 Department of Microbiology Quality Manual	Policy # MI_MD_FLUAR	Page 1 of 30
	Version: 3.0 CURRENT	
Section: Molecular Diagnostics Procedures	Subject Title: Influenza A B and RSV PCR by Luminex Aries	
Prepared by QA Committee		
Issued by: Laboratory Manager	Revision Date: 2/6/2024	
Approved by Laboratory Director: Microbiologist-in-Chief	Next Review Date: 2/6/2026	

Uncontrolled When Printed

TABLE OF CONTENTS



Introduction	3
Specimen Collection, Transport & Storage	3
Materials, Equipment & Facilities	3
Safety Considerations	4
Procedure.....	4
Powering Up - Weekly	4
Logging In	5
Preparing Sample Cassettes	5
Entering Orders on the ARIES® System	7
Loading the Sample Cassette to Magazine	9
Inserting Magazine to Available Module	10
Saving Results	12
Saving Positive Files to LIS sample order:	12
Interpretation of Results.....	16
Invalid Results	17
Reporting	18
Negative Report:	18
Positive Report:	18
INDETERMINATE	20
INVALID	21
RESPIRATORY VIRUS TESTING REQUESTS	23

UNIVERSITY HEALTH NETWORK/MOUNT SINAI HOSPITAL, DEPARTMENT OF MICROBIOLOGY

*NOTE: This document is **Uncontrolled When Printed**.*

Any documents appearing in paper form that do not state "CONTROLLED COPY" in red print are not controlled and should be checked against the document (titled as above) on the server prior to use.

Management System\UHN_Mount Sinai Hospital Microbiology\Standard Operating Procedures\Molecular Diagnostics Procedures\

  Department of Microbiology Quality Manual	Policy # MI_MD_FLUAR	Page 2 of 30
	Version: 3.0 CURRENT	
Section: Molecular Diagnostics Procedures	Subject Title: Influenza A B and RSV PCR by Luminex Aries	

Quality Control..... 24

Troubleshooting..... 24

Maintenance 26

Daily Maintenance 26

Weekly Maintenance 26



References 26

Related Documents..... 26

Appendix I: Saving Positive files into an LIS Order..... 26

Record of Edited Revisions..... 28

*NOTE: This document is **Uncontrolled When Printed**.*
Any documents appearing in paper form that do not state "CONTROLLED COPY" in red print are not controlled and should be checked against the document (titled as above) on the server prior to use.
Management System\UHN_Mount Sinai Hospital Microbiology\Standard Operating Procedures\Molecular Diagnostics Procedures\

  Department of Microbiology Quality Manual	Policy # MI_MD_FLUAR	Page 3 of 30
	Version: 3.0 CURRENT	
Section: Molecular Diagnostics Procedures	Subject Title: Influenza A B and RSV PCR by Luminex Aries	

Introduction

The ARIES® Flu A/B & RSV Assay uses Luminex Corporation’s PCR chemistry in combination with the Luminex® ARIES System. The ARIES System is capable of automated nucleic acid extraction, purification, real-time PCR detection of nucleic acid sequences, and data analysis. The ARIES Flu A/B & RSV Assay can directly detect and differentiate three respiratory pathogens: influenza A virus (H1N1 including seasonal, pandemic 2009 (pdm09), H3N2 (seasonal and variant (H3N2v)), influenza B virus (Yamagata and Victoria), and respiratory syncytial virus (RSV-A and RSV-B) from nucleic acid in nasopharyngeal swab (NPS) specimens from patients with signs and symptoms of respiratory tract infection.

Specimen Collection, Transport & Storage

1. Nasopharyngeal swab (NPS) samples should be obtained by appropriately trained individuals and stored in appropriate Universal Transport Medium (UTM) and Bartels FlexTrans (FT) transport medium.
2. BAL are collected in a sterile container and should be spun prior to testing if viscous or bloody.
3. Sputum: Reject with statement stating: “Test not performed due to unsuitable specimen type. Please submit Nasopharyngeal (NP) Swab or Bronchoalveolar Lavage (BAL).”
4. ETT: Test, but add statement stating: “This specimen type has NOT been validated for this test. Please interpret results with caution.

If there will be a long delay before sample processing (greater than three days from the date of collection), samples should be frozen at -70°C or colder and transported on dry ice.

Samples can be stored refrigerated at 2°C to 8°C for up to three days from the date of collection.

If samples will be used after three days from the date of collection, store frozen at -70°C or colder. Store left - over samples at -70°C or colder.

Materials, Equipment & Facilities

ARIES® Flu A/B & RSV Assay (Part Number 50-10014) contains 24 assay cassettes.



The cassettes are shipped with cooling packs. Store at room temperature (15°C to 30°C) after receipt.

UNIVERSITY HEALTH NETWORK/MOUNT SINAI HOSPITAL, DEPARTMENT OF MICROBIOLOGY

*NOTE: This document is **Uncontrolled When Printed**.*

Any documents appearing in paper form that do not state "CONTROLLED COPY" in red print are not controlled and should be checked against the document (titled as above) on the server prior to use.

Management System\UHN_Mount Sinai Hospital Microbiology\Standard Operating Procedures\Molecular Diagnostics Procedures\

  Department of Microbiology Quality Manual	Policy # MI_MD_FLUAR	Page 4 of 30
	Version: 3.0 CURRENT	
Section: Molecular Diagnostics Procedures	Subject Title: Influenza A B and RSV PCR by Luminex Aries	

Always check the expiration date on the kit box and cassettes.

ARIES® Flu A/B & RSV Assay Protocol File Kit (Part Number CN-0327-01)

Assay protocol file provided on a USB (89-00010-00-327) and package insert (89-30000-00-490)

Luminex® ARIES® System and accessories

- System magazines
- Sample Prep Tray
- Hand-held barcode reader

Variable volume Rainin Pipette: 1000uL

Aerosol Resistant Tips (ART)

Powder free gloves

Biological Safety Cabinet

Vortex mixer

Safety Considerations

PPE required:

- *Lab coat*
- *Gloves*
- *Eye or face protection*



For further information, consult the Safety Data sheet.

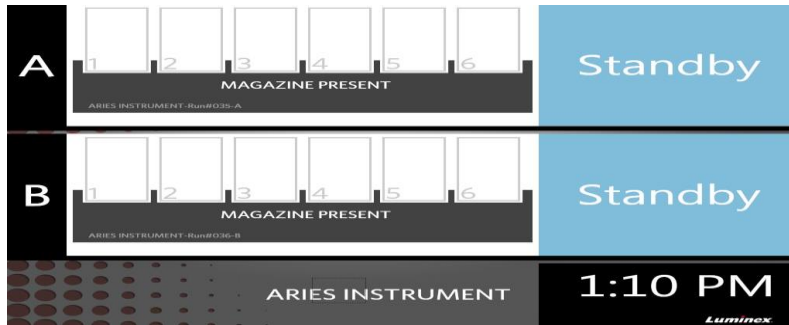
Procedure

Powering Up - Weekly

Push the power button (Do not hold) located at the front of the instrument. Powering up the ARIES System may take a few minutes.

