|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Simplexa COVID-19 Direct Assay | | | | | |
| **Purpose** | This procedure provides instructions for preparing samples, setting up the PCR reaction and running the *Simplexa™* COVID-19 direct assay on Nasopharyngeal (NP) and Nasal swabs in UTM or Saline (0.9%) and on bronchoalveolar lavage (BAL) specimens. | | | | |
| **Policy Statements** | This procedure applies to all technical staff performing testing on the Liaison MDX instruments. | | | | |
| **Principle and Clinical Significance** | SARS-CoV-2 (also called COVID-19 virus) is a beta coronavirus belonging to the family of Coronaviruses, named for the crown- like spikes on their surface. There are four main sub-groupings of coronaviruses, known as alpha, beta, gamma, and delta. Common human coronaviruses are 229E (alpha coronavirus), NL63 (alpha coronavirus), OC43 (beta coronavirus) and HKU1 (beta coronavirus), and these usually cause mild to moderate upper-respiratory tract illnesses, like the common cold. Other human coronaviruses such as MERS-CoV (the beta coronavirus that causes Middle East Respiratory Syndrome, or MERS) and SARS-CoV (the beta coronavirus that causes severe acute respiratory syndrome, or SARS) have caused more severe respiratory illness with higher rates of morbidity and mortality. The SARS-CoV-2 is a novel coronavirus that causes coronavirus disease 2019, or COVID-19. SARS-CoV-2 caused an outbreak beginning in December 2019 in Wuhan City, Hubei Province, China and has spread globally, being consequently declared a pandemic by the World Health Organization (WHO). Patients with COVID-19 have had mild to severe respiratory illness with symptoms of fever, cough and shortness of breath, and many patients have had complications including pneumonia in both lungs.1-7  **Principle**  The DiaSorin Molecular Simplexa™ COVID-19 Direct assay system is a real-time RT-PCR system that enables the direct amplification of Coronavirus SARS-CoV-2 RNA from nasopharyngeal swabs (NPS), nasal swabs (NS), or bronchoalveolar lavage (BAL) specimens. The system consists of the Simplexa™ COVID-19 Direct assay, the LIAISON® MDX (with LIAISON® MDX Studio Software), the Direct Amplification Disc and associated accessories.  In the Simplexa™ COVID-19 Direct assay, fluorescent probes are used together with corresponding forward and reverse primers to amplify SARS-CoV-2 viral RNA and internal control RNA. The assay targets two different regions of the SARS-CoV-2 genome, ORF1ab and S gene. The S gene encodes the spike glycoprotein of the SARS-CoV-2 (COVID-19 virus) and is also targeted to specifically detect the presence of SARS-CoV-2. The ORF1ab region encodes well-conserved non-structural proteins and therefore is less susceptible to recombination. An RNA internal control is used to detect RT-PCR failure and/or inhibition.1 | | | | |
| **Test Code** | **COVC –** Nasopharyngeal (NP) and Nasal swabs (Anterior Nares)  **COVB –** Bronchoscopy samples | | | | |
| **Sample** | 1. **Acceptable specimens:**     * Nasopharyngeal (NP) swabs: Mini-tip flocked swabs placed in 3 mL UTM or Saline (0.9%)    * Nasal swabs (anterior nare) (NARE): Flocked swabs placed in 3 mL UTM or Saline (0.9%)    * Bronchoalveolar lavage (BAL): undiluted 2. **Unacceptable specimens:** Improperly labeled or unlabeled samples. Calcium alginate swabs, other body fluids, other swabs, other respiratory samples. 3. **Specimen Collection and Transport**:    * Refer to *Lab Test Directory* on StarNet 4. **Specimen assessment:**    * Refer to the policy MCVI 2.1 *Specimen Rejection Criteria* 5. **Specimen Storage:**    * Specimens should be refrigerated (2-8°C) up to 7 days | | | | |
