Simplexa™ RSV & Influenza A/B Direct Procedure

PURPOSE

- This procedure provides instructions for preparing samples, setting up the PCR reaction and running the *Simplexa™* RSV & Influenza A/B Direct for the detection of RSV & influenza A/B from nasal specimens

POLICY STATEMENT

- PCR testing is performed daily, 0700 –1530

ABBREVIATIONS

- ABC : Analyzer Before Computer
- BSC: BioSafety Cabinet
- BSL: BioSafety level
- CBA: Computer Before Analyzer
- Ct : crossing threshold
- DAD : Direct Amplification Disc
- F/T : freeze/thaw
- IC : internal control
- LIS: laboratory information system
- MM : master mix
- NA : Nucleic Acid
- NEGC : negative control
- NP: nasopharyngeal swab
- NW: nasal wash specimen
- PCR: polymerase chain reaction
- POSC: positive control
- PPE: personal protective equipment
- RIP: Simplexa RSV & Influenza A/B PCR
- UNAC: Specimen unacceptable, please recollect
- UTM: universal viral transport media
- Area/Room 1: Clean room
- Area/Room 2: Processing room
- Area/Room 3: Amplification room

DOCUMENTATION/RECORDS

- Simplexa run-specific Segment Report
- LIS Incomplete and worksheets
- Pending Log
- Daily Maintenance Log

SAFETY CONSIDERATIONS

- Standard precautions for infectious agents. Refer to MB 2.02, Biohazard containment
- Use of engineering controls: Refer to MB 3.01 Engineering Controls to Prevent Nucleic Acid Contamination
- General Safety: MB 2.01 Safe Work Practices
- *Caution:* PPE including protective eyewear must be worn when working with concentrated Extran

MATERIALS REQUIRED

Equipment	Reagents	Supplies
Room 1: Clean room ▪ -10 to -30° C freezer ▪ Laminar flow Hood Room 2: Processing ▪ Refrigerator 2 – 8° C ▪ BSC BSL-2 ▪ -70° C freezer ▪ 100 or 200 µl pipette Room 3: Amplification ▪ 3M Integrated Cycler	Simplexa Flu A/B & RSV Direct kit MOL2651 ▪ Reaction Mix (24) 50 µl	2.0 mL cryovials
	Simplexa Flu A/B & RSV Control Pack MOL1455 ▪ 10 tubes, 100 µl	Nitrile gloves (powder-free)
	Negative control – UTM	Filtered pipette tips, 100 or 200 µl
	Sani-Cloth Bleach wipes	Gripper rack
	70% alcohol	Cryovial storage box
	5% Extran	Sharps disposal container
	Universal viral transport media (UTM)	Replacement Foil wedge

QUALITY CONTROL

A. Assay Controls; refer to MB 9.03
   1. POSC and NEGC: run daily, first run of the day
      a. POSC – Simplexa Flu A/B & RSV Positive Control Pack
      b. NEGC – UTM
   2. An IC is incorporated into each reaction mixture

B. 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

C. Before reporting patient results, all controls must yield valid results. Refer to MB 9.05, Procedures G, Evaluating and Interpreting Results.

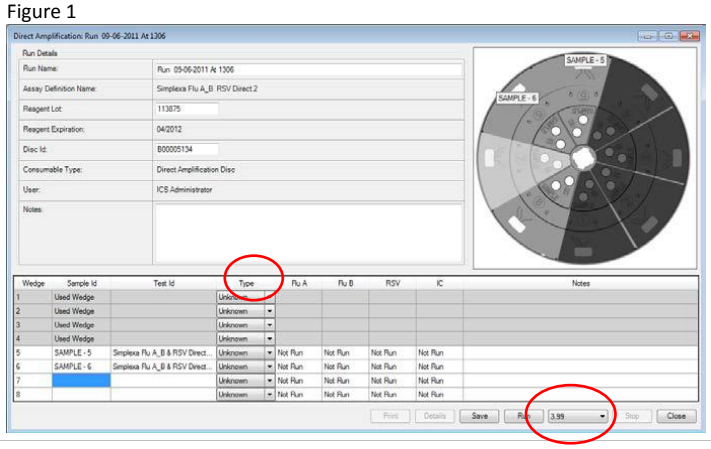
PROCEDURE A: Follow the steps in the table below to prepare specimens for testing

