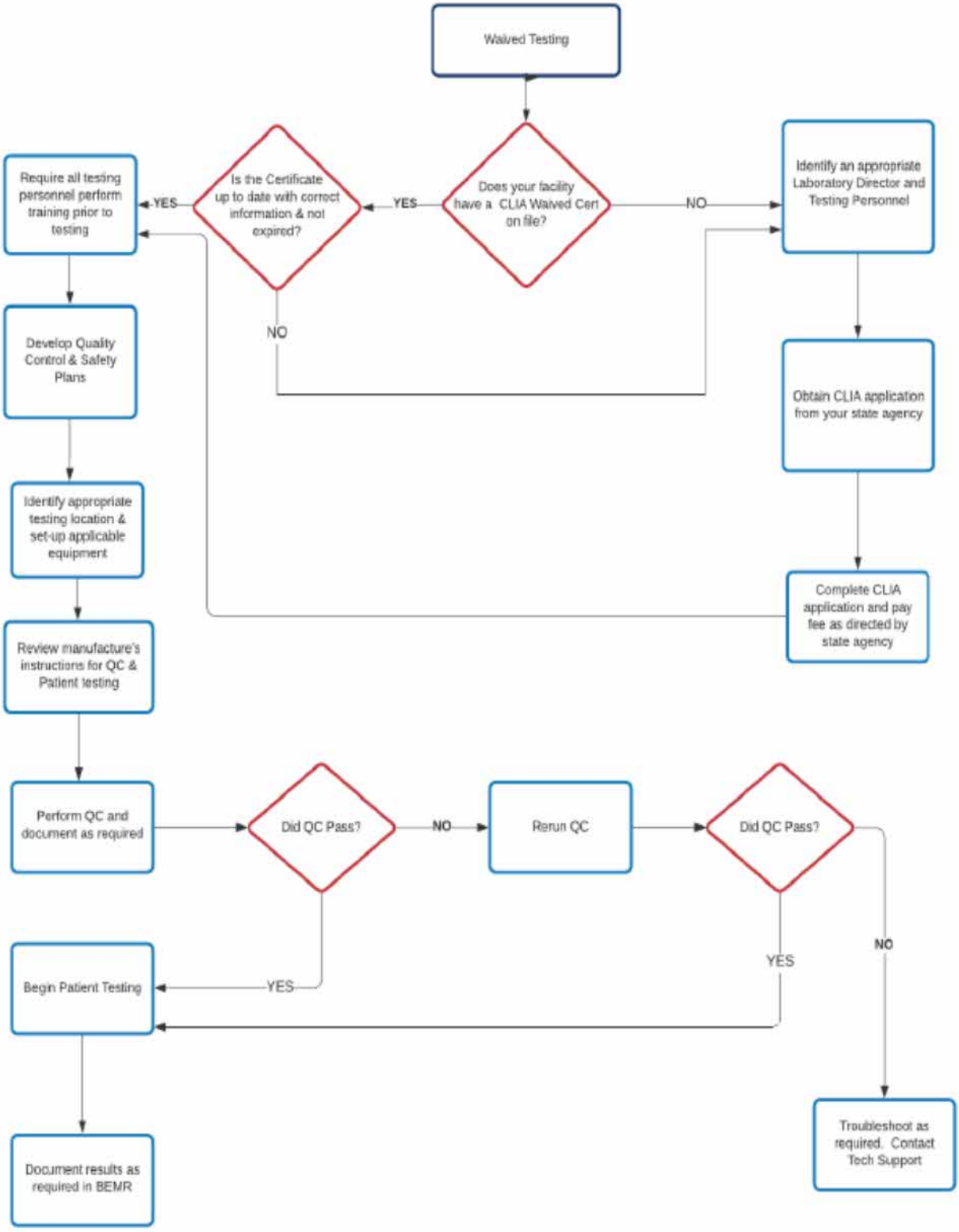
This rest of this reference document includes:

1. Lab testing implementation algorithm
2. ID Now intended use
3. **Instructions for Charting (ONLY FOR FACILITIES WITH ABBOTT ID NOW)**
4. Training checklists (Persons utilizing the instrument should have training and documentation of ability)
5. References
    a. Additional BOP Guidance
    b. Modules 1-8 Videos available at:
        i. https://www.alere.com/en/home/support/product-demos/id-now-training-videos.html
    c. Helpful documents:
        i. https://www.alere.com/en/home/product-details/id-now-covid-19.html

*Please be aware that the original instructions for the ABBOTT RAPID ID COVID-19 instrument included use of viral transport media for testing that would not take place immediately or at point of care. This has been found to dilute sample and may lead to false negative results. Thus, the use of viral transport media should not be used for samples being tested by the Abbott Rapid ID instrument.

See https://www.abbott.com/corpnewsroom/product-and-innovation/customer-update-on-our-idnow-covid-19-test.html

BOP IMPLEMENTATION OF COVID - 19 LAB TESTING



ID NOW™

COVID-19

INTENDED USE

ID NOW COVID-19 assay performed on the ID NOW Instrument is a rapid molecular *in vitro* diagnostic test utilizing an isothermal nucleic acid amplification technology intended for the qualitative detection of nucleic acid from the SARS-CoV-2 viral RNA in direct nasal, nasopharyngeal or throat swabs who are suspected of COVID-19 by their healthcare provider. *Testing is authorized for laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform moderate complexity/high complexity tests and has been CLIA waived during the current COVID pandemic. The ID NOW COVID-19 assay is also authorized to be distributed and used in patient care settings outside of the clinical laboratory environment.*

Results are for the identification of SARS-CoV-2 RNA. The SARS-CoV-2RNA is generally detectable in respiratory samples during the acute phase of infection. Positive results are indicative of the presence of SARS-CoV-2 RNA; clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. **Positive results do not rule out bacterial infection or co-infection with other viruses. Testing facilities within the United States and its territories are required to report all positive results to the appropriate public health authorities.**

Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information.

The ID NOW COVID-19 test is intended for use by medical professionals or trained operators who are proficient in performing tests using the ID NOW Instrument. The ID NOW COVID-19 test is only for use under the Food and Drug Administration's Emergency Use Authorization.

SUMMARY and EXPLANATION of the TEST

An outbreak of respiratory illness of unknown etiology in Wuhan City, Hubei Province, China was initially reported to WHO on December 31, 2019.[1] Chinese authorities identified a novel coronavirus (2019-nCoV), which has resulted in thousands of confirmed human infections in multiple provinces throughout China and in several Southeast Asian countries, Europe and more recently the United States. Cases of severe illness and deaths have been reported. The International Committee for Taxonomy of Viruses (ICTV) renamed the virus SARS-CoV-2.[2]

ID NOW COVID-19 is a rapid (13 minutes or less), instrument-based isothermal test for the qualitative detection and diagnosis of SARS-CoV-2 from nasal, nasopharyngeal and throat swabs. The ID NOW Instrument has a small footprint and easy to use graphical user interface for convenience within a busy hospital or near patient testing environments. The ID NOW COVID-19 kit contains all components required to carry out an assay for SARS-CoV-2 on the ID NOW Instrument.

PRINCIPLES of the PROCEDURE

ID NOW COVID-19 is an automated assay that utilizes isothermal nucleic acid amplification technology for the qualitative detection of SARS-CoV-2 viral nucleic acids. It is comprised of a Sample Receiver, containing elution/lysis buffer, a Test Base, comprising two sealed reaction tubes, each containing a lyophilized pellet, a Transfer Cartridge for transfer of the eluted sample to the Test Base, and the ID NOW Instrument.

The reaction tubes in the Test Base contain the reagents required for amplification of SARS-CoV-2, as well as an internal control. The templates (similar to primers) designed to target SARS-CoV-2 RNA amplify a unique region of the RdRp segment. Fluorescently-labeled molecular beacons are used to specifically identify each of the amplified RNA targets.

