TRAINING UPDATE

Lab Location:	SGMC & WOMC	**Date Distributed:**	6/21/2021
Department:	Core Lab	**Due Date:**	7/15/2021

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:

Simplexa™ COVID-19 Direct Test SGMC.M1016 v3

Simplexa COVID-19 Direct Test PCR Quality Control Log AG.F573.3

Description of change(s):

SOP:

Section	Reason
6.3	Changed external QC frequency per IQCP
16	Added IQCP info

FORM:

Updated external QC frequency to match SOP

This revised SOP & Form were implemented on June 21, 2021

Document your compliance with this training update by taking the quiz in the MTS system.

Adventist HealthCare

Simplexa™ COVID-19 Direct Test PCR
Quality Control Log

☐ Shady Grove Medical Center
☐ White Oak Medical Center

Last external QC performed (date): _____ **Next external QC is due = *Month*** _____ *Circle day below*

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

1. **External Positive and Negative Controls** are tested and documented with each new kit lot or shipment or every 31 days, whichever is more frequent.
2. **Internal controls** must be documented each time the test is performed.
3. If QC results are not acceptable, document corrective action. Do not accept patient results before reviewing QC results for proper reactions.

Date	**Patient Name / MR#**	**Reagent MIX**	**RNA IC Internal Control**	**External Pos Control** S gene & ORF1ab both must be "**DET**" to be valid			**External Neg Control** S gene & ORF1ab both must be "**NTD**" to be valid			**Tech Code**
		Lot # / Expire	**Valid / Invalid**	**Lot # / Expire**	**ORF gene result**	**S gene result**	**Lot # / Expire**	**ORF gene result**	**S gene result**	

Weekly review:	Weekly review:	Weekly review:
Weekly review:	Weekly review:	Monthly review:

Technical SOP

Title	**Simplexa™ COVID-19 Direct Test**	
Prepared by	Ron Master	Date: 3/5/2021
Owner	Ron Master	Date: 3/5/2021

Laboratory Approval	**Local Effective Date:**	
Print Name and Title	**Signature**	**Date**
Refer to the electronic signature page for approval and approval dates.		

TABLE OF CONTENTS

1. TEST INFORMATION

Assay	Method/Instrument	Test Code
COVID-19 PCR, Qualitative	Real-time reverse transcriptase polymerase chain reaction (RT-PCR)	COVID

Synonyms/Abbreviations
SARS-CoV-2 PCR, SARS CoV-2 RNA (COVID-19)

Department
Core Lab

2. ANALYTICAL 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), 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.

3. SPECIMEN REQUIREMENTS

3.1 Patient Preparation

Component	Special Notations
Fasting/Special Diets	N/A
Specimen Collection and/or Timing	Follow manufacturer's instructions. Avoid nasal sprays, ointments, gels and antibiotics prior to collection. Avoid use of throat lozenges. 1. Insert the collected swab into a UTM/VTM tube. Place the swab head at least ½ inch below the surface of the media and swirl the swab in the media. 2. Break the swab shaft and leave the swab in the UTM tube (i.e. sample tube)

Component	Special Notations
	3. Attach the cap securely. Store at room temperature (up to 24 hours) or refrigerate (up to 72 hours)
Special Collection Procedures	N/A
Other	N/A

3.2 Specimen Type & Handling

Criteria		
Type -Preferred **-Other Acceptable**	Sterile nasopharyngeal swabs, in approved UTM/VTM (Viral Transport media). See list of acceptable swabs/VTM kits below	
Approved Collection Container	**Specimen Collection Kit** Nasopharyngeal Swab Collection Kits Nasopharyngeal swabs (NPS) or nasal swabs (NS) in Copan Universal Transport Media (UTM) or BD Universal Viral Transport (UVT) or equivalent, Remel M5, Remel M6, Copan ESwab™ (Liquid Amies), Puritan® UniTranz-RT®, or saline (0.9% sodium chloride in water). Use only swabs with a synthetic tip (e.g. Dacron, nylon, or rayon) and an aluminum or plastic shaft. Do not use calcium alginate swabs, as they may contain substances that inhibit PCR testing.	
Volume - Optimum **- Minimum**	3.0 mL 1.0 mL	
Transport Container & Temperature	Sample collection kit at room temperature	
Stability & Storage Requirements	Room Temperature:	0-24 hours
	Refrigerated (2-8℃)	0 -72 hours
	Frozen: (-70℃) or colder	Indefinitely (≥ 72 hours) (and transport on dry ice)
Timing Considerations	N/A	
Unacceptable Specimens & Actions to Take	• Specimens containing calcium alginate swabs, cotton swabs with wooden shaft. • Dry Swabs, Swabs transported without UTM/VTM • Swabs not listed on the Approved Collection List • Specimens exceeding stability • Quantity Not Sufficient • Specimens from leaking, uncapped or broken container	
Compromising Physical Characteristics	None	
Other Considerations	None	

NOTE: Labeling requirements for all reagents, calibrators and controls include: (1) Open date, (2) Substance name, (3) Lot number, (4) Date of preparation, (5) Expiration date, (6) Initials of tech, and (7) Any special storage instructions. Check all for visible signs of degradation.