Testing Preparation

<table>
<tr><th>Activity</th><th>Step</th><th>Action</th><th>Related Doc</th></tr>
<tr><td>RIP</td><td>1</td><td>Call worksheet RIP; use this worksheet for sample identification throughout testing.</td><td>MB 1.01 Specimen Management</td></tr>
<tr><td>Sample Order
Room 2</td><td>2</td><td>Position samples and controls in first disc as follows:
<table>
<tr><th>Sample</th><th>Position</th></tr>
<tr><td>POSC</td><td>Position 1</td></tr>
<tr><td>NEGC</td><td>Position 2</td></tr>
<tr><td>Patient samples</td><td>3 – nn (max. 24 per run)</td></tr>
</table></td><td>MB 3.01 Engineering Controls
MB 2.01 Safe Work Practices</td></tr>
<tr><td>Organizing run
Room 2</td><td>3</td><td>Using the RIP worksheet as a layout, organize patient specimens and labels
<table>
<tr><th>Step</th><th>Action</th></tr>
<tr><td>a</td><td>Color code worksheets and labels per run</td></tr>
<tr><td>b</td><td>Number patients on worksheet in consecutive order</td></tr>
<tr><td>c</td><td>Number corresponding patient labels according to assigned numbers on worksheet, color coded by run</td></tr>
<tr><td>d</td><td>Number each primary patient specimen according to worksheet</td></tr>
</table></td><td></td></tr>
<tr><td>Transfer NP swabs, nasal washes/aspirates</td><td>4</td><td>Number and label a 2.0 ml cryovial for each nasal wash/aspirate and NP swab specimen to be tested
<table>
<tr><th>Step</th><th>Action</th></tr>
<tr><td>a</td><td>Number cap of each cryovial according to assigned number on worksheet</td></tr>
<tr><td>b</td><td>Properly label the cryovial with patient bar-coded label matching the number on the cap to the number on the label</td></tr>
<tr><td>c</td><td>Vortex specimen in original container until well mixed</td></tr>
<tr><td>d</td><td>Verify number on primary and secondary container before transfer</td></tr>
<tr><td>e</td><td>Transfer specimen into cryovial with corresponding number on cap
▪ Only one tube can be open at a time</td></tr>
</table></td><td></td></tr>
<tr><td>Change gloves</td><td>5</td><td>Change gloves</td><td></td></tr>
</table>

PROCEDURE B: Follow the steps in the table below for setting up the computer

Computer set-up

<table>
<tr><th>Activity</th><th>Step</th><th>Action</th><th>Related Doc</th></tr>
<tr><td>Computer Set-up Room 3</td><td>1</td><td>Set up Simplexa; take run specific patient labels into room 3
<table>
<tr><th>Step</th><th>Prompt</th><th>Action/Entry</th></tr>
<tr><td>a</td><td>------</td><td>Turn on the Simplexa Integrated Cyclers (ABC)</td></tr>
<tr><td>b</td><td>------</td><td>Turn on the Simplexa computer</td></tr>
<tr><td>c</td><td>------</td><td>Log on computer</td></tr>
<tr><td>d</td><td>User name</td><td>administrator</td></tr>
<tr><td>e</td><td>Password</td><td>focusIC#1</td></tr>
<tr><td>f</td><td>-----</td><td>Double-click on Integrated Cycler DX icon to open program</td></tr>
<tr><td>g</td><td>User name</td><td>Enter personal user code</td></tr>
<tr><td>h</td><td>Password</td><td>Enter personal password code</td></tr>
<tr><td>i</td><td>Assay definition</td><td>From the main screen, scan the reagent lot barcode, small data matrix located on the lower left corner of the REF card</td></tr>
<tr><td>j</td><td>Disc ID</td><td>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
  </td></tr>
<tr><td>k</td><td>-----</td><td>Number available wedges according to worksheet layout</td></tr>
<tr><td>l</td><td>-----</td><td>Enter sample IDs: scan barcode ID from each label consecutively
▪ Type drop down box: : select Unknown (default)</td></tr>
<tr><td>m</td><td>-----</td><td>Enter controls according to layout
▪ POSC – select PC-FABR from the Type drop down box
▪ NEGC – select NTC from the Type drop down box</td></tr>
<tr><td>n</td><td>-----</td><td>Load DAD into instrument</td></tr>
<tr><td>o</td><td>-----</td><td>Select the instrument from the drop down box (lower right)</td></tr>
<tr><td>p</td><td>-----</td><td>Click Run to begin processing the disc
! Once run is started, it cannot be cancelled; canceling will require reloading new samples into unused wedges.
! Users cannot be changed while running</td></tr>
<tr><td>q</td><td>-----</td><td>Recycle labels when run is complete; do not take back to room 2</td></tr>
</table></td><td></td></tr>
<tr><td>New user</td><td>2</td><td>To switch users: Select File: Switch Users
Note: Change users before starting instrument(s)</td><td></td></tr>
<tr><td>Change PPE</td><td>3</td><td>Remove lab coat and change gloves before leaving area</td><td></td></tr>
</table>