To perform the assay, the Sample Receiver and Test Base are inserted into the ID NOW Instrument. The sample is added to the Sample Receiver and transferred via the Transfer Cartridge to the Test Base, initiating target amplification. Heating, mixing and detection are provided by the instrument.

PRECAUTIONS

1. For *in vitro* diagnostic use.
2. For use under an Emergency Use Authorization Only.
3. Federal Law restricts this device to sale by or on the order of a licensed practitioner (US only).
4. Laboratories within the United States and its territories are required to report all positive results to the appropriate public health laboratories.
5. To be used in conjunction with the ID NOW Instrument.
6. Treat all specimens as potentially infectious. Follow universal precautions when handling samples, this kit and its contents.
7. **Proper sample collection, storage and transport are essential for correct results.**
8. **Leave test pieces sealed in their foil pouches until just before use.**
9. **Do not tamper with test pieces prior to or after use.**
10. **Do not use kit past its expiration date.**
11. Do not mix components from different kit lots or from other ID NOW assays.
12. Solutions used to make the control swabs are inactivated using standard methods. However, patient samples, controls, and test pieces should be handled as though they could transmit disease. Observe established precautions against microbial hazards during use and disposal.
13. If any assay components are dropped, cracked, found to be damaged or opened when received, DO NOT USE and discard. Do not use scissors or sharp objects to open foil pouches as damage to test pieces can occur.
14. **Do not open the Sample Receiver before placing in the instrument**. It will prohibit the Elution Buffer from reaching temperature and may impact test performance.
15. If the Sample Receiver is spilled while opening, clean the instrument per instructions provided in the instrument User Manual and cancel test. Repeat test with a new Sample Receiver.
16. All test pieces must be removed from the instrument according to removal instructions displayed on the instrument and disposed of according to country and local requirements. Pieces must not be separated once they are assembled.
17. **All test pieces are single use items. Do not use with multiple specimens**.

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1. Once reacted, the Test Base contains large amounts of amplified target (Amplicon). Do not disassemble the Test Base and Transfer Cartridge. **In the case of a positive sample, this could lead to amplicon leakage and potential ID NOW COVID-19 false positive test results.**
2. **At a low frequency, clinical samples can contain inhibitors that may generate invalid results. Site to site invalid rates may vary.**
3. Due to the high sensitivity of the assays run on the instrument, contamination of the work area with previous positive samples may cause false positive results. Handle samples according to standard laboratory practices. **Clean instruments and surrounding surfaces according to instructions provided in the cleaning section of the instrument User Manual**. Refer to Section 1.6, Maintenance & Cleaning, for further information.

STORAGE and STABILITY

Store kit at 2-30°C. The ID NOW COVID-19 kit is stable until the expiration date marked on the outer packaging and containers. Ensure all **test components are at room temperature before use.**

QUALITY CONTROL

ID NOW COVID-19 has built-in procedural controls. The result of the Procedural Control is displayed on the screen and is automatically stored in the instrument with each test result. This can be reviewed later by selecting Review Memory on the instrument.

Procedural Controls:

ID NOW COVID-19 contains an internal control that has been designed to control for sample inhibition and assay reagent function. In positive samples where target amplification is strong, the internal control is ignored

and the target amplification serves as the 'control' to confirm that the clinical sample was not inhibitory and that assay reagent performance was robust. **At a very low frequency, clinical samples can contain inhibitors that may generate invalid results.**

Procedural Control Valid displayed on the instrument screen indicates that the assay reagents maintained their functional integrity and the sample did not significantly inhibit assay performance.

External Positive and Negative Controls:

Good laboratory practice suggests the use of positive and negative controls to ensure that test reagents are working and that the test is correctly performed. **ID NOW COVID-19 kits contain Positive and Negative Control Swabs. These swabs will monitor the entire assay**. Test these swabs once with each new shipment received and once for each untrained operator. Further controls may be tested in order to conform with local, state and/or federal regulations, accrediting groups, or your lab's standard Quality Control procedures.