| **Special Safety Precautions** | * Standard precautions. Refer to MB 2.02 Biohazard Containment * Use of engineering controls: Refer to MB 3.01 Engineering Controls to Prevent Nucleic Acid Contamination   Microbiologists are subject to occupational risks associated with specimen handling. Refer to the safety policies located in the safety section of the *Microbiology*, *Virology, and Molecular Policy Manual*:   1. [*Safety in the Microbiology/Virology Laboratory*](file:///G:\Lab%20Procedures\Microbiology\1NEW%20Micro%20Procedure%20Manual.%20(same%20as%20in%20Starnet)\MCVI%203%20Safety\MCVI%203.2%20Safety%20in%20the%20Microbiology%20Lab.docx) 2. [*Safe Work Practices in Molecular*](https://starnet.childrenshc.org/References/labsop/molbio/safety/mb-2.01-safe-work-practices-in-molecular.pdf)  * [*Biohazardous Spills*](file:///G:\Lab%20Procedures\Microbiology\1NEW%20Micro%20Procedure%20Manual.%20(same%20as%20in%20Starnet)\MCVI%203%20Safety\MCVI%203.4%20Biohazardous%20Spills.docx) * [*Biohazardous Spill in Molecular*](https://starnet.childrenshc.org/References/labsop/molbio/safety/mb-2.03-biohazardous-spills-in-molecular.pdf) * [*Biohazard Containment*](https://starnet.childrenshc.org/References/labsop/index.php?view=folder&folder=molbio)  1. Wear appropriate personal protective equipment (PPE) including disposable gloves and lab coats. 2. Handle all samples and waste materials as if they were capable of transmitting infectious agents. 3. Change gloves often when handling reagents or samples. 4. Dispose of materials used in this assay, including reagents, used buffer vials in biohazardous waste. | | | | |
| **Materials** | |  |  |  | | --- | --- | --- | | **Reagents** | **Supplies** | **Equipment** | | Simplexa COVID-19 Direct Reaction Mix Kit (MOL 4151)   * Reaction Mix (24) 50 µl * Store at -10 to – 30 °C   Direct Amplification Disc (DAD) Kit (MOL1455)  Simplexa COVID-19 Positive Control Pack (MOL 4160)   * 10 tubes, 100 µl   Negative control – UTM  Sani-Cloth Bleach wipes  70% alcohol  5% Extran | Gloves (powder-free)  Filtered pipette tips, 100 and 200 uL, extended tips  Sharps disposal container  Replacement foil wedge | Room 1: Clean room   * -10 to -30° C freezer * Laminar flow Hood   Room 2: Processing   * Refrigerator 2 – 8° C * BSC BSL-2 * -70⁰ C freezer * 100 or 200 µl pipette * Vortex * Centrifuge   Room 3: Amplification  Liaison MDX | | | | | |
|
| **Calibration** | Spectral calibrations performed on instruments by a DiaSorin Molecular Technical Field Specialist. | | | | |
| **Quality Control** | **Daily Quality Control:**  Internal quality control is included in all reactions. The internal control must be valid in order to obtain valid negative patient results. A valid internal control result is not required for valid positive results.  **External Quality Control:**   * Perform QC using external manufactured positive and negative controls every 30 days AND/OR with new lots/shipments. Record and file results in the appropriate binder. * POSC – Simplexa COVID-19 Positive Control Pack, stored at -70°C * NEGC – UTM, stored at 2-25°C * An IC is incorporated into each reaction mixture   QC Monitors:   |  |  | | --- | --- | | **Control** | **Control Monitor** | | Positive Control (POSC) | Reagent failure and primer-probe integrity | | Negative Control (NEGC) | Reagent and/or environmental contamination, cumulative effect | | Internal Control (IC) | PCR inhibition in specimen, reagent failure or process error |  * Before reporting patient results, all controls must yield valid results   + NOTE: a valid positive result does not require an IC result * If results are invalid, obtain new reagents and controls; repeat testing   **Preparing Negative Control (NEGC)**   1. Wear lab coat and gloves dedicated to the Clean room 1 2. Label cryo-storage box with contents 3. Lot number (L/N), expiration date and date of preparation 4. Aliquot 300 µl of UTM into 1.5 microcentrifuge tubes 5. Refrigerate aliquots in room 2 6. Record lot information in appropriate binder   **Preparing Manufactured Positive Control (POSC)8**   1. Remove POSC from – 70⁰ C, thaw POSC at room temperature    1. Do not refreeze 2. Label with open date and expiration date (24 hours) 3. Vortex tube 5 – 10 seconds to mix 4. Quick spin POSC before use   Test controls as you would patient samples.  **Record and file results in QC binder**  **NOTE:** QC testing on each instrument is to be performed on a rotating basis.  **Expected Control Results**   |  |  |  |  | | --- | --- | --- | --- | | **Control Type** | **ORF1ab target** | **S gene target** | **RNA Internal Control (RNA IC)** | | **POSC: Simplexa™ COVID-19 Positive Control1** | Positive | Positive | Not applicable2 | | **NEGC: UTM** | Negative | Negative | Valid |   1. Typical Ct values for the Positive Control range between 22 - 32.  2. Detection of the Simplexa™ RNA Internal Control (RNA IC) is not required for a valid result when SARS-CoV-2 is detected.  **Wipe testing:**   * Perform wipe testing every 30 days to monitor for contamination. * See MB 3.02 Wipe Testing for Amplicon Contamination   **NOTE:** External quality control may be performed on an as needed basis if certain circumstances arise. Examples include:   * Drift in results (e.g., increasing/decreasing positivity rates) * Potential contamination (negative control) * After dramatic instrument maintenance or movement | | | | |
| **Assay Procedure** | **NOTE:** Always clean hood before sample handling.  **All testing supplies must be cleaned with 10% bleach followed by water and 70% alcohol.**  **Testing Preparation: Room 2**   1. Create **a manual COVC worksheet or call a COVB worksheet if testing a bronch sample**; use this worksheet for sample identification throughout testing.   **Pulling Manual Worksheets for DiaSorin COVID-19 Direct testing:**  **Creating a batch:**          **Scan CID numbers, hit enter when finished to get a batch #:**      **Print worksheet to set up run:**         1. Position samples and controls (when applicable) in disc as follows:  |  |  | | --- | --- | | Sample | Position | | Patient samples | Position 1-nn | | POSC | After last patient sample | | NEGC | After POSC |  1. Using the worksheet as a layout, organize patient specimens and labels    1. Color code worksheets and labels per run    2. Number patients on worksheet in consecutive order according to available disk wells    3. Number corresponding patient labels according to assigned numbers on worksheet and disk, color coded by run    4. Number each primary patient specimen according to worksheet    5. Write the last four numbers of the CID on the disk well prior to pipetting   **PCR set-up (Room 2) and amplification (Room 3):**   1. Remove one MM for each sample to be tested from - 20⁰ C freezer (Room 1) and thaw at room temperature (approximate range 18 to 25⁰C).   **NOTE:** Use MM within 30 minutes.   1. When thawed, gently flick MM tubes to mix; briefly centrifuge. Do not vortex or refreeze. 2. Vortex specimen tubes prior to set-up 3. Remove DAD from package and set on disc cold block 4. Number wedges according to worksheet layout 5. Peel back the foil cover, one at a time, to expose the SAMPLE and Reaction (R) wells.   **!** Do not touch underside of foil to prevent cross contamination    Pipette 50 µl of MM into the Reaction (R) well first before sample  **NOTE:**   * To prevent aerosols and possible contamination, hold the pipette at a 30-degree angle inserting the tip under the roof of the well     *Caution:* Avoid placing pipette tip at the bottom of the well to prevent possible punctures in the foil that may lead to instrument contamination   1. Vortex sample 5-10 seconds. With a 200uL extended pipette tip, pipette 50 µl of sample/control into the SAMPLE well   *Caution:* Pipette leakage outside of well may lead to external disc contamination when resealing wedge   1. Seal the foil wedge before opening the next foil cover 2. After all wedges are filled, carefully remove the perforated foil tab    1. If foil is torn, it must be replaced with a replacement foil wedge to prevent carryover contamination 3. Use the disc applicator to seal the foil firmly on all wedges 4. Remove lab coat and change gloves   **Computer Set-up: Room 3**   1. Set up Liaison; take run specific patient labels and DAD into room 3 2. Turn on the Liaison MDX (ABC) by flipping the switch in the back and