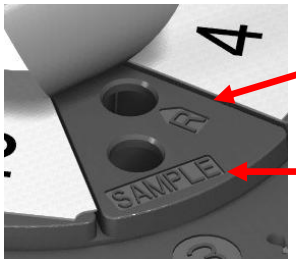
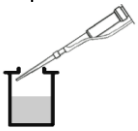
PROCEDURE C: Follow the steps in the table below for reagent handling

Reagent Handling

Activity	Step	Action	Related Doc
Room 1	1	Remove one MM tube for each sample to be tested from - 20° C freezer and thaw at room temperature ▪ *Use MM within 30 min*	MB 9.04 Reagent and Control Prep
	2	Remove lab coat; move the MM tubes to room 2	
Room 2	3	Remove POSC from -70° C freezer to thaw at room temperature	
	4	When thawed, gently flick POSC and MM tubes to mix; briefly centrifuge ▪ Do not vortex ▪ Do not refreeze	MB 9.03 Storage and Stability
	5	Proceed to PCR set-up	

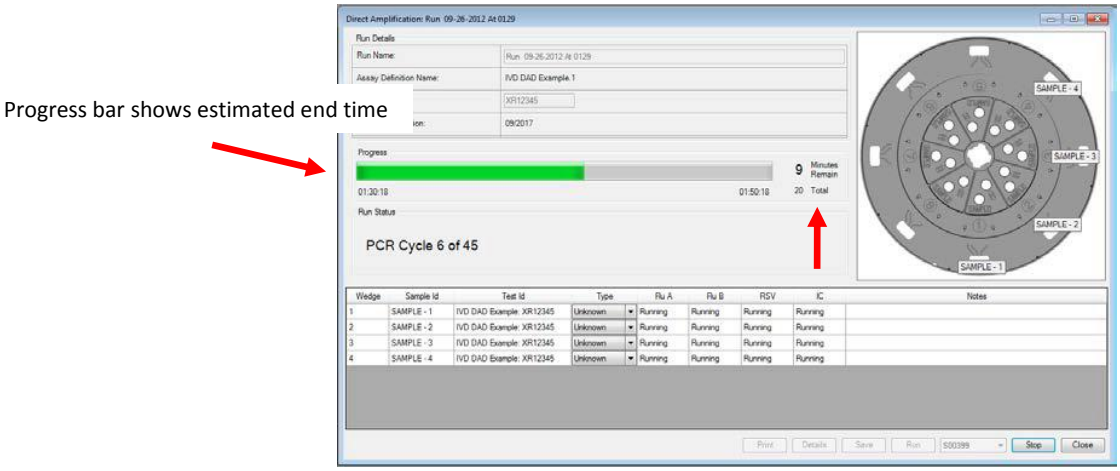
PROCEDURE D: Follow the steps in the table below for PCR set-up and amplification