4. REAGENTS

The package insert for a new lot of kits or reagents must be reviewed for any changes before the kit is used.

4.1 Reagent Summary

Reagents / Kits	Supplier & Catalog Number
Simplexa™ COVID-19 Direct Reaction Mix	MOL4151 (24 tests)
Direct Amplification Disc Kit	MOL1455

4.2 Reagent Preparation and Storage

Simplexa™ COVID-19 Direct Reaction Mix	
Simplexa™ COVID-19 Direct Reaction Mix (RM)	DNA polymerase, Reverse transcriptase, RNase inhibitor, buffer, dNTPs, encapsulated RNA Template, fluorescent probes and corresponding forward and reverse primers specific or detection of SARS-CoV-2 viral RNA and for the Internal Control
	S target with FAM probe fluorophore
	ORF1ab target with JOE probe fluorophore
	Internal Control RNA (IC) with Q670 probe fluorophore
Simplexa™ COVID-19 Direct Barcode Card	Assay specific parameters and lot information.
Storage	Store frozen at -10°C to -30°C. (Do not use a frost-free freezer). Allow reagents to thaw at room temperature (approximate range 18 to 25 °C) before use. Use within thirty (30) minutes of thawing.
Stability	After removing Reaction Mix from freezer storage, initiate the test within thirty (30) minutes. Before use, reagent is stable until the expiration date indicated on label. Do not vortex the Reaction Mix. Do not refreeze the Reaction Mix.

5. CALIBRATORS/STANDARDS

Not applicable

6. QUALITY CONTROL

6.1 Controls Used

Quality Control	Supplier & Catalog Number
Simplexa™ COVID-19 Positive Control Pack	MOL4160, PS #207038
No Template Control (NTC)	Universal transport media (UTM)

6.2 Control Preparation and Storage

Control Kit Components:	
Simplexa™ COVID-19 Direct Positive Control	Synthetic gene fragments for SARS-CoV-2 ORF1ab and S gene target regions in UTM. MOL4161. 10 vials. 50uL/vial.
Storage	Store controls at -10 to -30ºC (do not use a frost-free freezer).
Stability	Before use, stable until the expiration date indicated on label. Do not refreeze.
Preparation	Allow controls to thaw at room temperature (approximate range 18 to 25ºC) before use.

6.3 Number and Frequency

QC Frequency	
1	**Internal Control:** An RNA Internal Control (RNA IC) is included in every assay. Failure of the RNA IC will result in an Invalid test result.
2	**External Control:** External QC (both positive and negative) must be run with each new lot or shipment or every 31 days, whichever is more frequent. ~~• once per day of testing and should be included with the assay run~~ ~~• with each new lot or shipment~~ ~~• every 31 days~~ External controls must be treated in the same manner as patient samples.

6.4 Tolerance Limits and Criteria for Acceptable QC

A. Tolerance Limits

Tolerance Limits	
1.	RNA Internal Control is performed on each test. Failure to yield a valid RNA Internal Control indicates the test is invalid, and patient results cannot be resulted.

Tolerance Limits	
2.	External Control runs must produce the expected result (Detected or Not Detected) and interpretation (valid) prior to running patient samples.

B. Criteria for Acceptable QC
- Each test must produce a valid RNA Internal Control result.
- If the negative control or the positive controls are flagged as Invalid, then the patient result is invalid and must be repeated.
- Controls and patient data must be reviewed for acceptability and for atypical or unexpected results or trends prior to reporting patient results.
- DO NOT release results from runs with unacceptable controls or with unusual patterns, trends or distribution in patient values.

C. Corrective Action
- All rejected runs must be effectively addressed and include the following documentation:
  - Control(s) that failed (e.g., positive control with negative result or invalid controls) and/or atypical or unexpected patient results
  - Actions taken
  - Statement of what was done with the patient samples from the affected run/batch,
  - Date and initials of the person recording the information.
- Patient samples in failed analytical runs must be reanalyzed.

NOTE: The laboratory director or designee may override rejection of partial or complete runs. Justification for the override must be documented in detail.

6.5 Documentation

- Record all Quality Control results (failed and successful) manually or electronically.
- Quality control records are reviewed daily at the bench, weekly by the Group Lead or designee, and monthly by the Supervisor/Manager or designee.
- Refer to complete policies and procedures for QC documentation and for record retention requirements in the Laboratory QC Program.
- Refer to Quest Diagnostics Records Management Program for Quality Control record retention requirements.

7. EQUIPMENT and SUPPLIES

7.1 Assay Platform

- LIAISON® MDX with LIAISON® MDX Studio Software version 1.1 or higher.