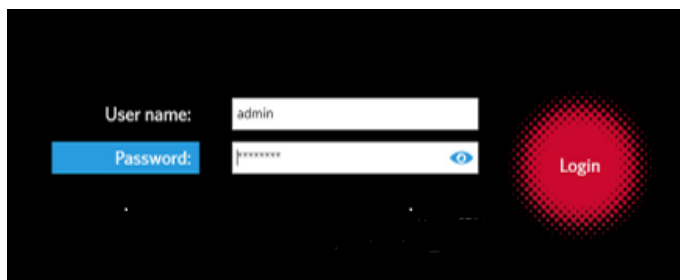
The ARIES™ status screen is the first screen that displays once the instrument is powered up which allows you to monitor your runs.

  Department of Microbiology Quality Manual	Policy # MI_MD_FLUAR	Page 5 of 30
	Version: 3.0 CURRENT	
Section: Molecular Diagnostics Procedures	Subject Title: Influenza A B and RSV PCR by Luminex Aries	



Logging In

Touch or click anywhere within the ARIES status screen.



User name : Admin

Password. : password

Preparing Sample Cassettes

Cautionary notes: Avoid creating aerosols. Use only ART tips. Change gloves frequently.

Dispose of waste properly, in sealed discard bags. Avoid cross contamination.

Do not wear gloves when using the keyboards, barcode reader and ARIES® touch screen


1. Place the sample tube in the Sample Prep Tray.
2. Remove the assay cassette from its packaging and visually inspect the cassette for any damage. If the cassette(s) appears damaged in any way or if you see any leaks, **DO NOT USE THE CASSETTE.**
3. Close the cassette cap to seal the cassette sample chamber.
4. Attach the small sample barcode on the side of the cassette.

UNIVERSITY HEALTH NETWORK/MOUNT SINAI HOSPITAL, DEPARTMENT OF MICROBIOLOGY

*NOTE: This document is **Uncontrolled When Printed.***

Any documents appearing in paper form that do not state "CONTROLLED COPY" in red print are not controlled and should be checked against the document (titled as above) on the server prior to use.

Management System\UHN_Mount Sinai Hospital Microbiology\Standard Operating Procedures\Molecular Diagnostics Procedures\

 Department of Microbiology Quality Manual	Policy # MI_MD_FLUAR	Page 6 of 30
	Version: 3.0 CURRENT	
Section: Molecular Diagnostics Procedures	Subject Title: Influenza A B and RSV PCR by Luminex Aries	

- Pull the tab to remove the foil seal on the back of the cassette. Use caution when pulling the back seal off the cassettes. **The foil is sharp and may cause injury.** Ensure all foil and plastic is removed from the cassette.



- Place the cassette in the Sample Prep Tray next to the sample.



NOTE: Set-up one sample at a time.



- Vortex the primary sample for 5 to 10 seconds to homogenize the mixture.
- Open the cassette cap to access the cassette sample chamber.
- Using an 1000ul pipettor and aerosol barrier pipette tip, aspirate 200 μ L of sample from the sample tube. Place the sample in the cassette sample chamber by inserting the pipette tip near the bottom of the chamber before expelling the sample.
Ensure that the correct amounts of sample are used.
- Close the cassette cap to seal the cassette sample chamber. Failure to ensure the cassette fully closed may cause a delay or failure in results and expose the user to biohazards.

UNIVERSITY HEALTH NETWORK/MOUNT SINAI HOSPITAL, DEPARTMENT OF MICROBIOLOGY

*NOTE: This document is **Uncontrolled When Printed**.*

Any documents appearing in paper form that do not state "CONTROLLED COPY" in red print are not controlled and should be checked against the document (titled as above) on the server prior to use.

Management System\UHN_Mount Sinai Hospital Microbiology\Standard Operating Procedures\Molecular Diagnostics Procedures\

  Department of Microbiology Quality Manual	Policy # MI_MD_FLUAR	Page 7 of 30
	Version: 3.0 CURRENT	
Section: Molecular Diagnostics Procedures	Subject Title: Influenza A B and RSV PCR by Luminex Aries	

Entering Orders on the ARIES® System


1. From System Navigation menu display,

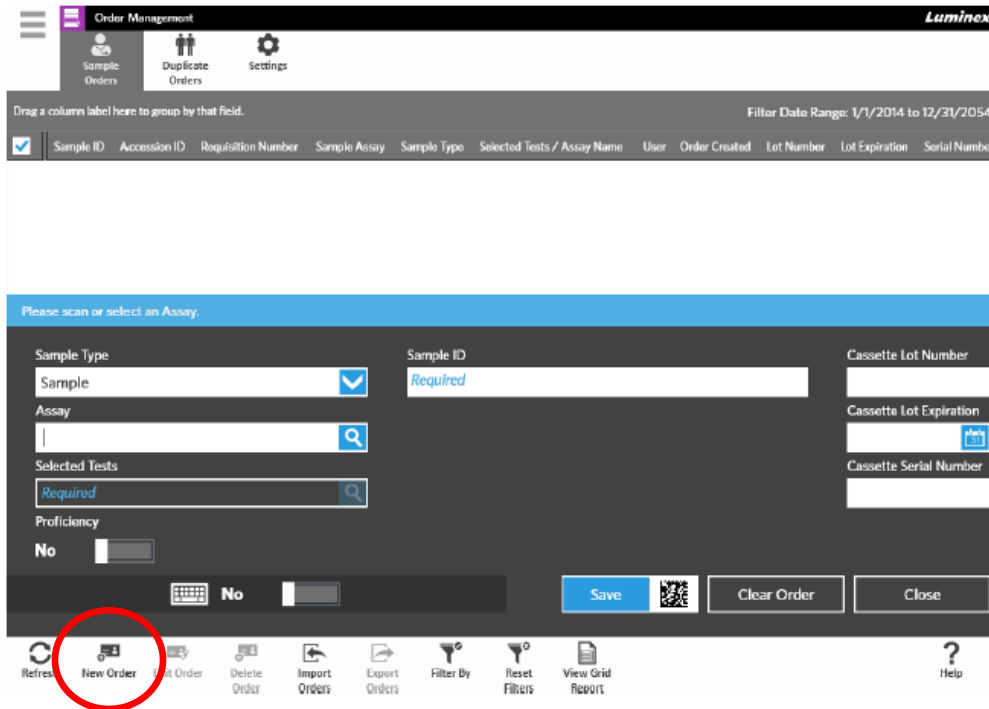



Select  in the upper left-hand corner of the touch screen



2. Choose  **Order Management**


 Department of Microbiology Quality Manual	Policy # MI_MD_FLUAR	Page 8 of 30
	Version: 3.0 CURRENT	
Section: Molecular Diagnostics Procedures	Subject Title: Influenza A B and RSV PCR by Luminex Aries	




3. Choose  second icon at the bottom of screen to display the New Order dialog box
4. Scan the matrix barcode of assay (ARIES Flu A/B & RSV) found on top or side of the cassette.(Cassette Lot Number, Lot Expiration and Serial Number) with the hand-held barcode reader.
5. Scan the sample barcode (Sample ID) with the hand-held barcode reader.