PCR set-up and amplification

Activity	Step	Action	Related Doc
Vortex samples Room 2	1	Vortex specimen tubes prior to set-up if they have been sitting for more than 30 min	
	2	Remove DAD from package and set on disc cold block	
Load MM Room 2	3	Number wedges according to worksheet layout	Simplexa Operator's Manual IVD
	4	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 Figure 2:  Figure 3: 	
	5	Pipette 50 µl of MM into the Reaction (R) well first before sample *Tip* ▪ To prevent aerosols and possible contamination, hold the pipette at a 30-degree angle inserting the tip under the roof of the well to reduce possible contamination  ▪ *Caution:* Avoid placing pipette tip at the bottom of the well to prevent possible punctures in the foil that may lead to instrument contamination	

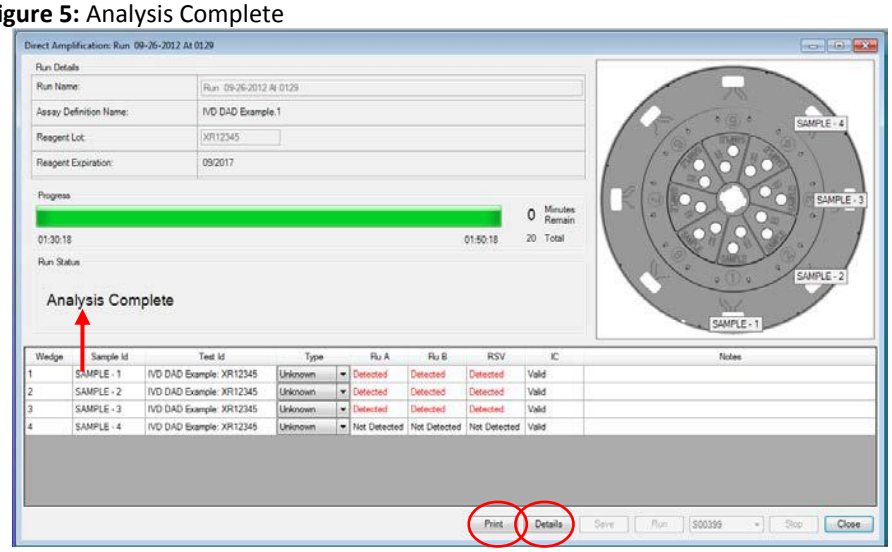
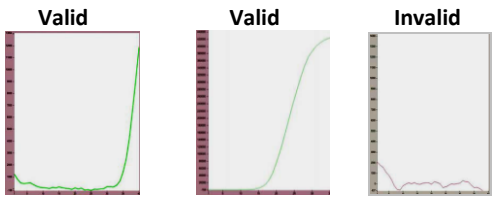
Activity	Step	Action	Related Doc
Load samples	6	Pipette 50 µl of sample/control into the SAMPLE well ▪ *Caution:* Pipette leakage outside of well may lead to external disc contamination when resealing wedge	
Seal disc remove tabs	7	Seal the foil wedge before opening the next foil cover	
	8	After all wedges are filled, carefully remove the perforated foil tab ▪ If foil is torn, it must be replaced with a replacement foil wedge to prevent carryover contamination	
Change gloves	9	Use the disc applicator to seal the foil firmly on all wedges 	
	10	Remove lab coat and change gloves	
	11	Move to room 3	
Room 3 **Start Run**	12	Place disc into the instrument; close lid	
	13	Select test instrument from drop down box	
	14	Start run	
Change PPE	15	Remove lab coat	
	16	Change gloves before leaving room 3	
Run time	17	Approximate run time: 1 h 15 min	
	18	On the screen, a progress bar indicates time to completion; refer to Fig. 4	
Run completion	19	When run is complete, remove disc from instrument; *check well volumes*	
	20	Place in bio-bag	
	21	If disc is completely used, discard in red biohazard container	
	22	If there are unused wedges, retain disc in a sealed bio-bag in room 2	