7.2 Equipment

- 50 µL fixed volume pipette (VWR Signature™ Fixed Volume Ergonomic High-Performance Pipettor Model VWR FE50 or equivalent)
- Freezer (manual defrost) at -10 to -30°C (for kit component and/or specimen frozen storage)
- Refrigerator at 2 to 8°C (for specimens)
- Vortex for mixing patient samples

7.3 Supplies

- Universal Transport Media (UTM, Copan) or Universal Viral Transport (UVT, BD) to be used as a No Template Control (NTC)
- Sterile, nuclease-free disposable pipette tips with filters (Extra Long tips ≥ 91 mm are recommended for pipetting directly from primary collection tubes)
- 6.5 inch fine-tip transfer pipettes (REF-343779)
- Disposable, powder-free gloves
- Rack

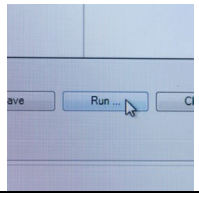
8. PROCEDURE

NOTE: For all procedures involving specimens, buttoned lab coats, gloves, and face protection are required minimum personal protective equipment. Report all accidents to your supervisor.

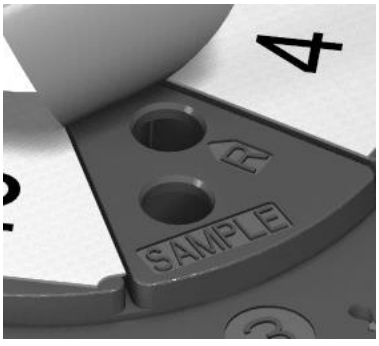
8.1	Instrument Set-up Protocol
1.	**Laptop Login (See addendum 1)** Login in using your AHC Network login/password **DO NOT LOG OUT when a run is in progress or it will terminate the run. **Liaison Studio Software Login** Username: admin Password: fastman
2.	Refer to the LIAISON® MDX Operator Manual for details on how to configure the LIAISON® MDX Studio Software to add an assay definition, set up and analyze runs on the LIAISON® MDX.
3.	**Powering on the System** • Power on the LIAISON® MDX. • Power on any computer peripherals (i.e. printer). • Power on the computer. • Start the LIAISON® MDX Studio.

8.1	Instrument Set-up Protocol
4.	**Powering the System Down** • Close all software applications. Save changes as necessary. • Select Start Menu > Turn Off Computer. Select Shut Down from the displayed window. • After the computer has turned off, power off any computer peripherals (i.e. printer). • Turn off the power switch on the rear of the LIAISON® MDX.
5.	Perform and document any required maintenance. Refer to addendum 2 for details.

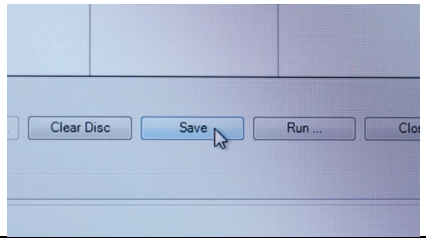
8.2	Running QC
1.	Select controls that need to be tested.
2.	Thaw the Positive Control and Reaction Mix vials at room temperature (approximate range 18 to 25 °C). Thaw one Reaction Mix vial for each sample or control to be tested.
3.	Scan the barcode on the Simplexa™ COVID-19 Direct Reaction Mix vial or barcode card. 
4.	Scan the disc barcode from the Direct Amplification Disc (DAD). 
5.	Scan or type in each control identifier. The Type for the positive control must be “PC-CV19” and both the Sample ID and the Type must be “NTC” for the negative control.
6.	For one wedge at a time, peel the adhesive foil back to expose the Sample (SAMPLE) and Reaction wells (R) without completely removing the adhesive foil cover (Figure 1 & 2). Avoid touching the under-side of the foil that will be in contact with the wells and disc surface. 
7.	Ensure that the reaction mix is completely thawed. Briefly tap the tube on the bench several times to assure the liquid is in bottom of tube.

8.2	Running QC
8.	Use the fixed volume pipette to transfer 50 µL of the reaction-mix into Reaction well (R). 
9.	Use a 6.5 inch transfer pipette with a fine tip to transfer 2 drops of the control **OR** use the fixed volume pipette to transfer 50 µL of the control into Sample well (SAMPLE). **Note**: Be careful to hold the transfer pipette vertically to control drop size. 
10.	Cover and seal the wells with the peeled adhesive foil, pressing down firmly near the edge of the disc. If the original foil is torn do not load the wells in the wedge. Instead load another wedge.
11.	Carefully remove the tab portion of the cover at the perforation. 
12.	Repeat steps 6 to 11 for the next control(s).
13.	Load the sealed Direct Amplification Disc into the LIAISON® MDX and start the run.   

8.3	Test Runs
	Before testing, clean the work area with a solution of 1:10 dilution of household chlorine bleach and then repeat the cleaning of the work area with 70% alcohol. Wipe work surfaces dry completely before proceeding.
1.	Select samples that need to be tested.
2.	Thaw Reaction Mix vials at room temperature (approximate range 18 to 25 °C). Thaw one (1) Reaction Mix vial for each sample or control to be tested. **Reaction mix must be used within 30 minutes of thawing.**

8.3	Test Runs
3.	Scan the barcode on the Simplexa™ COVID-19 Direct Reaction Mix vial or barcode card. **Note**: If the barcode reader is not functioning, samples can be programmed manually. Refer to Addendum 3 for details. 
4.	Scan the disc barcode on the Direct Amplification Disc (DAD). 
5.	Scan or type in each sample identifier.  When all samples have been entered into the run, select "**Save**" Print the disk map to guide the loading of the Direct Amplification Disc (DAD).
6.	Place the Direct Amplification Disc (DAD) on the provided cold plate. For one wedge at a time, peel the adhesive foil back to expose the Sample (SAMPLE) and Reaction (R) wells without completely removing the adhesive foil cover. Avoid touching the underside of the foil that will be in contact with the wells and disc surface.  