The required sample information can also be entered manually by selecting any field on the New Order dialog box. A touch screen keyboard or a drop-down menu displays.

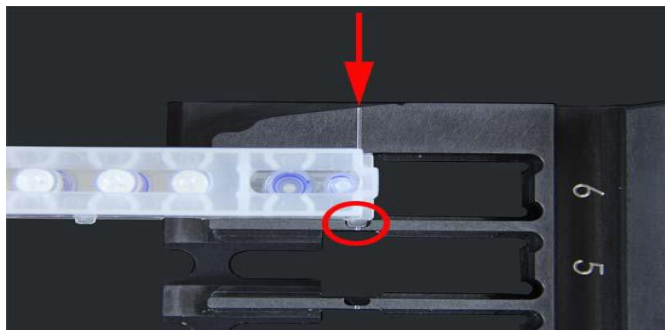
NOTE : When entering sample information manually , never touch keyboard 123 because it will shrink the screen. (If the screen is missing, it's possible to attach a keyboard into it to return the touchscreen keyboard back on (press new order)

 Department of Microbiology Quality Manual	Policy # MI_MD_FLUAR	Page 9 of 30
	Version: 3.0 CURRENT	
Section: Molecular Diagnostics Procedures	Subject Title: Influenza A B and RSV PCR by Luminex Aries	

6. Scan the Data matrix barcode on the screen next to Save  with the hand-held barcode reader or manually select Save.

Loading the Sample Cassette to Magazine

1. Ensure that the correct amount of sample is present in sample chamber.
Failure to add sample will result in a FALSE NEGATIVE result.
2. Place the cassette into the magazine by lining the cassette up with the first notch (there is a tab on the cassette that fits into the notch). The PCR tube must face towards the numbers on the magazine.





3. Gently insert the cassette down into the magazine.
4. Gently slide the cassette all the way back towards the numbers. Repeat for all other cassettes



Do not use your index finger to push the cassette into the magazine. You may indirectly dispense the reagent. Luminex recommends using the palm of your hand to slide the cassette into proper position.

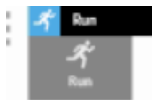
UNIVERSITY HEALTH NETWORK/MOUNT SINAI HOSPITAL, DEPARTMENT OF MICROBIOLOGY

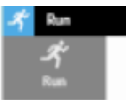
  Department of Microbiology Quality Manual	Policy # MI_MD_FLUAR	Page 10 of 30
	Version: 3.0 CURRENT	
Section: Molecular Diagnostics Procedures	Subject Title: Influenza A B and RSV PCR by Luminex Aries	

Inserting Magazine to Available Module


AUTORUN : ONCE THE MAGAZINE HAS BEEN INSERTED THE RUN WILL START AUTOMATICALLY

Once the magazines are pushed in, the switch of the module is activated and the analyzer initiates automatically. And the magazine cannot be pulled out until the testing is completed. **DO NOT attempt to pull out the magazine from the module once they were pushed into place.**



1. Select  in the upper left-hand corner of the touch screen. The System Navigation menu displays.
2. Change the run name to “yyyymmddyourinitialsrun” number example 20170217zz1
 - a. **IMPORTANT:** Please do NOT use special characters, spaces, or upper-case letters for the run name.




3. Align and insert the magazine into the ARIES®System module
4. Choose  Status to display the status of the magazine(s), their estimated time to completion.

UNIVERSITY HEALTH NETWORK/MOUNT SINAI HOSPITAL, DEPARTMENT OF MICROBIOLOGY

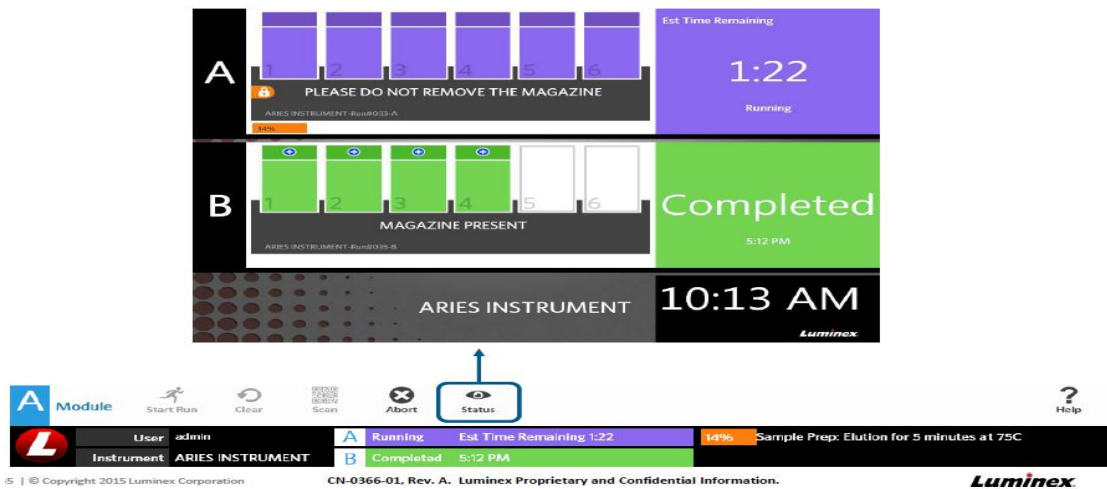
*NOTE: This document is **Uncontrolled When Printed.***

Any documents appearing in paper form that do not state "CONTROLLED COPY" in red print are not controlled and should be checked against the document (titled as above) on the server prior to use.


Management System\UHN_Mount Sinai Hospital Microbiology\Standard Operating Procedures\Molecular Diagnostics Procedures\

 Department of Microbiology Quality Manual	Policy # MI_MD_FLUAR	Page 11 of 30
	Version: 3.0 CURRENT	
Section: Molecular Diagnostics Procedures	Subject Title: Influenza A B and RSV PCR by Luminex Aries	

Status Screen



The Run page includes visual indicators such as a status bar, an estimated time to completion indicator, and a Run Complete notification once the run has completed.