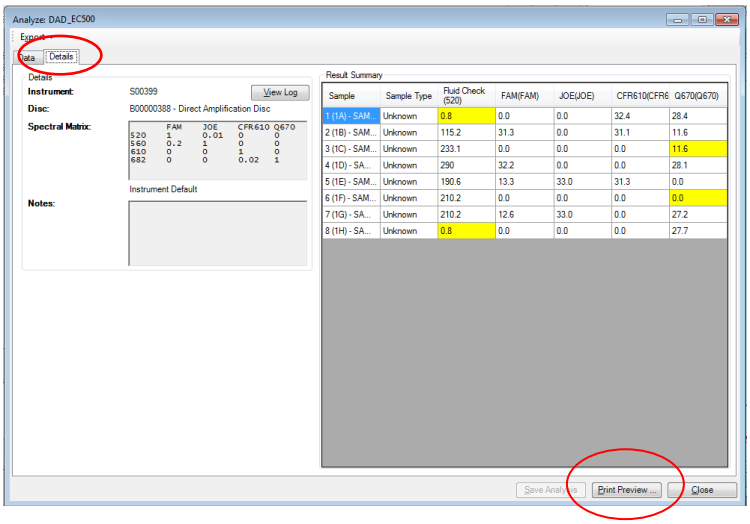
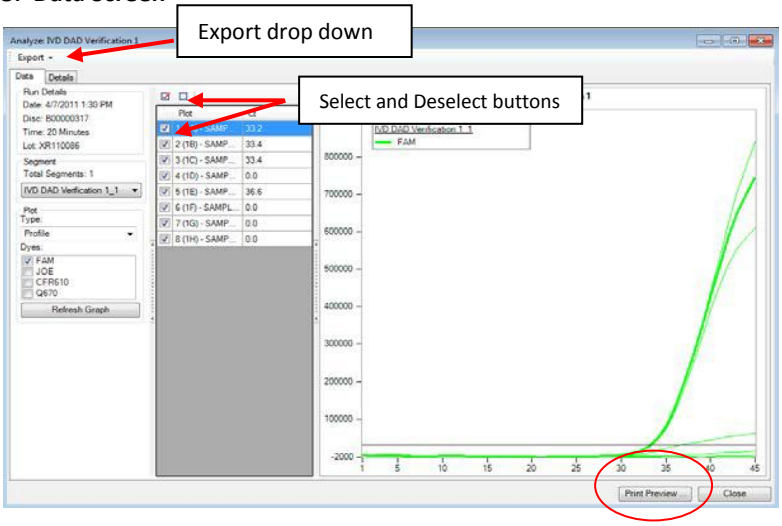
Figure 4: Progress in Real-Time



PROCEDURE E: Follow the steps in the table below for reviewing data and sample failures

Reviewing and printing Completed Runs

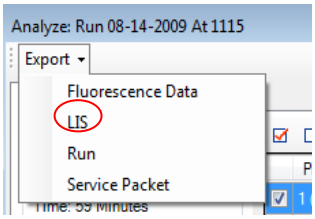
Activity	Step	Action	Related doc
Analysis Complete	1	When the run is complete**,** the results will display on the screen; positive results appear red **Figure 5:** Analysis Complete 	
Print **Review amplification curves**	2	Click the **Print** button to print a full report of the results, Fig. 5 | Step | Action | |---|---| | a | √ Include Ct values | | b | √ Include graphs | | c | Scroll through the report , reviewing comments, failures and amplification curves | | d | A valid curve shows a smooth, exponential increase, Fig. 6 | | E | Invalid curve may be linear or a curve with data “spikes” where the curve crosses the threshold | | f | Click **Print** | | g | Export results to LIS; refer to procedure F | **Figure 6:** Valid and invalid amplification curves 	
Detailed analysis	3	For a detailed analysis of the completed run, click the **Details** button to open the Analysis Window	

Activity	Step	Action	Related doc
Analyzing Runs ***Detail tab***	4	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 7**: Details Screen 	
Analyzing Runs ***Data tab***	5	Click **Data tab** to *Select* or *Deselect* samples to be exported to LIS ▪ Select or deselect samples to view graphs (optional); reviewed in Fig. 5 ▪ Select or deselect samples to export to LIS ▪ Export results to LIS; refer to procedure F **Figure 8: Data Screen** Export drop down Data / Detail tabs Select and Deselect buttons To view graphs by dye, click on the dye checkbox 	Refer to procedure G for evaluating QC and patient results Refer to procedure F for Exporting results to LIS