the Liaison computer 3. Log on computer    1. User: Administrator    2. Password: focusIC#1 4. Double-click on Integrated Cycler DX icon to open program 5. Enter personal user and password code    1. To switch users: Select **File: Switch Users** 6. From the main screen, scan the reagent lot barcode, small data matrix located on the lower left corner of the REF card 7. Scan the disc barcode on the DAD to show disc layout  * Used wedges are shown in black and unavailable for use * Available wedges are shown in gray Fig. 1   **Figure 1**     1. Enter sample IDs: scan barcode ID from each label consecutively    1. **Type** drop down box: **:** select **Unknown** (default)    2. Check CIDs against the labeled disk locations as samples are scanned in 2. When applicable**,** enter controls according to layout  * POSC – scan the barcode provided on the positive control vial label * NOTE: the positive QC vial label is to be placed on the back of the COVID-19 reagent lot barcode card after use of the first vial. If the QC barcode is unavailable type in the lot number. * NEGC – select **NTC** from the Type drop down box  1. Load the DAD into instrument 2. Select the instrument from the drop down box (lower right) 3. Click **Run** to begin processing the disc; Approximate run time: 90 min. The progress bar on screen indicates time to completion.   **!** Once run is started, it cannot be cancelled; canceling will require reloading new samples into unused wedges.  **!** Users cannot be changed while running   1. Recycle labels when run is complete; do not take back to room 2 2. Remove lab coat and change gloves before leaving area 3. When run is complete, remove disc from instrument; *check well volumes.* Place disk in bio-bag and discard if completely used. If there are unused wedges, retain disc in a sealed bio-bag in room 2. Upon completion of the run, the software automatically calculates and displays results.   **Note:** in room 2 - soak applicator and disc cold block in 5% extran followed by a water rinse. | | | | |
| **Interpretation/ Results and Reporting** | **Reviewing and Printing Completed Runs** When the run is complete, the results are interpreted by the software and will display on the screen; positive results appear red **Figure 2:** Analysis Complete   Click the Print button to print a full report of the results, Fig. 2  * 1. √ Include Ct values   2. √ Include graphs   3. Scroll through the report , reviewing comments, failures and amplification curves      + A valid curve shows a smooth, exponential increase, Fig. 3      + Invalid curve may be linear or a curve with data “spikes” where the curve crosses the threshold      + Review “QC statement/Note” on the Segment Report for failures and error messages   4. Click **Print**   5. Export results to LIS; refer to procedure   **Figure 3:** Valid and invalid amplification curves  **Valid Valid Invalid**    **For a detailed analysis of the completed run, click the** Details **button to open the Analysis Window** Click on the run Details tab to display a summary of the run, fluid checks, Ct values and any sample failures that are highlighted in yellow **Figure 4**: Details Screen     1. For each CID (Sample ID) entered, the software displays a result (“Detected”, “Not Detected”, “Invalid” or “EC500”) for the ORF1ab and S gene targets.  |  |  |  |  | | --- | --- | --- | --- | | **Result** | **Interpretation** | **Notes** | **Action** | | **Detected** | Indicates the presence of ORF1ab and/or S gene RNA in the patient sample. |  | Export results to LIS | | **Not Detected** | Indicates the absence of ORF1ab and/or S gene RNA in the patient sample. |  | Export results to LIS | | **Invalid** | Indicates the inability to determine the presence or absence of ORF1ab and/or S gene RNA in the patient sample. | Results may be due to:   1. DNA internal Control failure 2. Failure to detect sufficient specimen. | Repeat testing. (see procedure below)  NEAT and 1:4 dilution  Document result in problem log. | | **EC500** | Indicates