CONTROL SWAB PROCEDURE

External Positive and Negative Control swabs are provided and should be tested following the Run QC Test instructions on the ID NOW Instrument. Refer to Quality Control Swab Test Procedure or Instrument User Manual for further details.

Note: The ID NOW Instrument reports QC results as Pass or Fail.

If the correct control results are not obtained, do not perform patient tests or report patient results. Contact Technical Support during normal business hours before testing patient specimens.

SPECIMEN COLLECTION and HANDLING

Use freshly collected specimens for optimal test performance. Inadequate specimen collection or improper sample handling/storage/transport may yield erroneous results. Refer to the CDC Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons for Coronavirus Disease 2019 (COVID-19) https://www.cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical-specimens.html.

Throat Swab

For optimal test performance, use the swabs provided in the test kit. Alternatively foam, polyester, HydraFlock® and nylon flocked throat swabs can be used to collect throat swab samples.

Rayon swabs are not suitable for use in this assay.

Collect patient specimen by swabbing the posterior pharynx, tonsils and other inflamed areas. Avoid touching the tongue, cheeks and teeth with the swab.3

Nasal Swab

For optimal test performance, use the swabs provided in the test kit. Alternatively, rayon, foam, HydraFlock® Flocked swab (standard tip), HydraFlock® Flocked swab (mini tip), Copan Mini Tip Flocked Swab, or Copan Standard Flocked swabs can be used to collect nasal swab samples.

Puritan PurFlock Standard Tip Ultra Flocked Swabs, Puritan PurFlock Mini Tip Ultra Flocked Swabs and Copan Standard Rayon Tip Swabs are not suitable for use in this assay.

To collect a nasal swab sample, carefully insert the swab into the nostril exhibiting the most visible drainage, or the nostril that is most congested if drainage is not visible. Using gentle rotation, push the swab until resistance is met at the level of the turbinates (less than one inch into the nostril). Rotate the swab several times against the nasal wall then slowly remove from the nostril. Using the same swab, repeat sample collection in the other nostril.

Nasopharyngeal Swab

Use **sterile rayon, foam, polyester or flocked flexible-shaft NP swabs** to collect a nasopharyngeal sample.

To collect a nasopharyngeal swab sample, carefully insert the swab into the nostril exhibiting the most visible drainage, or the nostril that is most congested if drainage is not visible. Pass the swab directly backwards without tipping the swab head up or down. The nasal passage runs parallel to the floor, not

parallel to the bridge of the nose. Using **gentle rotation, insert the swab into the anterior nares parallel** to the palate advancing the **swab into the nasopharynx, leave in place for a few seconds, and then slowly rotate the swab as it is being withdrawn.**

To ensure proper collection, the swab should be passed a distance that is halfway of that from the nose to the tip of the ear. This is about half the length of the swab. DO NOT USE FORCE while inserting the swab. The swab should travel smoothly with minimal resistance; if resistance is encountered, withdraw the swab a little bit without taking it out of the nostril. Then elevate the back of the swab and move it forward into the nasopharynx.

SPECIMEN TRANSPORT and STORAGE

Direct nasal, throat or nasopharyngeal swabs should be **tested as soon as possible after collection**. If immediate testing is not possible, the nasal, throat or nasopharyngeal **swab can be held in its original package at room temperature (15-30°C) for up to two (2) hours prior to testing**. If a direct nasal, throat or nasopharyngeal swab specimen will be held longer than two (2) hours, it must be refrigerated at 2-8°C and tested within 24 hours from the time of sample collection.

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RESULT INTERPRETATION

When the test is complete, the results are clearly displayed on the instrument screen.