PROCEDURE F: Follow the steps in the table below for exporting data to LIS from the analysis screen

Exporting Data to LIS

Activity	Step	Action	Related Doc
	1	Confirm daily POSC and NEGC are valid before reporting patient results	

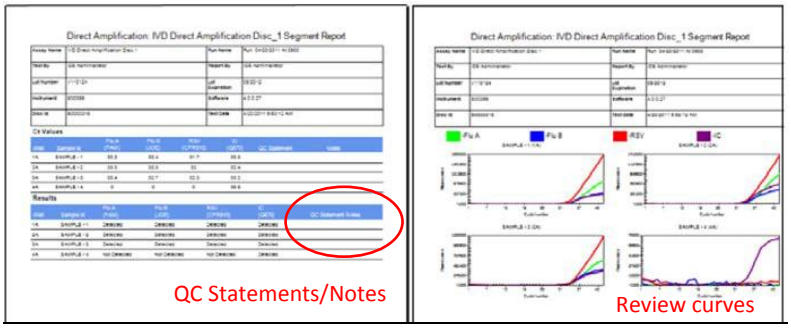
Activity	Step	Action	Related Doc
	2	Positive patient results: Confirm name, accession number and disc location of primary sample before releasing results	
Select data	3	If all test results were valid upon review, select √ results to be exported on the **Data** tab, refer to Fig.8	MB 9.07 Reporting and Archiving Results
	4	*Do not* send invalid patient results or POSC and NEGC. Deselect by clicking on individual box(es)	
Export	5	From the Export drop down box, select **LIS** and then **LIS folder;** click **OK** **Figure 9: Export to LIS** 	
	6	A message that the run exported successfully will appear. Click **OK**	

PROCEDURE G: Follow the activities below for evaluating QC and patient results

QC and Patient Results

Activity	Step	Action		Related doc
LIS interps	1	Patient results will be translated in LIS as *Positive* or *Negative* for Flu A, Flu B and/or RSV. If the sample is interpreted as "Invalid" by Simplexa, results will need to entered manually as *Equivocal* or *Unresolved* after review		MB 9.07 Resulting and Archiving Results
Review	2	Review patient and QC amplification curves before releasing results ▪ Check for exponential growth and data spikes ▪ Check for possible inhibition or low target signal ▪ Review "QC statement/Note" on the Segment Report for failures and error messages		
Simplexa software interps	3	QC and patient results are interpreted by the software		
		If	Then	
		Detected; LIS positive	Flu A, Flu B and /or RSV are present in the sample	
		Not Detected; LIS negative	Flu A, Flu B and /or RSV are absent in the sample	
		Invalid result	▪ Unable to determine the presence or absence of Flu A, Flu B and/ or RSV ▪ Possible IC failure ▪ Insufficient sample volume a. Retest sample with new mm from the same kit or from a new kit	
		EC500	Indicates a data quality error; weak or late amplification; repeat testing	

<table>
<tr><th>Activity</th><th>Step</th><th>Action</th><th>Related doc</th></tr>
<tr><td>QC conditions not met

Invalid assay</td><td>4</td><td>Failure indications will be highlighted in yellow on the Details tab, Fig. 7
<table>
<tr><th>Step</th><th>Action</th></tr>
<tr><td>a</td><td>Click the Print Preview button to review the “Data Quality message” and error code on the Segment report under QC Notes, Fig. 7</td></tr>
<tr><td>b</td><td>Review sample graph for amplification and Ct values</td></tr>
<tr><td>c</td><td>Refer to Troubleshooting Guide for additional information</td></tr>
<tr><td>d</td><td>Click the Print button to generate a report; place in molecular office review box</td></tr>
<tr><td>e</td><td>Record corrective action on QC and Equipment Failure Log</td></tr>
<tr><td>f</td><td>Record number of failed samples on Failed Run log and a brief explanation</td></tr>
</table>
Figure 10: Review
 