8.3	Test Runs
7.	Ensure that the Reaction Mix is completely thawed. Briefly spin down the tubes as needed. (Do not vortex the Reaction Mix)
8.	Use the fixed volume pipette to transfer 50 µL of the Reaction Mix into Reaction (R) well. 
9.	Use a 6.5 inch transfer pipette with a fine tip to transfer 2 drops of the sample **OR** use the fixed volume pipette to transfer 50 µL of sample into the Sample well. **Note**: Be careful to hold the transfer pipette vertically to control the drop size.  **If using a 50 µL pipette, after removing the pipette tip, wipe the end of the pipette with gauze moistened with 70% alcohol.**
10.	Cover the wedge sealing the wells with the peeled adhesive foil, pressing down firmly near the edge of the wedge. If the original foil is torn do not load the wells in the wedge. Instead load another wedge.
11.	Tear off the tab portion of the foil cover along the perforation. 
12.	Repeat steps 6 to 11 for the next sample(s).

8.3	Test Runs
13.	Load the sealed DAD into the LIAISON® MDX and Click "Save"; then click "Run" to start the run   
14.	Upon completion of the run, the software automatically calculates and displays results.

8.4	Results
1.	For each accession ID (Sample ID) entered, the software displays a result ("Positive", "Negative", "Invalid", "EC500, EC505 or EC515") for SARS-CoV-2 RNA.
2.	Print the report as needed.
3.	The MDX does not automatically transmit the results to the LIS when the run is completed. To transmit results to the LIS, you must click on the "Export LIS" button. Results will then auto file into the LIS.
4.	Log out of the laptop, after the run is completed.

NOTE: In the event that the test system becomes inoperable, notify supervision or designee for further direction. Patient specimens must be stored in a manner that maintains the integrity of the specimen.

9. CALCULATIONS

None

10. REPORTING RESULTS AND REPEAT CRITERIA

10.1 Interpretation of Data

Interpreting QC Material:

Control Type	ORF1ab target	S gene target	RNA Internal Control (RNA IC)
Simplexa™ COVID-19 Positive Control	Detected	Detected	Valid
No Template Control (NTC)	Not detected	Not detected	Valid

Typical Ct values for the Positive Control range between 22 to 32.

Detection of the Simplexa™ RNA Internal Control (RNA IC) is not required for a valid result when SARS-CoV-2 is detected.

Interpreting Patient Results

Results		Interpretation
SARS-Cov-2 Target		
ORF1ab	S gene	
Detected	**Detected**	Result indicates the presence of SARS-CoV-2 RNA in the patient sample.
Detected	-----	Result indicates the presence of SARS-CoV-2 RNA in the patient sample.
-----	**Detected**	Result indicates the presence of SARS-CoV-2 RNA in the patient sample.
Not detected	**Not detected**	Result indicates the absence of SARS-CoV-2 RNA in the patient sample.
Invalid		Result indicates inability to conclusively determine presence or absence of SARS-CoV- 2 RNA in the patient sample. This result may be due to 1) Internal Control (IC) failure, or 2) failure to detect sufficient specimen volume. The sample needs to be retested. See "Invalid Results" section below.
EC500		Data processing error due to noise, weak or late amplification in the signal. Repeat the sample. If the problem persists, contact Technical Service.
EC505		Insufficient information to determine whether amplification was present. If the problem persists, contact Technical Service.
EC515		Internal control amplification is not within specification. Result is invalid, repeat the sample. If the problem persists, contact Technical Service.

***** In the case of one SARS-CoV-2 target positive/one SARS-CoV-2 target negative, result is suggestive of: 1) a sample at concentrations near or below the limit of detection of the test, 2) a mutation in one of the target regions, or 3) other factors.

10.2 Units of Measure

N/A

10.3 Analytical Measurement Range (AMR)

N/A

10.4 Review Patient Data

- Review patient results for unusual patterns, trends or distribution.

- Report atypical or unexpected results or trends for this test to appropriate supervisory personnel, prior to releasing results.