Instrument Display	Interpretation of Results and Follow-up Actions
	**COVID-19 Positive** Positive results do not rule out bacterial infection or co-infection with other viruses.
	**COVID-19 Negative** This result does not rule out co-infections with other pathogens. Perform regular COVID-19 PCR test if the Abbott ID Now test is negative and person is symptomatic.
	**The presence or absence of COVID-19 Viral RNAs cannot be determined.** Repeat testing of the sample using new test components. If repeated Invalid results are obtained, results should be confirmed by another method prior to reporting the results.

***Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions**. Negative results must be combined with clinical observations, patient history, and epidemiological information.

Abbott RAPID ID Testing Charting

The COVID-19 RNA testing is available in the BEMR flowsheets. All COVID waived testing must be documented in the Flow Sheets.

Please follow the instructions that were sent out by David Hamilton in reference to using the Abbott ID Now machine for POC testing.

Instructions for entering results in BEMR Flowsheets

1. Navigate to the chart menu, select Flowsheets.
1. Enter inmate name or Reg # in the Reg # field
2. Select COVID-19 RNA from the menu on the left.
3. Click the Add button.
4. From the dropdown menu enter result; positive, negative or invalid
5. For Positive values click the save and refer to provider which will begin a clinical encounter and save it.
6. For negative or invalid tests click the Ok button to return to the previous screen.
7. Click the Save button.

Additional BEMR Tools, Tips and Instructions are available on our Sallyport web page at:

(b)(7)(E); (b)(7)(F)

Abbott

ID NOW™ Certification of Training

FLU A/B 2____ Strep A 2____ RSV____COVID-19 _____ (Check all that apply)

This is to verify that personnel responsible for running the ID NOW™ at _____ have been thoroughly in-serviced on the test and the test procedure. This has included:

- **Review of the package insert**
- **Demonstration of the product assay**
- **Successful performance of the ID NOW™ assays and interpretation of results**

Names of the personnel who have been trained with the ID NOW™ and are responsible for reporting patient results:

PRINT NAME	SIGNATURE	DATE

Signature of Laboratory Director(s) responsible for personnel and testing:

_____ _____

SIGNATURE DATE

_____ _____

SIGNATURE DATE

_____ _____

TRAINER DATE

Training Evaluation Instructions[1]

Purpose:

The individual overseeing testing acts as an advocate for employees by gathering and distributing the resources needed by employees in order for them to be able to do a good job and by providing positive encouragement for a job well done. They should display the interpersonal skills required to engage employees and enhance their self-confidence.

Feedback from employees on the training experience provides valuable information to employers seeking to improve or identify gaps in their training programs. This method also opens an avenue of communication between the employee and employer.

Many training programs fail to deliver the expected organizational benefits. Having a well-structured measuring system in place can help you determine where the problem lies.

Contents:

There are many ways to evaluate training. A blank evaluation form is included for your use, along with an example evaluation form that demonstrates how to correctly enter site specific information.

1. Blank Training Evaluation.

Instructions for Completing the Training Evaluation:

1. After training is completed, the trainee should complete the Training Evaluation.

2. The trainee should be honest and open about the training experience without fear of remedial action or other adverse reactions as a result of the evaluation.

3. Management should review and compile the results to assess the training program's effectiveness and make improvements and changes to the program as necessary.

[1] From https://www.cdc.gov/labquality/docs/waived-tests/15_255581-test-or-not-test-booklet.pdf Accessed April 23, 2020.

Facility:

Location:

Training Checklist

Trainee: _____

Date: _____ Trainer:_____

Test: _____

Trainer should review all material listed below and verify that the trainee has read the appropriate procedures or manufacturer instructions involved and understands them. File completed form appropriately.