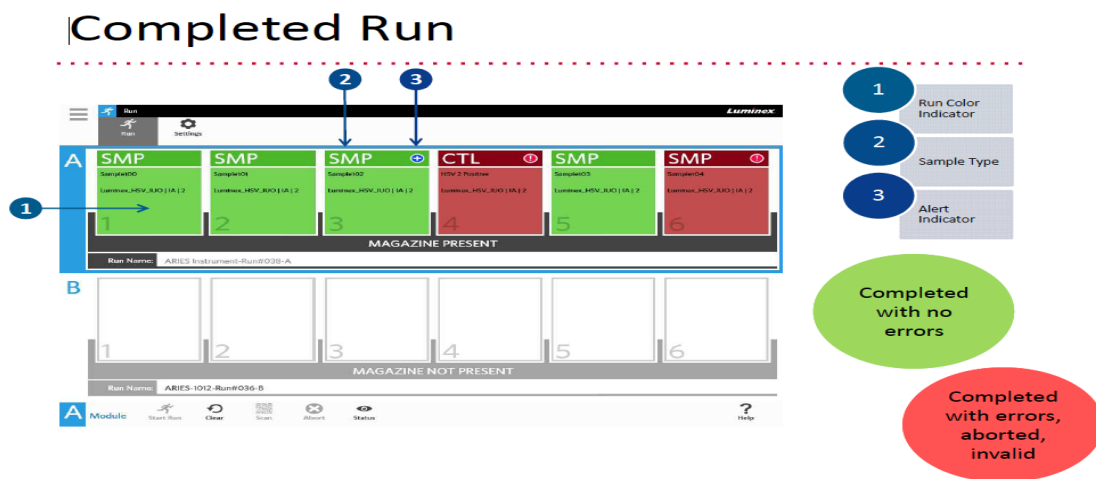
 Department of Microbiology Quality Manual	Policy # MI_MD_FLUAR	Page 12 of 30
	Version: 3.0 CURRENT	
Section: Molecular Diagnostics Procedures	Subject Title: Influenza A B and RSV PCR by Luminex Aries	

Saving Results

The **detailed** report and the individual **summary** report are auto exported to the “1 Aries folder in the T Drive.

Save the positive detailed report from the TDrive/1Aries into the LIS sample order.

See [troubleshooting section](#) if results fail to export.




Saving Positive Files to LIS sample order:

1. Open the positive specimen in order entry
2. Click on the soft media Icon
3. In the soft media window, choose the tab “Add file”.
4. Click on the file icon and to the following file location:
T Drive /Microbiology/Virology /1Aries
5. Paste the Order number in Search Window
6. Click the Detailed Report , Click Open
7. Click green Check Mark
8. Click Okay and save order.

Should results need to be printed from the Aries instrument itself:

1. From System Navigation menu display,

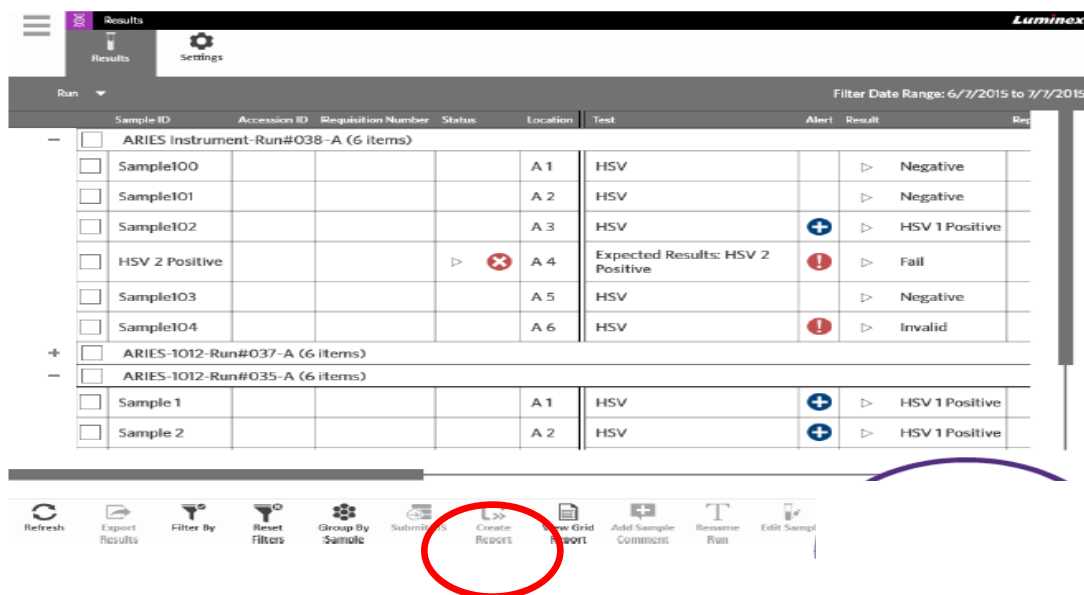


Select  in the upper left-hand corner of the touch screen

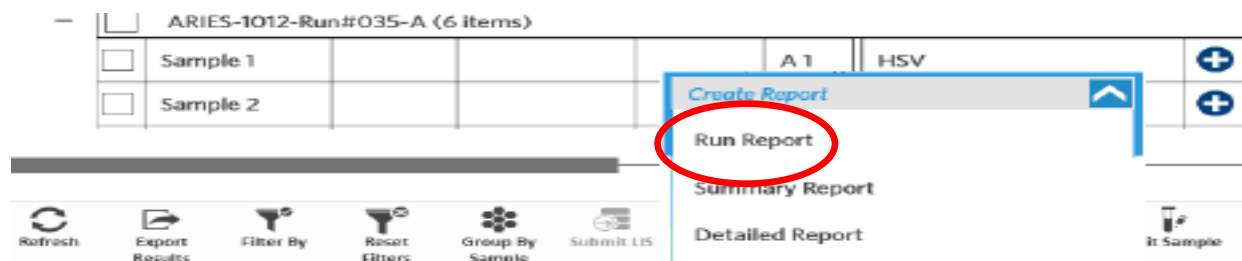
2. Choose



3. Select the completed run and report to be printed



****Report icon grays out if no report was selected**





UNIVERSITY HEALTH NETWORK/MOUNT SINAI HOSPITAL, DEPARTMENT OF MICROBIOLOGY

NOTE: This document is *Uncontrolled When Printed*.

Any documents appearing in paper form that do not state "CONTROLLED COPY" in red print are not controlled and should be checked against the document (titled as above) on the server prior to use.

Management System\UHN_Mount Sinai Hospital Microbiology\Standard Operating Procedures\Molecular Diagnostics Procedures\

  Department of Microbiology Quality Manual	Policy # MI_MD_FLUAR	Page 14 of 30
	Version: 3.0 CURRENT	
Section: Molecular Diagnostics Procedures	Subject Title: Influenza A B and RSV PCR by Luminex Aries	


4. Choose Create Report
5. Choose Run Report

Run Report displays the run results for all samples in the run and any comments or logs associated with that run.