10.5 Repeat Criteria and Resulting

- **see Addendum 1 for Sunquest reporting instructions**

IF the result is …	THEN…
Not detected	Result as **NTD** (Not Detected)
Detected	Result as **DET** (Detected)
Invalid	**Note**: First make sure that no one logged out of the laptop before the run was completed. If so, then all the results for the run are marked as "Invalid". 1. In case of an "Invalid" result, re-test the sample with a new Reaction Mix vial from the same kit or a new kit. If the problem is unresolved, contact the DiaSorin Molecular Technical Services department. Contact information can be found on the last page of this document. 2. If valid results are obtained on the repeat run, record on the QC Log and indicate the original Invalid/Error was repeated and that valid results were obtained upon repeat. 3. If the second result remains Invalid/Error (or if the original specimen was QNS for repeat), obtain a new nasal / nasopharyngeal specimen from the patient and repeat the test. 4. If the patient is not available for re-collection OR the recollected specimen still results as Invalid/Error, indicate on the QC Log that the test was confirmed as INVALID. <u>Resulting repeat INVALID results</u>: Report as **INVD** Add comment **INVLT** - this code translates to: *Unable to report. Repeat analysis of this specimen yielded invalid, inconsistent or unacceptable results.*"

11. EXPECTED VALUES

11.1 Reference Ranges

Not Detected

11.2 Critical Values

None

11.3 Standard Required Messages

The following comment is automatically added to the report by the LIS (code MDXC):

Please review the "Fact Sheets" and FDA authorized labeling available for healthcare providers and patients using the following websites:
https://www.fda.gov/media/142191/download
https://www.fda.gov/media/136048/download

This test has been authorized by the FDA under an Emergency Use Authorization(EUA) for use by authorized laboratories.

12. 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.[1,2,3] 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).[2,4] 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.[5]

13. PROCEDURE NOTES

- **FDA Status:** Emergency Use Authorization (EUA)
- **Validated Test Modifications:** None

14. LIMITATIONS OF METHOD

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. After handling samples and kit reagents, remove gloves and wash hands thoroughly.

14.1 Precision

Refer to package insert

14.2 Interfering Substances

Refer to package insert

14.3 Clinical Sensitivity/Specificity/Predictive Values

Refer to Package Insert

15. SAFETY

Refer to your local and corporate safety manuals and Safety Data Sheet (SDS) for detailed information on safety practices and procedures and a complete description of hazards.

16. RELATED DOCUMENTS

- Biological Safety Cabinet, Micro procedure
- Laboratory Quality Control Program
- Laboratory Safety Manual
- Safety Data Sheets (SDS)
- Simplexa COVID-19 Direct Test PCR Quality Control Log (AG.F573)
- Diasorin MDX Maintenance Record (AG.F572)
- DiaSorin Molecular Simplexa™ COVID-19 Direct Assay System Individual Quality Control Plans (VC 948, VC 949)

17. REFERENCES

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5. Centers for Disease Control and Prevention. Coronavirus Disease 2019 (COVID-19). https://www.cdc.gov/coronavirus/2019-ncov/about/index.html
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9. QDMD738 – Molecular Best Practices.
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12. Clinical and Laboratory Standards Institute (CLSI). Protection of laboratory workers from occupationally acquired infections. Approved Guideline-Fourth Edition. CLSI Document M29-A4: Wayne, PA; CLSI, 2014

18. DOCUMENT HISTORY

Version	Date	Section	Revision	Revised By	Approved By
1	3/16/21	6.3	Added ext. QC requirement to match log	L Barrett	R Master
1	3/16/21	7.3, 8	Added fine tip transfer pipette	R Master	R Master
1	3/16/21	8.3	Added note for manually programming	L Barrett	R Master
1	3/16/21	10.1	Changed from Pos/Neg to Detected/Not	L Barrett	R Master
1	3/16/21	19	Added addendum 3	L Barrett	R Master
2	6/16/21	6.3	Changed external QC frequency per IQCP	L Barrett	R Master
2	6/16/21	16	Added IQCP info	L Barrett	R Master

19. ADDENDA

Addendum	Title
1	Reporting Results in Sunquest
2	Instrument Maintenance
3	Programming Manual Test Run