Checklist	***Date Completed***	***Trainee Initials***	***Trainer Initials***
1. Trainee reads and understands procedure			
2. Trainer discusses principle of test procedure so that trainee understands scope and purpose of the test.			
3. Trainer identifies materials to perform test and trainee knows location of materials needed.			
4. Trainee observes proper sample collection and handling.			
5. Trainee observes test procedure performed by trainer.			
6. Trainee performs the procedure and should be able to: a. Identify proper sample type, use of the appropriate collection device, labeling, and handling of samples b. Organize work area for testing c. Perform quality control (QC) samples & training panel prior to performing patient samples. d. Set up timer and follow incubation times per the procedure e. Interpretation of results 1) positive 2) negative 3) invalid f. Decontaminate and clean work area, including proper disposal of hazardous waste and sharps			
7. Data entry/Computer. a. Test order and accessioning b. QC and interpretation of results c. Report results and log QC data			

Trainee Comments: _____

Trainee Signature:_____ Date:_____

Trainer Comments: _____

Trainer Signature: _____ Date:_____

Competency and Performance Assessment Instructions[2]

Purpose:

The ability of each person to perform their duties should be assessed following training and periodically thereafter. Retraining and reassessment of employee performance needs to be done when problems are identified with employee performance. The training and assessment program should be documented and specific for each job description. Activities requiring judgment or interpretive skills need to be included in the assessment.

Performance assessment can

- identify key training areas,
- identify processes that need improvement,
- provide supervisors and managers with data on employee performance, and
- provide evidence to customers and management that the laboratory assures quality with trained staff.

Some elements of performance assessment include:

- observing routine patient test performance, including sample handling, processing and testing;
- monitoring recording and reporting of test results;
- reviewing intermediate test results or worksheets, QC records, proficiency testing results, and preventive maintenance records;
- observing performance of instrument maintenance and function checks;
- assessing test performance through testing previously analyzed samples, internal blind testing samples, or external proficiency testing samples; and
- evaluating problem-solving skills.

Contents:

There are many ways to assess testing competency. A blank assessment is included for your use, along with an example assessment that demonstrates how to correctly enter site-specific information.

1. Blank Performance Assessment.

Instructions for Completing the Performance Assessment:

1. Record the facility name and location.
2. Record the employee's name and the procedure being observed.
3. Have the employee perform the procedure.
4. Record whether the steps completed were satisfactory or unsatisfactory, note any comments, and document any corrective action needed.
5. Sign and date the form.
6. Have the employee sign and date the form and provide comments.

[2] From https://www.cdc.gov/labquality/docs/waived-tests/15_255581-test-or-not-test-booklet.pdf Accessed April 23, 2020.

Facility:

Location:

TEMPERATURE LOG

Refrigerator/freezer Location_____ **Month/Year** _____

Acceptable temperature range _____

Date	Temperature	Checked by:	Date	Temperature	Checked by:
1			17		
2			18		
3			19		
4			20		
5			21		
6			22		
7			23		
8			24		
9			25		
10			26		
11			27		
12			28		
13			29		
14			30		
15			31		
16					

**Enter # for weekends and holidays when temperature is not monitored.*

Corrective Action for Out of Range Temperature

Date	Action Taken	Initials

Reviewed by: _____ **Date:** _____

Quality Control Log Instructions[3]

Purpose:

The Clinical Laboratory Improvement Amendments of 1988 (CLIA) requirements for waived testing state that a testing site must follow the current manufacturer's instructions provided with the test. This includes instructions for quality control (QC).

QC is designed to detect problems that might arise because of reagent or test kit deterioration, instrument malfunction, improper environmental conditions, or operator error. Performing QC testing procedures provides assurance that the test is performing as expected and alerts the user when problems occur. QC procedures should describe the type of controls to be used, how to perform QC testing, frequency of QC testing, and actions to be taken when QC results are unacceptable.

QC material should be treated the same as patient samples by being tested in the same way that patient samples would be tested. QC is usually performed with:

1. each new operator,
2. after an instrument is serviced,
3. when reagent lots are changed,
4. when test kit temperatures exceed the manufacturer's limits,
5. after calibration, and
6. when patient results seem questionable.

Refer to the manufacturer's instructions for specific QC requirements for each test that your facility performs. Each testing site should determine the appropriate QC frequency for each test system. Keep in mind that the frequency of QC testing cannot be less than what is specified in the manufacturer's instructions.