FOR POSITIVE RESULTS Choose “Detailed Report”

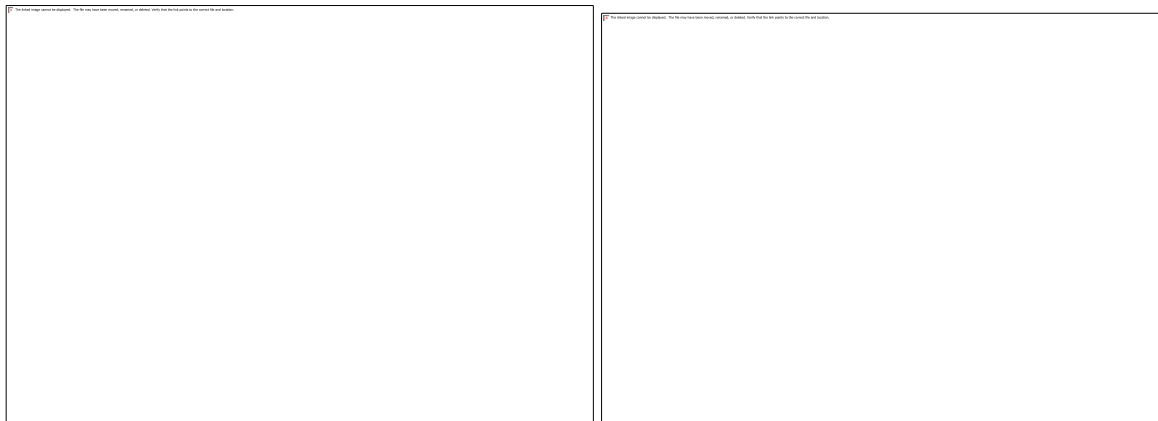
Detailed Report displays all information for one individual sample, the Amplification and Melt Graphs, and any comments or logs associated with that sample



6. Once the report opens, choose  to print the report
7. Close

At the end of every run

- Remove the magazine from Aries.
- Remove the cassette from magazine by sliding it back and up. Do not remove the PCR tube. NEVER SOAK the magazines.
- There should be no visible wetness, the plugs should be depressed (actuated), and the PCR tube should have wax on the top of the eluate.





- Discard the cassette in biohazard bag.
- Soak the Sample Prep Tray after every use in 10 % bleach bath for 10 minutes. Rinse with DI water and dry

UNIVERSITY HEALTH NETWORK/MOUNT SINAI HOSPITAL, DEPARTMENT OF MICROBIOLOGY

*NOTE: This document is **Uncontrolled When Printed**.*

Any documents appearing in paper form that do not state "CONTROLLED COPY" in red print are not controlled and should be checked against the document (titled as above) on the server prior to use.

Management System\UHN_Mount Sinai Hospital Microbiology\Standard Operating Procedures\Molecular Diagnostics Procedures\

  <p>Department of Microbiology</p> <p>Quality Manual</p>	<p>Policy # MI_MD_FLUAR</p>	<p>Page 15 of 30</p>
<p>Section: Molecular Diagnostics Procedures</p>	<p>Version: 3.0 CURRENT</p> <p>Subject Title: Influenza A B and RSV PCR by Luminex Aries</p>	

UNIVERSITY HEALTH NETWORK/MOUNT SINAI HOSPITAL, DEPARTMENT OF MICROBIOLOGY

*NOTE: This document is **Uncontrolled When Printed**.*

Any documents appearing in paper form that do not state "CONTROLLED COPY" in red print are not controlled and should be checked against the document (titled as above) on the server prior to use.

Management System\UHN_Mount Sinai Hospital Microbiology\Standard Operating Procedures\Molecular Diagnostics Procedures\


Interpretation of Results

Example	SPC		Influenza A		Influenza B		RSV		Interpretation
	Tm Value	Ct Value	Tm Value	Ct Value ¹	Tm Value	Ct Value ¹	Tm Value	Ct Value ¹	
1	+	N/A	+	+	+/-	-/N/A	+/-	-/N/A	Influenza A POSITIVE ^{1,2,3} Influenza B Negative RSV Negative
2	+	N/A	+/-	-/N/A	+	+	+/-	-/N/A	Influenza A Negative Influenza B POSITIVE ^{1,2,3} RSV Negative
3	+	N/A	+/-	-/N/A	+/-	-/N/A	+	+	Influenza A Negative Influenza B Negative RSV POSITIVE ³
4	+	N/A	+	+	+/-	-/N/A	+	+	Influenza A POSITIVE ^{1,2,3} Influenza B Negative RSV POSITIVE, ³
5	+	N/A	+/-	-/N/A	+	+	+	+	Influenza A Negative Influenza B POSITIVE ^{1,3} RSV POSITIVE, ³
6	+	+	+/-	-/N/A	+/-	-/N/A	+/-	-/N/A	Influenza A Negative Influenza B Negative RSV Negative

¹ Any positive results with a **CT \geq 38.6** (greater or equal to) for **influenza A, B and RSV** should be interpreted as **NEGATIVE**

² Any positive result with a **Ct 38.0 to 38.5**. for **influenza A, B and RSV** should be interpreted as **INDETERMINATE**.

³ Consult with Senior/Charge for any Positive results with unusual observations seen with the amplification and melt curve.

 Department of Microbiology Quality Manual	Policy # MI_MD_FLUAR	Page 17 of 30
	Version: 3.0 CURRENT	
Section: Molecular Diagnostics Procedures		Subject Title: Influenza A B and RSV PCR by Luminex Aries

Invalid Results



Example	SPC		Influenza A		Influenza B		RSV		Interpretation
	Tm Value	Ct Value	Tm Value	Ct Value 1	Tm Value	Ct Value 1	Tm Value	Ct Value 1	
72	+	N/A	+/-	+/-/^ N/A	+/-	+/-/^ N/A	+/-	+/-/^ N/A	INVALID
83	+	-/^	+/-	-/N/A	+/-	-/N/A	+/-	-/N/A	INVALID
9	-	+	N/A	N/A	N/A	N/A	N/A	N/A	INVALID

¹If a TM value is “=” then the associated Ct is “N/A” (not available)

²An invalid result will occur when no Ct value is detected (^) for a pathogen, or combination of pathogens, the SPC Ct will be N/A

³An invalid result will occur when all pathogens are negative and the SPC Ct value does not meet acceptance criteria (-), or no Ct value is detected (^)

	Legend
SPC	Sample Processing Control
Ct Value	Amplification cycle cross point
Tm	Melting Temperature
+	Value meets acceptance criteria
-	Value does not meet acceptance criteria
^	No Ct value is detected
/	Or

  Department of Microbiology Quality Manual	Policy # MI_MD_FLUAR	Page 18 of 30
	Version: 3.0 CURRENT	
Section: Molecular Diagnostics Procedures	Subject Title: Influenza A B and RSV PCR by Luminex Aries	

Reporting

Negative Report:

In the Respiratory Viral Detection test comment:

Comment: }ARI-

“Negative for Influenza A,B and Respiratory syncytial virus (RSV) by ARIES Flu A/B and RSV Assay, Luminex Corporation.”