Addendum 1

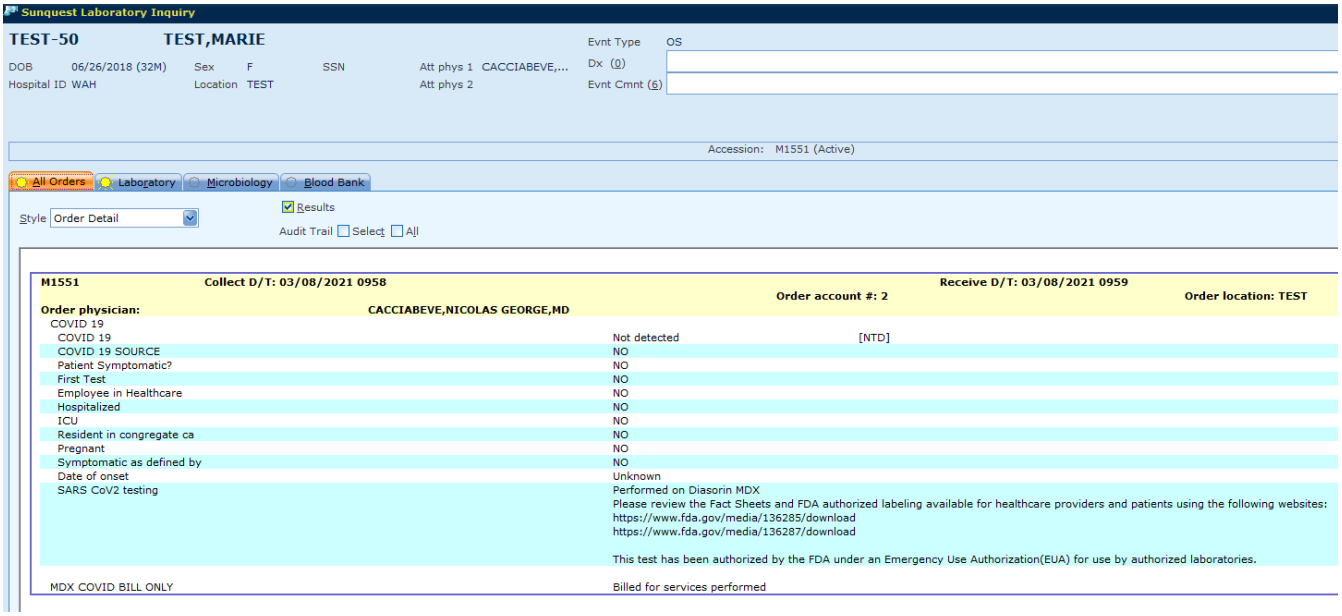
Reporting Results in Sunquest

Logging in/out of laptop notes:

- You MUST login to the laptop with your AHC network credentials
- Do NOT log out of the laptop while a test is running. By doing so the testing that is in progress is canceled and all the results are marked "invalid".
- You MUST log out of the laptop when testing is completed.

Resulting in Sunquest:

1. Results auto file into Sunquest once the Export LIS button has been selected on completed results on the MDX.
   - EUA documentation is automatically resulted for test SCTP.
   - Bill only test MDXCOV is automatically generated



2. If you have to enter the results manually into the LIS use function MEM in SmarTerm using worksheet SIM2 (SGMC) or WIM2 (WOMC).

Addendum 2

Instrument Maintenance

Frequency	Task	Refer to
Weekly	Clean the surface of the instrument with a lint free cloth.	n/a
Monthly	Back up to USB drive.	§8 "Managing the LIAISON® MDX"
Biannually	Spectral Calibration is required periodically. The system will remind users to contact DiaSorin Technical Services for assistance in performing this task.	§1.12 "Technical Service and Troubleshooting"
As Needed	Decontaminate the LIAISON® MDX	§11 "Appendix C – Cleaning and Maintenance"
	Clean the computer and barcode scanner	§11 "Appendix C – Cleaning and Maintenance"
	Check that the area around the LIAISON® MDX is not obstructed by chemicals or laboratory supplies	n/a
	As determined by DiaSorin, a full System Calibration may be required after instrument maintenance or following certain equipment repairs. Please contact DiaSorin Technical Services for additional information.	n/a

Cleaning & Decontamination Instructions

Decontaminating the LIAISON® MDX

1	Users should follow standard good lab practices of proper protective equipment including, but not limited to, wearing latex-free gloves, lab coat and protective eye wear. All used materials should be considered biohazards and disposed of properly.
2	Visually inspect the protective casing of the instrument. Discontinue use and contact Technical Service if there is noticeable damage.
3	Close the instrument lid (if open), power off the instrument, remove the power cord and USB cable. Wet a fresh lint-free wipe with the 10% bleach solution and wipe all exterior instrument surfaces. A contact time of 10 minutes is recommended to disinfect from bacterial, viral, and nucleic acid contamination.  

4	Wet a fresh lint-free wipe with the 70% isopropyl alcohol solution and wipe all exterior instrument surfaces.  
5	Re-attach the power cord and power on the instrument. The USB cable does not need to be attached to open the lid. Press and hold the front panel button until the LED begins blinking rapidly. Release the button. The lid solenoid will fire and the lid will open. Power off the unit and remove the power cord. 
6	Visually inspect the rotor assembly for any signs of damage. Discontinue use and contact Technical Service if there is noticeable damage.
7	Remove the cover from the hanger on the inner lid by lifting the cover upwards and away from the hanger. 
8	Wipe the interior and exterior of the magnetic cover with a wetted lint free wipe with the 10% bleach solution. DO NOT WIPE THE COVER WITH THE 70% isopropyl alcohol or bleach solution. Any alcohol based solvent will damage the plastic cover. 

9	Wipe all the interior surfaces of the instrument EXCEPT the magnetic cover with a wetted wipe using the 10% bleach solution. Maintain wet surfaces for at least 10 minutes for disinfection. 
10	Wipe all interior instrument surfaces with a wetted wipe using the 70% isopropyl alcohol solution (see Figure 11-7 – How to clean the interior surface).
11	After all of the interior instrument surfaces are clean and dry, replace the cover on the hanger on the inner lid. Re-attach the power cord and USB cable (see Figure 11-4 – How to remove the cover).

Software Maintenance

When the database size exceeds 1 gigabyte in size, the software will begin to remind users to perform maintenance tasks.

The LIAISON® MDX requires routine maintenance to maintain system integrity and run/analysis performance. This includes creating disaster recovery database backups.

Creating a Disaster Recovery Database Backup
Database Backup creates a complete backup of the LIAISON® MDX Studio database. The backup provides for disaster recovery where an entire system or database is lost.
Main Database will create a backup of the primary database which includes assays, setups and run data. Users must have Administrator privilege-levels to perform database backups. See §8.5 “Managing Users”.