an error for the particular analyte(s). | Data processing error due to noise, weak or late amplification in the signal. | Repeat testing. (see procedure below)  NEAT and 1:4 dilution  Document result in problem log. | | **EC505** | Indicates an error for the particular viral analyte(s). | Insufficient information to determine whether amplification was present. | Repeat testing. (see procedure below)  NEAT and 1:4 dilution  Document result in problem log. | | **EC515** | Indicates an error for the particular viral analyte(s). | Internal control amplification is not within specification. Result is invalid, repeat the sample. | Repeat testing. (see procedure below)  NEAT and 1:4 dilution  Document result in problem log. | | **System Error** |  | Read error dialog box containing software messages regarding the cause of the problem and possible solutions. | Follow directions given by software, repeat testing if necessary. Contact DiaSorin technical support  **1-800-838-4548, option 3.**  See “Exporting a Service Packet” procedure below if necessary |  Click Data tab to *Select* or *Deselect* samples to be exported to LISSelect or deselect samples to view graphs (optional)Select or deselect samples to export to LISExport results to LIS (see procedure below) **Figure 5: Data Screen**  Export drop down    To view graphs by dye, click on the dye checkbox  Data / Detail tabs  Select and Deselect buttons  **Exporting Data to LIS**   1. When applicable, confirm POSC and NEGC are valid before reporting patient results 2. Positive patient results: Confirm name, CID number and disc location of primary sample before releasing results 3. If all test results were valid upon review, select **√** results to be exported onthe **Data** tab, refer to Fig.5    1. *Do not* send invalid patient results or POSC and NEGC. Deselect by clicking on individual box(es) 4. From the Export drop down box, select **LIS** and then **LIS folder;** click **OK**   **Figure 6:** Export to LIS     1. A message that the run exported successfully will appear. Click **OK** 2. Patient results will be translated in LIS as *Positive* or *Negative* for COVID-19*.* 3. If the sample is interpreted as “Invalid” by Simplexa, results will need to be entered manually as *Equivocal* or *Unresolved* after review.   Do not report patient results until problem is resolved  Record problem and corrective action in the ***QC and Equipment Failure* *Log*** | | | | |
| **Result Reporting: Sunquest** | 1. After results have been exported to LIS: log into Sunquest:    1. Click on the Sunquest icon to log on    2. Enter user, password and location [R] 2. Click on **Result Entry** from the menu options 3. Select **SIM** from drop down box   **Figure 1:** Interface Configuration:     1. Click on the  button located in the lower left corner    1. If the page says “Waiting for cups….”, the results were not successfully transmitted or the results page was accessed too quickly before the transmission was completed  |  |  | | --- | --- | | If | Then | | * Specimen box reads *Preprocessing passed* with no further messages * Test box has no messages * Sample results are acceptable | Click Save and then Accept (Fig. 5) |   **NOTE:** All samples will automatically have the following result comment attached: “The DiaSorin Molecular Simplexa COVID-19 Direct Assay was issued an Emergency Use Authorization (EUA) by the FDA on March 19, 2020.”   1. Staple worksheet containing specimen identifiers used during testing and the test Segment Report together 2. Place report in the COVID-19 result log book   **Duplicate results**   1. If a run is exported more than once, uncheck the duplicate results OR valid result and release the checked results      1. Click  button located on the lower left corner 2. **Click** Release All and accept 3. Print a completed worksheet to file with the results. Check results against worksheet for accuracy.   Printing completed manual worksheets: | | | | |