In the media PCABR date tested (F6) is added.

All negative reports are autofinalized, check to see if result is in the LIS.

RESPIRATORY VIRUS TESTING REQUESTS: For negative samples requesting further respiratory virus testing, see [Respiratory Virus Testing Requests](#) resulting section.



Positive Report:

Positive results are automatically downloaded from the ARIES instrument as an isolate. The positive results go to the Virology Worklist/1 VPRP (Resp. PCR Positive). These results must be verified and finalized after checking the ct. Save positive reports into each respective LIS order by following Appendix I.

Exceptions:

- Any positive **Flu A, B or RSV** results with a **CT \geq 38.6** report as **NEGATIVE**.
- Any positive result with a **Ct 38.0 to 38.5** for **influenza A, B or RSV** should be interpreted and resulted as an **INDETERMINATE** isolate.

Report as a numbered Isolate in the isolate window

  Department of Microbiology Quality Manual	Policy # MI_MD_FLUAR	Page 19 of 30
	Version: 3.0 CURRENT	
Section: Molecular Diagnostics Procedures	Subject Title: Influenza A B and RSV PCR by Luminex Aries	

Influenza A Positive *

- A. For all influenza A positive results from **ICU** or those requested by **IPAC** for subtyping should be send to PHOL for Flu A subtyping:

Select: \AR+S

“DETECTED,

by ARIES Flu A/B and RSV Assay, Luminex Corporation

This sample has been forwarded to PHLO.

(Public Health Laboratory Ontario) for subtyping.

Results to follow.”

Add date to media PHL when sample is sent to PHL.

- B. All non-ICU influenza A positive without requests for typing:

Select: \ARI+

“DETECTED,



by ARIES Flu A/B and RSV Assay, Luminex Corporation

All positive Reports should be finalized by reporting technologist.

Phone all positive results to ward / physician, and notify Infection Control Practitioner as per "[Isolate Notification and Freezing Table QPCMI16003](#)"

Notify Medical Officer of Health (MOH) for Influenza A, and Influenza B.

***All Influenza A isolates should be forwarded to Toronto Public Health (PHL) for subtyping.**

  Department of Microbiology Quality Manual	Policy # MI_MD_FLUAR	Page 20 of 30
	Version: 3.0 CURRENT	
Section: Molecular Diagnostics Procedures	Subject Title: Influenza A B and RSV PCR by Luminex Aries	

Use instant report MIC10 to print a PHL requisition. Affix a TIBDN Flu A subtyping label under test requested. Make a 0.5mL aliquot to send out. Keep samples and PHL requisition in order and package for send out at the end of the shift.

RESPIRATORY VIRUS REQUESTS: Samples testing positive in house for a respiratory virus will not be sent out for any further respiratory testing at PHOL. For positive samples requesting further respiratory virus testing, other than flu subtyping, under test “Respiratory viral detection referred out” select keypad option }REFV and finalize test.

Influenza B and RSV Positive. Select: \ARI+ ARIES

“DETECTED,
by ARIES Flu A/B and RSV Assay, Luminex Corporation”

All positive Reports should be finalized by reporting technologist.

Phone all positive results to ward/physician, and notify Infection Control Practitioner as per "[Isolate Notification and Freezing Table QPCMI16003](#)"

Notify Medical Officer of Health (MOH) for Influenza A, and Influenza B.

RESPIRATORY VIRUS REQUESTS: Samples testing positive in house for a respiratory virus will not be sent out for any further respiratory testing at PHOL. For positive samples requesting further respiratory virus testing, under test “Respiratory viral detection referred out” select keypad option }REFV and finalize test.

INDETERMINATE

Indeterminate results are positive results with a Ct range of 38.0-38.5.

Results are automatically downloaded from the ARIES instrument as an isolate.



Indeterminate report:

UNIVERSITY HEALTH NETWORK/MOUNT SINAI HOSPITAL, DEPARTMENT OF MICROBIOLOGY

*NOTE: This document is **Uncontrolled When Printed**.*

Any documents appearing in paper form that do not state "CONTROLLED COPY" in red print are not controlled and should be checked against the document (titled as above) on the server prior to use.

Management System\UHN_Mount Sinai Hospital Microbiology\Standard Operating Procedures\Molecular Diagnostics Procedures\

  Department of Microbiology Quality Manual	Policy # MI_MD_FLUAR	Page 21 of 30
	Version: 3.0 CURRENT	
Section: Molecular Diagnostics Procedures	Subject Title: Influenza A B and RSV PCR by Luminex Aries	

Report as a numbered Isolate in the isolate window.

- Updated the isolate comment from DETECTED to INDETERMINATE

Select: **INDa Ind ARIES**

“An indeterminate result may be due to a very low level of virus or non-specific cross-reactivity. Results should be interpreted within the context of the clinical signs, symptoms, and history of the patient.”

All reports should be finalized by reporting technologist.

Phone **all Indeterminate** results to ward / physician, and notify Infection Control Practitioner as per "[Isolate Notification and Freezing Table QPCMI16003](#)"

INVALID

An invalid result is due to the sample processing control not amplifying. This is most likely due to inhibition. Dilute the specimen 1:5 and repeat the test, if still INVALID, report as Invalid as a TEST comment.

Invalid Report:



Select: }ARiv

“Invalid for Influenza A,B and Respiratory syncytial virus (RSV) by ARIES Flu A/B and RSV Assay, Luminex Corporation.

(Likely due to specimen integrity, unable to obtain valid test result after repeated attempts”

All invalid reports should be finalized by reporting technologist.

Phone all Invalid results to ward.



  <p>Department of Microbiology</p> <p>Quality Manual</p>	<p>Policy # MI_MD_FLUAR</p>	<p>Page 22 of 30</p>
<p>Section: Molecular Diagnostics Procedures</p>	<p>Version: 3.0 CURRENT</p> <p>Subject Title: Influenza A B and RSV PCR by Luminex Aries</p>	

UNIVERSITY HEALTH NETWORK/MOUNT SINAI HOSPITAL, DEPARTMENT OF MICROBIOLOGY

*NOTE: This document is **Uncontrolled When Printed**.*

Any documents appearing in paper form that do not state "CONTROLLED COPY" in red print are not controlled and should be checked against the document (titled as above) on the server prior to use.