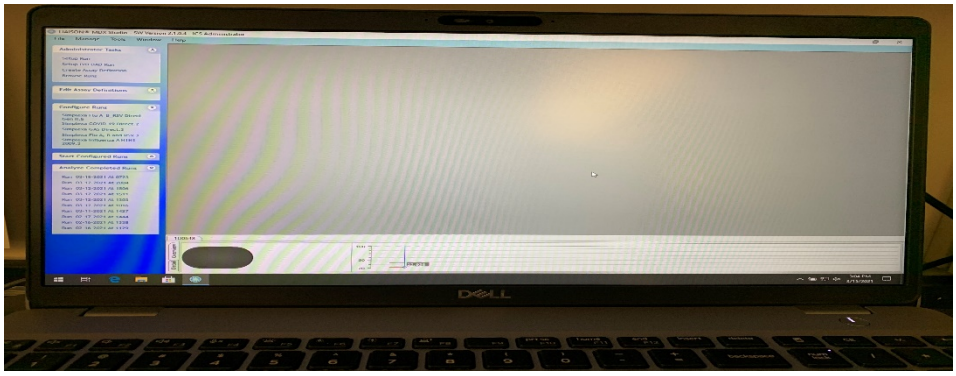
Creating a Database Backup

1. Ensure that no runs are currently executing - as run data is being captured to the database and the backup will include incomplete data.
2. Select menu item Tools > Database Tools > Backup Database.
3. Browse to and select a location to store the backup database. The file (*.icb) should be copied to a USB drive.

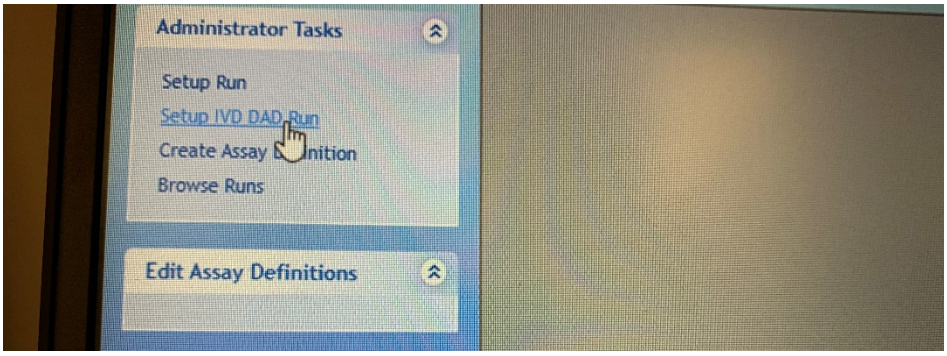
Addendum 3

Programming Manual Test Run

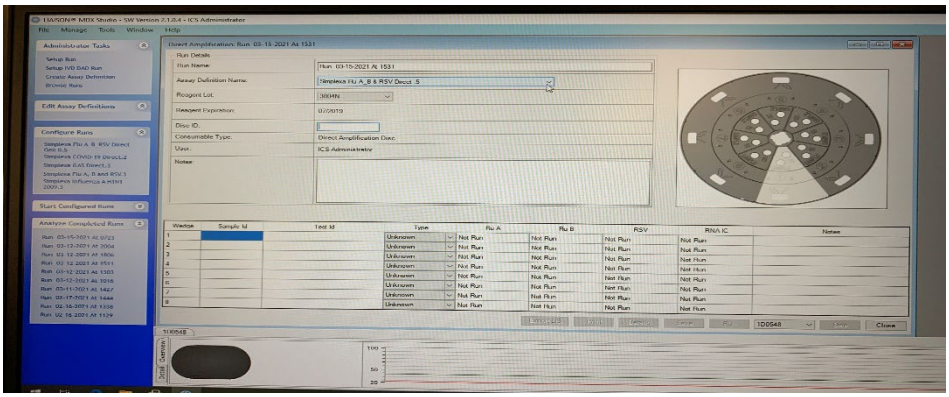
1. OPEN Liaison MDX Studio



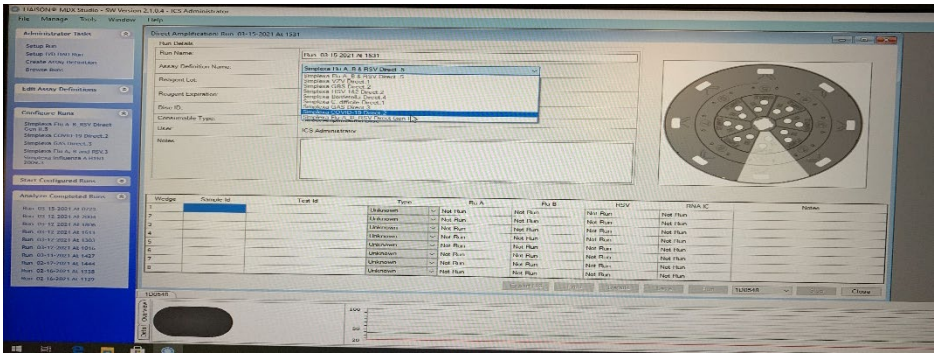
2. On the left side of the studio **click Setup/VD DAD Run** under Administration Tasks