</td><td>Simplexa Operator's Manual IVD Appendix B: Troubleshooting

MB 9.06 Troubleshooting Guide</td></tr>
<tr><td></td><td>5</td><td>
<table>
<tr><th>If</th><th>Then</th></tr>
<tr><td>Valid assay: Controls as expected</td><td>▪ Report patient results</td></tr>
<tr><td>Invalid assay conditions:

POSC/ NEGC failure</td><td>▪ Do not report patient results; invalid run
▪ Failure caused by reagent or system failure
a. Review graphs for amplification
b. Notify technical director or designee for review
c. Repeat testing</td></tr>
<tr><td>NEGC positive</td><td>▪ Do not report patient results; invalid run
▪ Possible contamination of samples
a. Review graphs for amplification
b. Review the specimen handling/ preparation technique
c. Notify technical director or designee for review
d. Repeat testing</td></tr>
<tr><td>Internal Control failure</td><td>▪ Possible sample inhibition
a. F/T sample; avoid pipetting mucus
b. Quick spin if large amount of mucus present
c. Repeat testing
▪ IC did not amplify due to pipetting error
a. MM and sample reversed; placed in wrong wells</td></tr>
<tr><td>Problem unresolved</td><td>▪ Refer to Troubleshooting section of the Operator’s Manual and MB 9.06 Troubleshooting guide
a. Call DiaSorin/Focus technical service, 1-800-838-4548, option 3
b. Notify section technical director or designee</td></tr>
</table>
</td><td>Simplexa Operator's Manual IVD Appendix B: Troubleshooting

MB 9.06 Troubleshooting Guide</td></tr>
<tr><td>Problem Log</td><td>6</td><td colspan="2">Do not report patient results until problem is resolved</td></tr>
<tr><td></td><td>7</td><td colspan="2">Record problem and corrective action in the QC and Equipment Failure Log</td></tr>
</table>

PROCEDURE H: Follow the activities below for repeat testing

Repeat Testing

<table>
<tr><th>Activity</th><th>Step</th><th>Action</th><th>Related doc</th></tr>
<tr><td>Timeframe</td><td>1</td><td>Perform repeat testing from original specimen aliquot</td><td rowspan="3"></td></tr>
<tr><td></td><td>2</td><td>Repeat within 3 days if stored at 2 – 8° C</td></tr>
<tr><td>Vortex</td><td>3</td><td>Vortex the specimen tubes prior to retesting</td></tr>
<tr><td>Type of Failure</td><td>4</td><td>Review type of failure and any error messages containing the cause of the problem and possible solutions; refer to available troubleshooting guides for additional information
<table>
<tr><th>Failure</th><th>Action</th></tr>
<tr><td>System error</td><td>▪ Read error dialog box containing software messages regarding the cause of the problem and possible solutions
a. Review amplification curves for exponential growth
b. Follow recommended actions
c. Repeat run including a POSC/NEGC
d. Contact technical service if problem does not resolve</td></tr>
<tr><td>Reagent failure</td><td>a. Review proper storage conditions
b. Use MM within 30 min after thaw
c. MM subjected to 1 F/T only
d. Repeat testing</td></tr>
<tr><td>IC failure</td><td>▪ IC did not amplify due to sample inhibition
a. F/T sample; avoid pipetting mucus if present
b. Quick spin if large amount of mucus present
c. Repeat testing
d. If sample remains unresolved, call caregiver for new collection
▪ IC did not amplify due to pipetting error
b. MM and sample reversed; placed in wrong wells
c. Repeat testing</td></tr>
<tr><td>Insufficient volume</td><td>▪ Not enough sample reached the detection chamber for testing
a. Check sample for mucus
b. F/T or quick spin to remove mucus
c. Repeat testing</td></tr>
<tr><td>POSC failure</td><td>▪ Target not detected
a. System/reagent failure
b. Repeat run including POSC and NEGC; vortex patient samples prior to testing
c. Flick POSC to mix before repeat testing
d. If POSC fails on repeat, thaw new POSC
▪ Target and IC not detected
a. Review pipetting, possible sample and MM reversed
b. Repeat run including POSC and NEGC</td></tr>
<tr><td>NEGC</td><td>▪ NEGC contaminated
a. Repeat run including POSC and NEGC
b. Review patient graphs for low level contamination
c. Review specimen handling/processing technique
▪ IC not detected
a. System/reagent failure
b. Possible pipetting error, sample and MM reversed
c. Repeat run including POSC and NEGC</td></tr>
<tr><td>Failure unresolved</td><td>a. Call DiaSorin/Focus technical service
b. Notify section technical director or designee</td></tr>
</table></td><td>Simplexa Operator's Manual IVD Appendix B: Troubleshooting