Management System\UHN_Mount Sinai Hospital Microbiology\Standard Operating Procedures\Molecular Diagnostics Procedures\

  Department of Microbiology Quality Manual	Policy # MI_MD_FLUAR	Page 23 of 30
	Version: 3.0 CURRENT	
Section: Molecular Diagnostics Procedures	Subject Title: Influenza A B and RSV PCR by Luminex Aries	

RESPIRATORY VIRUS TESTING REQUESTS

Use the PHOL “Respiratory Virus testing” algorithm found in the “Test Information” section of the [Respiratory Virus Test Information](#) page to determine if specimen will be tested at PHOL.

A. For specimens testing *positive* in house:

Samples testing positive in house for a respiratory virus will not be sent out for any further respiratory testing at PHOL. For positive samples requesting further respiratory virus testing, under test “Respiratory viral detection referred out” select keypad option }REFV and finalize test.

B. For specimens *not* meeting PHOL Respiratory Virus Testing requirements:

Under test “Respiratory viral detection referred out” select keypad option }NOMX and finalize test result.

“Public Health Ontario (PHO) has updated the Respiratory Viral Testing Algorithm and this sample does not currently qualify for Referred Out Multiplex Respiratory Viral PCR (MRVP) testing. Please contact the Virology Lab with any questions at (416)-586-4800 extension 4182. Influenza A/B & RSV PCR testing is performed in-house year round.”

C. For specimen applicable for PHOL Respiratory Virus Testing:



Under test “Respiratory viral detection referred out” select keypad option }PHLV. Enter the current Respiratory Virus test method performed by PHOL in the comment. Enter a date in the media as the day sent to PHOL and interim test. Print a PHOL requisition using instant report MIC10. Document the requested test on the PHOL requisition and label “Negative for Influenza A,B and Respiratory syncytial virus (RSV)” under test requested on the requisition. Package 0.5mL of samples with the requisition to be sent to PHOL.

UNIVERSITY HEALTH NETWORK/MOUNT SINAI HOSPITAL, DEPARTMENT OF MICROBIOLOGY

*NOTE: This document is **Uncontrolled When Printed**.*

Any documents appearing in paper form that do not state "CONTROLLED COPY" in red print are not controlled and should be checked against the document (titled as above) on the server prior to use.

Management System\UHN_Mount Sinai Hospital Microbiology\Standard Operating Procedures\Molecular Diagnostics Procedures\

  Department of Microbiology Quality Manual	Policy # MI_MD_FLUAR	Page 24 of 30
	Version: 3.0 CURRENT	
Section: Molecular Diagnostics Procedures	Subject Title: Influenza A B and RSV PCR by Luminex Aries	

Quality Control

All In-house External control materials: FluA, FluB, and RSV should be run with each new lot or shipment on each instrument.

Report all failed QC to senior/ charge technologist

- Do not release results pending resolution of QC failure.
- Inform charge/senior technologist.
- Record in Reagent Log Chart, Instrument Maintenance Log or Incident Report where appropriate.
- If the QC failure was due to a simple matter of position reversal or misplacement, the run can be released (positive QC material yielded positive result, negative yielded negative result).

Troubleshooting

For any unusual results or equipment problems, report to Seniors or Charge Technologist.

Common troubleshooting:



Issue	Solution
Result not exporting	Results should immediately export to LIS upon completion. If results are not in LIS after 5 minutes post completion the report can be manually submitted: At the Aries instrument: <ul style="list-style-type: none"> • Choose “Results” (top left drop down menu bar) • Select the run • Choose “submit to LIS” from the bottom menu
Lost Connection to K:drive / T:drive	Upon restarting the ARIES, the connection to the K:drive for auto-reporting and T:drive for exporting Run result may need to be re-connected: From the main screen

UNIVERSITY HEALTH NETWORK/MOUNT SINAI HOSPITAL, DEPARTMENT OF MICROBIOLOGY

*NOTE: This document is **Uncontrolled When Printed**.*

Any documents appearing in paper form that do not state "CONTROLLED COPY" in red print are not controlled and should be checked against the document (titled as above) on the server prior to use.

Management System\UHN_Mount Sinai Hospital Microbiology\Standard Operating Procedures\Molecular Diagnostics Procedures\

  Department of Microbiology Quality Manual	Policy # MI_MD_FLUAR	Page 25 of 30
	Version: 3.0 CURRENT	
Section: Molecular Diagnostics Procedures	Subject Title: Influenza A B and RSV PCR by Luminex Aries	



	<ul style="list-style-type: none"> • Select the Menu icon • Administration • Settings • Network Drives <p>If both the K drive and T drive appear, both drives are successfully connected. If a red “X” appears over the icon, select the drive icon and choose “Reconnect Drive”. If the “X” disappears the connection was successful. If not call LIS for troubleshooting support.</p>
--	---

Technical Support Contact Information:

Telephone: 512-381-4397

North America Toll Free: 1-877-785-2323

Email: support@luminexcorp.com

  Department of Microbiology Quality Manual	Policy # MI_MD_FLUAR	Page 26 of 30
	Version: 3.0 CURRENT	
Section: Molecular Diagnostics Procedures	Subject Title: Influenza A B and RSV PCR by Luminex Aries	

Maintenance

Daily Maintenance

End of day Cleaning:

- Wipe down the magazines, touch screen, barcode reader, keyboards and mouse with RNase Away, then DI water and 70% alcohol. NEVER SOAK the magazines.
- Clean Biological Safety Cabinet (BSC) by wiping surfaces with a 1% working solution hypo chloride (made daily), followed by wiping surfaces with 70% alcohol.
- Clean pipette with slightly dampened Kimwipe with a 1% working solution hypo chloride, followed by slightly dampened KimWipe with 70% alcohol.
- Discard biohazard boxes.

Weekly Maintenance

Reboot the instrument with magazines inserted by turning it off using the power button at the front of the instrument. Start up time approximately 5 minutes.

Backup and Archive Procedure

Refer to SARS-CoV-2 Virus PCR by Luminex Aries

References

Luminex Kit Package Insert/RUO Aries ® FLU A/B & RSV
 Luminex Aries ® End User Training , Luminex Learning CN-0366-01
 Operational Manual/ RUO ARIES System

Related Documents

[Virology Accessioning Manual](#)

Appendix I: Saving Positive files into an LIS Order

Positive files are saved in the T:drive and can be imported to and LIS order for review.


To save a file:

UNIVERSITY HEALTH NETWORK/MOUNT SINAI HOSPITAL, DEPARTMENT OF MICROBIOLOGY



*NOTE: This document is **Uncontrolled When Printed**.*

Any documents appearing in paper form that do not state "CONTROLLED COPY" in red print are not controlled and should be checked against the document (titled as above) on the server prior to use.