Contents:

There are many ways to log QC results. A blank QC log is included for your use, along with an example log that demonstrates how to correctly enter site specific information.

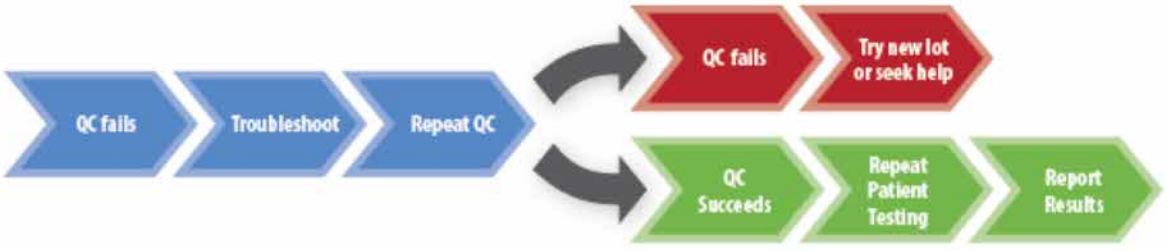
- Example Quality Control-Qualitative Test Log Completed.
- Blank Quality Control-Qualitative Test Log.
- Example Quality Control-Quantitative Test Log Completed.
- Blank Quality Control-Quantitative Test Log.

Note: Qualitative tests are interpreted as positive, negative; reactive, non-reactive; or invalid. Quantitative tests give a number result that corresponds to the amount of substance being measured, are reported in specific measurement units, and have an expected range.

[3] From https://www.cdc.gov/clia/docs/waived-tests/ready-set-test-booklet.pdf. Accessed April 23, 2020.

Instructions for Performing External Control Testing and Recording Results:

1. Obtain the QC material. Check the expiration date and check that the material has been stored and handled according to the manufacturer's requirements and instructions.
2. Record the initials of the person performing the test, test date, test name, lot number, and expiration date of the test on the QC Log.
3. Record the lot number for the QC material on the QC Log.
4. Test the QC material following the manufacturer's instructions and record the results on the QC Log.
5. If the results are acceptable, QC passes, and patient results can be reported.
6. If controls do not give the expected results, patient results should not be reported until the problem is identified and corrected.
   - Check to see if the instructions in the manufacturer's instructions were followed correctly.
   - Look for possible sources of error such as outdated reagents or test devices.
   - Check to see if reagents were stored correctly.
   - Make sure controls or reagents were not cross-contaminated by accidentally switching caps on kit or control vials.
   - Follow the troubleshooting steps in the manufacturer's instructions or site specific procedure.
   - For additional assistance, contact the manufacturer, technical representative, and/or the person who directs or supervises the testing.
   - Once the problem is identified and corrected, repeat QC testing. If the QC results are acceptable, re-test patient samples and report the final acceptable results.



Instructions for Logging or Recording Results

Purpose:

Recording test results legibly, completely, and filing records in an organized, easy to find manner are recommended practices for all testing.

Contents:

There are many ways to record results. A blank Results log is included for your use, along with an example log that demonstrates how to enter site specific information.

1. Blank Results Log – Qualitative Test.

Instructions for Logging or Recording Results:

Results Log – Qualitative Test

1. Record the facility information and test name on the top of the form.
2. Enter the date of the test, sample number, patient name or identification, test results, lot number and expiration date of test.
3. The person performing the test should initial the results after verifying all of the information has been entered correctly.

Results Log with QC – Qualitative Test

1. Record the facility information and test name on the top of the form.
2. Record the QC material lot number, expiration date, positive and negative control results.
3. If the results are acceptable, QC passes and patient results can be reported.
4. If the results are not acceptable, QC fails. Troubleshoot (check expiration dates, storage condition etc.), re-test the QC and document the corrective action taken.

Facility:

Location:

Results Log – Qualitative Test

Test Name: _____

	Date	Sample ID / Patient ID	Patient Name	Test Result	Test Lot number / Test Exp. Date	Initials
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						
11						
12						
13						
14						
15						