MB 9.06 Troubleshooting Guide

MB 9.03 Storage and Stability

DiaSorin/Focus technical service, **1-800-838-4548, option 3**</td></tr>
</table>

PROCEDURE I: Follow the steps in the table below for Simplexa instrument shutdown in room 3

Computer and Instrument Shutdown

Activity	Step	Action
CBA	1	CBA: Shut down computer and then the analyzers when all runs are completed (Computer before analyzer)
	2	Click on the **Close** button or "X" out of the program
Shutdown menu	3	Click on the **Start** button (Windows icon)
	4	Next to **Restart**, click on ▶
	5	Select **Shutdown** from the drop down menu
CBA	6	After the computer has shutdown, turn off the analyzers
Clean	7	Decontaminate work area; refer to MB 9.08

PROCEDURE J: Follow the steps in the table below for storing test specimens

Storage and Retention of test specimens

Activity	Step	Action
Storage	1	Store test samples in -70° C freezer, shelf 4, for 3 - 6 mo.
	2	Write date range on cryo-storage box including month, day and year
Disposal	3	Discard samples after elapsed time in red biohazard container

METHOD PERFORMANCE

- Clinical Sensitivity/Specificity [2, 4]:
  1. Flu A: 97.1% / 97.9%
  2. Flu B: 100% / 99.9%
  3. RSV: 98.6% / 89.5%
- Analytical Sensitivity [2, 4]:
  1. Flu A: 0.1 – 0.05 $TCID_{50}$/ml
  2. Flu B: 1 – 20 $TCID_{50}$/ml
  3. RSV: 2 $TCID_{50}$/ml

ALTERNATE METHOD

1. Viral Respiratory Culture
2. Sunquest Order code: VRSP
3. Specimen container
   - 2 NP Swabs: BBL CultureSwab with Liquid Stuart's
   - Nasal wash/aspirate (0.5 – 1 ml): sterile screw top container
4. Logistics
   - Transport at RT or refrigerated
   - Laboratory: Transfer 1 ml of wash/aspirate into UTM or cut 2 NP swabs into UTM
   - Analytic time: 3 day
   - Testing : Daily

PROFICIENCY TESTING

- CAP ID3, 3 shipments per year, 5 challenges each

LIMITATIONS

- Results must be considered in conjunction with the clinical history, epidemiology data and other information available to the clinician evaluating the patient.
- If a novel influenza A is suspected based on clinical and epidemiological data, specimens should be collected and sent to Minnesota Dept. of Health for testing.
- This assay does not differentiate between influenza A subtypes, H1, H3 and 2009 H1.
- This assay does not differentiate between types RSV A and RSV B.
- Negative results do not rule out influenza A, influenza B or RSV.
- PCR detection of influenza A, influenza B or RSV does not distinguish between viable and non-viable organism.
- Test performance is not established for monitoring treatment for influenza A, influenza B or RSV
- False-negative results can occur if the viruses are below the level of the analytical sensitivity and if performed very early in the course of the illness.
- False-negative results may occur if the virus has genomic mutations, insertions, deletions or rearrangements
- Specimen integrity is dependent on the proper collection, transport, handling and storage of the specimen. Failure to meet set criteria can result in falsely negative results.
- When very high levels of influenza A are present with very low levels of RSV and influenza B, the signal from the RSV and FluB may not be detected due to competitive interference.
- False positive results can occur if proper handling and processing protocols are not followed.

REFERENCES

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Historical Record

Version	Written/Revised by:	Effective Date:	Summary of Revisions
1	P. Ackerman	11.30.2016	Initial Version