Management System\UHN_Mount Sinai Hospital Microbiology\Standard Operating Procedures\Molecular Diagnostics Procedures\

 Department of Microbiology Quality Manual	Policy # MI_MD_FLUAR	Page 27 of 30
	Version: 3.0 CURRENT	
Section: Molecular Diagnostics Procedures	Subject Title: Influenza A B and RSV PCR by Luminex Aries	

1. Open the sample in SoftMIC
2. Click on the Soft Media
3. In the Soft Media screen, select “Add file” from the left hand tabs
4. Click on the Folder icon
5. Select file location: T:drive/Microbiology/Virology/1Aries
6. Paste the Order number in search window
7. Choose the Detailed Report, click open
8. Click the green check mark in the soft media screen to load the file.
9. Click Yes. Save LIS order.

  Department of Microbiology Quality Manual	Policy # MI_MD_FLUAR	Page 28 of 30
	Version: 3.0 CURRENT	
Section: Molecular Diagnostics Procedures	Subject Title: Influenza A B and RSV PCR by Luminex Aries	

Record of Edited Revisions

Manual Section Name: Influenza A/B & RSV PCR by Luminex Aries


Page Number / Item	Date of Revision	Signature of Approval
Added note in interpretation of results on all positive targets: ¹ Any positive results with a CT \geq 27 for influenza A, B or RSV should be interpreted as INDETERMINATE	September 7, 2016	Dr. T. Mazzulli
Updated to CT to \geq 38 should be interpreted as NEGATIVE Added in reporting section resulting for Invalid results Removed section for Indeterminate results.	September 8, 2016	Dr. T. Mazzulli
Footnote to interpretation table added: “Any positive results with a CT 35.00-37.99 or unusual observations consult Senior/Charge showing amplification & melt curve. When senior/Charge is not available, evaluate curves, current Flu/RSV prevalence, previous history to report a positive or negative and leave report for checking in the morning. “ In Reporting section, for positive results added general exceptions section.	October 11, 2016	Dr. T. Mazzulli
Annual Review Interpretation tables footnotes removed and updated with only one exception for Flu A/B POSITIVE with CT \geq 38.6 report as NEGATIVE. Updated reporting positive results section with only exception for Flu A/B POSITIVE with CT \geq 38.6 report as NEGATIVE.	January 18, 2017	Dr. T. Mazzulli

UNIVERSITY HEALTH NETWORK/MOUNT SINAI HOSPITAL, DEPARTMENT OF MICROBIOLOGY

*NOTE: This document is **Uncontrolled When Printed**.*

Any documents appearing in paper form that do not state "CONTROLLED COPY" in red print are not controlled and should be checked against the document (titled as above) on the server prior to use.

Management System\UHN_Mount Sinai Hospital Microbiology\Standard Operating Procedures\Molecular Diagnostics Procedures\

 Department of Microbiology Quality Manual	Policy # MI_MD_FLUAR	Page 29 of 30
	Version: 3.0 CURRENT	
Section: Molecular Diagnostics Procedures	Subject Title: Influenza A B and RSV PCR by Luminex Aries	

Page Number / Item	Date of Revision	Signature of Approval
Updated login ID/password Created Troubleshooting section Invalids, modified dilution from 1:10 to 1:5 Added to interpretation table and results, flu A,B Interderminate CT 38.0-38.5. Added reporting section for Indeterminate samples. Added autoverification of negative results and translation of positive results to verify. Removed exception to interim for Para/Meta requests from PMH - these are no longer resulted with the Flu test.	August 17, 2017	Dr. T. Mazzulli
Annual Review Add step in end of run procedure to inspection of cartridge including images. (p.13) Update resulting section: <ul style="list-style-type: none"> • Flu A subtyping only for MSH adult in-patients • Multiplex resulting updated to Respiratory Virus testing resulting with link to PHOL algorithm • Additional comment for respiratory virus testing requests not meeting PHOL testing algorithm added • Updated notifications required to ward and IC for Invalid and Indeterminate results 	January 24, 2018	Dr. T. Mazzulli
p.11 Saving results section: addition of instruction to save Aries reports in LIS	March 28, 2018	Dr. T. Mazzulli
Annual Review Updated Indeterminate reporting criteria.	December 31, 2018	Dr. T. Mazzulli

Full document review included in all updates. Bi-annual review conducted when no revision had been made within 2 years.



Page Number / Item	Date of Revision	Edited by:
--------------------	------------------	------------

UNIVERSITY HEALTH NETWORK/MOUNT SINAI HOSPITAL, DEPARTMENT OF MICROBIOLOGY

*NOTE: This document is **Uncontrolled When Printed**.*

Any documents appearing in paper form that do not state "CONTROLLED COPY" in red print are not controlled and should be checked against the document (titled as above) on the server prior to use.

Management System\UHN_Mount Sinai Hospital Microbiology\Standard Operating Procedures\Molecular Diagnostics Procedures\

  Department of Microbiology Quality Manual	Policy # MI_MD_FLUAR	Page 30 of 30
	Version: 3.0 CURRENT	
Section: Molecular Diagnostics Procedures	Subject Title: Influenza A B and RSV PCR by Luminex Aries	

Page Number / Item	Date of Revision	Edited by:
Updated run name format: added note	Nov 30, 2020	Dorna Zareianjahromi
Minor formatting change	April 11, 2021	Jessica Bourke
Updated Inserting Magazine to Available Module	May 18, 2021	Oliver Li
Refer to Sarscov2 aries procedure for backup/archive	Aug 30, 2021	Wayne Chiu
Clarified the test of “Respiratory Viral detection referred out” is for further respiratory virus testing “other than flu subtyping” needed for in-house positive samples	Oct 11, 2022	Qin Liu
Added Bartels FT transport media as an approved media type	Nov 04, 2022	Qin Liu
Added Sputum and ETT instructions	Nov 7, 2022	Wayne Chiu
1. Added the Ct cut-off values for RSV reporting” <ul style="list-style-type: none"> • Ct ≥ 38.6: Negative • Ct = [38, 38.5]: Indeterminate • Ct < 38: Positive 2. Updated RSV Reporting	Jul 13, 2023	Qin Liu
<ul style="list-style-type: none"> • Added Safety considerations (pg4) • Deleted Flu A positive report for non-MSH inpatient (pg24) • Update Flu A positive report for all sites(pg 24) • Updated to send all flu A samples to PHOL for subtyping 	July 18, 2023	Qin Liu
Page 19 – Updated for influenza A positive samples from ICU or those specifically requested by IPAC should be sent to PHLO to typing. All other samples should not and reported with standard Aries reporting phrase only.	January 30, 2024	Jessica Bourke