| **Retesting Procedure: Invalids and EC500, EC505, or EC515 errors** | 1. Dilute 50 uL of specimen in 150uL UTM to obtain a 1:4 dilution    1. Label a cryovial with a patient foot label with 1:4 written on it    2. Pipette 150 uL UTM into the cryovial    3. Vortex the patient sample 5-10 seconds and pipette 50 uL sample into the cryovial    4. Vortex the cryovial 5-10 seconds 2. Retest the sample NEAT (undiluted) and test the 1:4 dilution  |  |  | | --- | --- | | **If** | **Then** | | Error resolves with undiluted sample | Report the valid result | | Error resolves with diluted sample | Report the result along with the comment code DILUT to indicate "Sample diluted due to inhibition.  Please consider submission of a new sample if clinical suspicion is high.” | | Error does not resolve | Report as UNR, document call, and request new sample for testing. |   **\*\***See “Alert Values and Phoned Results” Procedure below | | | | |
| **Alert Values Phoned Results** | **Alert Value:** Positive COVID-19 results must be called to the patient’s caregiver.  **Phoned Results, Sunquest GUI Interface**   1. Enter phoned results in **Result Entry** 2. Click on the interpretation box to expand the result 3. At the blinking cursor, add the code **CAL**, press tab, enter semi-colon, record who the result was relayed to and the time/date. 4. Type the first name and last initial of the person called and the date/time 5. Close the interpretation box 6. Click **Save** and then **Accept** on the Verify Release screen to file results in LIS | | | | |
| **Manual Entry of Results** | 1. Open Result Entry, select the Manual resulting mode (top left corner), from the configuration drop down select the appropriate test code. 2. Select the appropriate batch #. 3. Open the “workload” tab. 4. Select the method (SIM 1-4). 5. Click  in the lower right corner. 6. Enter the Specimen ID or scroll to the correct patient if necessary (lower left corner). 7. Type in results and applicable comments when necessary. 8. Check results against instrument print out, press tab, and click .  | **Result** | **Sunquest code** | **Interpretation** | | --- | --- | --- | | **Positive** | **POS** | 1. Positive | | **Negative** | **NEG** | 1. Negative | | **Unresolved Results** | **UNR**  **CAL** | 1. Unresolved: This sample is inhibitory to amplification and the results are inconclusive. Consider repeat collection if clinically indicated. | | **Diluted Results** | **POS/NEG**  **DILUT** | 1. DILUT: "Sample diluted due to inhibition.  Please consider submission of a new sample if clinical suspicion is high.” | | | | | |
| **Correcting Results** | 1. Open Result Entry, select the Manual resulting mode (top left corner), from the configuration drop down select the appropriate test code. Click  in the lower right corner. 2. Enter the Specimen ID, enter Tab and click Yes to modify the result. 3. Change the incorrect result. The corrected result comment will automatically append. Add the CAL comment, press tab, enter a semi-colon and record who was called and the time/date. 4. Click . Click  when the “Verify Release Destination” window opens. | | | | |
| **Sample Storage** | **Storage and Retention of Test Specimens**   1. Mark all positive samples on cap.    1. Write positive results on the side of the tube 2. Store in rack in the -70 °C freezer for a minimum of 1 month. 3. Discard samples after elapsed time in red biohazard container | | | | |
| **Equipment and Room Decontamination** | **Refer to:**  [MB 3.03 Cleaning and Decontamination of Equipment and Work Areas](https://starnet.childrenshc.org/References/labsop/molbio/engctl/mb-3.03-cleaning-and-decontamination-of-equipment-and-work-areas.pdf)  [MB 4.02 DiaSorain Liaison MDX Instrument Maintenance and Troubleshooting](file:///G:\Lab%20Procedures\Molecular%20Procedure%20Manual\MB%204.0%20Equipment\MB%204.02%20DiaSorain%20Liaison%20MDX%20Instrument%20Maintenance%20and%20Troubleshooting.docx) | | | | |