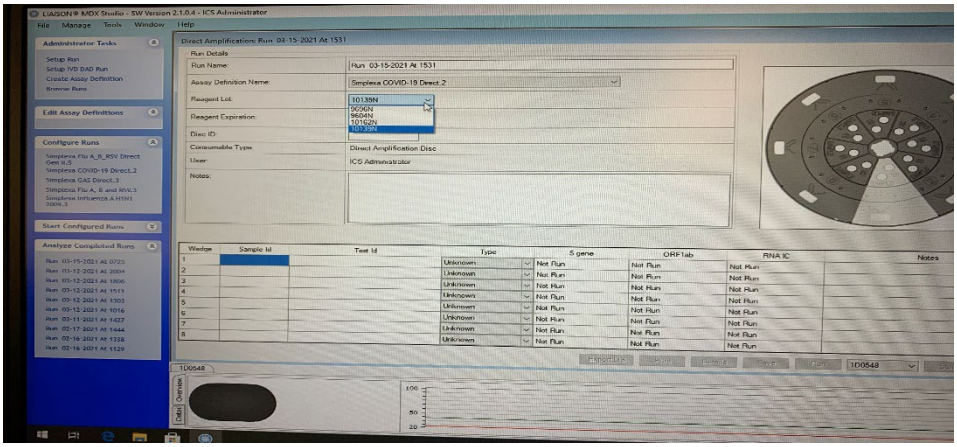
3. On direct amplification window under RUN details click **Assay Definition Name**



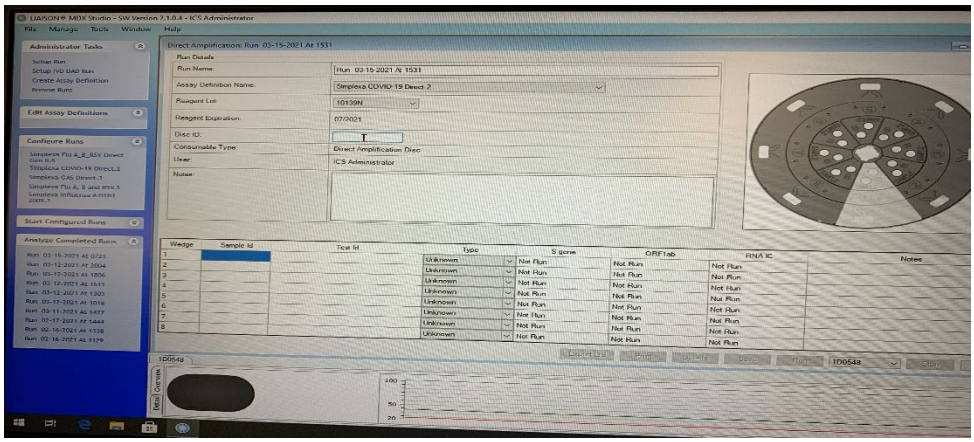
4. Select **Simplexa COVID-19 Direct 2** assay



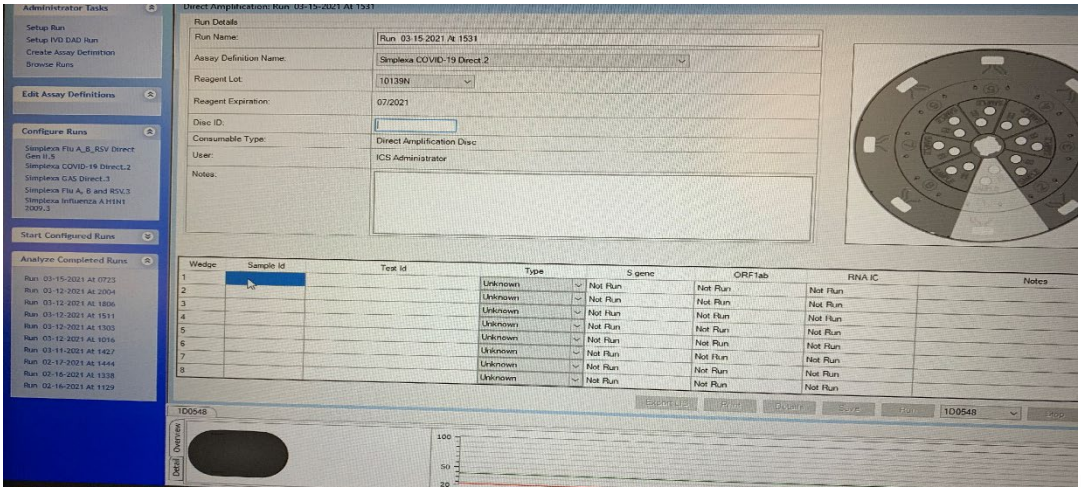
5. Select / check the Reagent Mix Lot from **Reagent lot** drop down option



6. Click on the **Disk ID** and scan the Direct Amplification Disk (DAD) barcode



7. Click on **Sample id** and scan your sample barcode or QC barcode, then save. Continue the next steps as automated run



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