| **Customer and Technical Support** | Call DiaSorin Technical Service at 1-800-838-4548 option #3. Technical service may ask you to generate and send a Service Packet file; see Troubleshooting above for downloading a \*.icz file. If it is determined that the instrument must be returned for service, decontaminate the Liason MDX before shipping, refer to procedure MB 4.02. Document all problems and actions in the QC and Equipment Failure Log. | | | | |
| **Limitations** | 1. For Emergency Use Authorization Only use only.  2. For *in vitro* diagnostic use.  3. For professional use only.  4. Testing of nasal swabs even if collected by a healthcare provider is limited to patients with symptoms of COVID-19.  5. Not for screening.  6. False-negative results may occur if the viruses are present at a level that is below the analytical sensitivity of the assay or if the virus has genomic mutations, insertions, deletions, or rearrangements or if performed very early in the course of illness.  7. As with other tests, false-positive results may occur. Repeat testing or testing with a different device may be indicated in some settings.  8. This test is a qualitative test and does not provide the quantitative value of detected organisms present.  9. Information on the kit barcode can only be transferred into the LIAISON® MDX Studio Software Studio through a bar-code scanner. If the scanner is not working, or if you are unable to transfer the information for any reason, contact DiaSorin Molecular Technical Services. | | | | |
| **Method Performance Specifications** | **According to the manufacturer (per the package insert):**    For additional performance characteristics refer to the [Simplexa COVID-19 Direct Package Insert](file:///G:\LAB\Molecular\Simplexa%20COVID-19\PIs\Simplexa%20COVID-19%20Direct%20Rev.%2004.pdf). | | | | |
| **References** | 1. Simplexa COVID-19 Direct Package Insert, REF: MOL4150, Rev. 05. In. Cypress, CA: DiaSorin Molecular.  2. World Health Organization: Coronavirus. <https://www.who.int/health-topics/coronavirus>  3. Centers for Disease Control and Pevention: Coronavirus. <https://www.cdc.gov/coronavirus/general-information.html>  4. Cheng ZJ, Shan JJI. 2019 Novel coronavirus: where we are and what we know. 2020:1-9.  5. Centers for Disease Control and Prevention: Coronavirus Disease 2019 (COVID-19).  6. US Department of Health and Human Services PHS/CDC/NIH. Biosafety in microbiology and biomendical laboratories. In. Washington DC: Government Printing Office, 2007.  7. Wayne P. MM3-A2 Molecular diagnostic methods for infectious disease; approved guideline, 2nd ed. In. Clinical Laboratory Standards Institute, 2006.  8. Simplexa COVID-19 Positive Control Pack Package Insert, REF: MOL4160, Rev. 01. In. Cypress, CA: DiaSorin Molecular. | | | | |
| **Alternate Methods** | 1. In house: SARS-CoV-2, Molecular Detection, RT-PCR (Test code: COVC) 2. Send out test to Mayo Clinic Laboratories: COVID-19, Molecular Detection, RT-PCR, Varies (Mayo lab test code: COVID, SCOV2) 3. Send out test to Quest Diagnostics: SARS-CoV-2 PCR (Quest lab test code: COVO) 4. Send out test to MDH: SARS-CoV2/COVID-19, Molecular Detection, RT-PCR (MDH test code: COVS) | | | | |
| **Proficiency Testing** | CAP (COV2): 2 shipments a year with 3 samples | | | | |
| **Training Plan/ Competency Assessment** | **Training Plan** | | | **Initial Competency Assessment** | |
| 1. Employee must read the procedure. 2. Employee will demonstrate the ability to perform procedure, record results, and document corrective action after instruction by the trainer. | | | 1. Direct observation | |
| **Historical Record** |  |  |  | |  |
|  | **Version** | **Written/Revised by:** | **Effective Date:** | | **Summary of Revisions** |
| 1 | Julie Laramie / Michelle Merryman | 06/01/2020 | | Initial Version |
| 2 | Julie Laramie | 07/07/2020 | | Changed QC frequency to every 30 days |
| 3 | Julie Laramie | 09/14/2020 | | Updated manual report entry |
| 4 | Julie Laramie | 11/30/2020 | | Added manual worksheet instructions, standardized worksheet, label, and disk labeling |
| **Archived by:** |  | **Archived date:** | |  |
|  |  |  |  | |  |