# Resulting and Archiving *RSV & Influenza A/B* Results

**PURPOSE**

This procedure provides instructions for resulting and filing *RSV & Influenza A/B* results in LIS.

**POLICY STATEMENT**

* Results will be available within 24 h; refer to the [Laboratory Services](https://www.childrensmn.org/Manuals/Lab/Chapters.asp?account=MicroBioViral) web page

**ABBREVIATIONS**

|  |  |
| --- | --- |
| * ASR: analyte-specific reagent
* ABC : Analyzer Before Computer
* BSC: BioSafety Cabinet
* BSL: BioSafety level
* CBA: Computer Before Analyzer
* Ct : crossing threshold
* DAD : Direct Amplification Disc
* FDA: US Food and Drug Administration
* 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 roomArea/Room 2: Processing roomArea/Room 3: Amplification room |

## DOCUMENTATION/RECORDS

* Simplexa Flu A/B & RSV Direct Segment Report - run-specific
* LIS Incomplete worksheets, Instrument reports
* Pending Log
* Daily Maintenance Log

**PROCEDURE A:** Follow the activities below for reporting and archiving patient results

**Reporting Patient Results**

| **Activity** | **Step** | Action |
| --- | --- | --- |
| **Export results** | 1 | Export patient test results from the *Simplexa* instrument to LIS; see MB 6.05 *procedure H* |
| Computer Entry | 2 | Enter results in Sunquest Result Entry

|  |  |  |
| --- | --- | --- |
| Step | Prompt | Action/Entry |
| a | ------ | Click on the Sunquest icon to log on |
| b | User | CExxxxxx |
| c | Password | xxxxxxx |
| d | Location | **R** |
| e | ----- | Click **OK** |

 |
|  | 3 | Select Result Entry from Menu options  |  |
| **SIM** | 4 | **Figure 1:** Interface Configuration:Select **SIM** from  drop down box |  |
|  | 5 | Click on the  button located in the lower left corner  |
| **SIM** | 6 | If the page says “Waiting for cups….”, the results were not successfully transmitted or the results page was accessed too quickly before the transmission was completed |
| **STYP code or missing code****Review Messages** | 7 | STYP codes: This specimen was grayed out and not checked for release because there was a problem with the specimen type code.**Figure 2:** Review messages located on the top and results  |
| SmarTerm | 8 | ***Solution:*** STYP codes can be corrected in *Sunquest Order Entry* or *SmarTerm MEM*

|  |  |  |
| --- | --- | --- |
| Step | Prompt | Action/Entry |
| a | ------ | Fixing specimen type codes in SmarTerm |
| b | FUNCTION | MEM |
| c | WORKSHEET | **NA** : Do not enter for manual entry without calculations |
| d | TEST | RIP |
| e | ACCEPT | A |
| f | ACC. NO. | * Enter accession number and missing code: F66931
* Replacing STYP code: M-F66931 (M for modify)
 |
| g | SAS | Replace existing code or enter missing code for specimen source |  |

 |
| Duplicate results | 9 | **Figure 3:** If a run is exported more than once, uncheck the duplicate results and release the checked  results |
|  | 10 | Click  button located on the lower left corner  |
|  | 11 | Figure 4: Duplicate Specimens  |  |
|  | 12 | Click Release All  |
|  | 13 | Figure 5: Verify Release to Lab; click Accept  |  |
|  |  | If | Then |
| **No Problems** | 14 | * Specimen box reads *Preprocessing passed* with no further messages
* Test box has no messages
* Sample results are acceptable
 | Click Save and then Accept (Fig. 5) |
|  | 15 | When applicable (30 day QC or new lot/shipment), record control results from RIP Segment Report on the appropriate worksheet |
| **Archive** | 16 | Staple worksheet containing specimen identifiers used during testing and RIP Segment Report together |
|  | 17 | Place report in the *RSV & Influenza* result log book |

**PROCEDURE B:** Follow the activities below for result manual entry in function MEM

**Manual entry in function MEM for unresolved and diluted specimens.**

| **Activity** | **Step** | Action |
| --- | --- | --- |
|  | 1 | If a specimen has failed the cup criteria (Fig. 2) and results do not display, enter results in function MEM  |
| **Manual Entry**SmarTerm | 2 |

|  |  |  |
| --- | --- | --- |
| Step | Prompt | Action/Entry |
| a | ------ | Manual entry in SmarTerm |
| b | FUNCTION | MEM |
| c | WORKSHEET | N/A: Do not enter for manual entry without calculations |
| d | TEST | RIP |
| e | ACCEPT | A |
| f | ACC. NO. | F66931 |
| g | SAS | NW |
| h | FAPCR | NEG-MFDA |
| i | FBPCR | NEG-MFDA |
| j | RSVR | POS-MFDA |
| l. | ACCEPT | A |

 |

**Table 1: Sunquest Result Codes**

| **Result** | **Sunquest code** | **Interpretation** |
| --- | --- | --- |
| **Positive** | **POS-MFDA**Interface | 1. Positive
2. Modified FDA approved test: The performance characteristics of this test have been determined by Children’s Hospitals and Clinics of MN
 |
| **Negative** | **NEG-MFDA**Interface | 1. Negative
2. Modified FDA approved test: The performance characteristics of this test have been determined by Children’s Hospitals and Clinics of MN
 |
| **Positive results via dilution** | **POS-DILUT-MFDA**Function MEMWorksheet: **NA**Test: RIP | 1. Positive
2. Sample diluted due to inhibition. Please consider submission of a new sample if clinical suspicion is high.
3. Modified FDA approved test: The performance characteristics of this test have been determined by Children’s Hospitals and Clinics of MN
 |
| **Negative results via dilution** | **NEG-DILUT-MFDA**Function MEMWorksheet: **NA**Test: RIP | 1. Negative
2. Sample diluted due to inhibition. Please consider submission of a new sample if clinical suspicion is high.
3. Modified FDA approved test: The performance characteristics of this test have been determined by Children’s Hospitals and Clinics of MN
 |
| **Unresolved Results** | **UNR-MFDA**Function MEMWorksheet: **NA**Test: RIP | 1. Unresolved: This sample is inhibitory to amplification and the results are inconclusive. Consider repeat collection if clinically indicated.
2. Modified FDA approved test: The performance characteristics of this test have been determined by Children’s Hospitals and Clinics of MN
3. Phoned Result  [Free text name]
 |
| **Corrected report** | Function MEMWorksheet: **NA**Test: RIP | 1. Modify results in function MEM by typing M followed by a hyphen: **M-T54966**
2. Enter correct numerical result FAPCR, FBPCR, and RSVR field(s). Computer will interpret and automatically put in a correction statement
3. Phoned Result  [Free text name]
 |

**PROCEDURE F:** Follow the activities below for modifying results in SmarTerm Function MEM

**Corrected Report**

| **Activity** | **Step** | Action |
| --- | --- | --- |
| **Manual Entry****Modifying results**SmarTerm | 1 | Corrected report: Changing data and interpretation

|  |  |  |
| --- | --- | --- |
| Step | Prompt | Action/Entry |
| a | ----- | Manual entry in SmarTerm |
| b | FUNCTION | MEM |
| c | WORKSHEET | N/A: Do not enter for manual entry without calculations |
| d | TEST | RIP |
| e | ACCEPT | A |
| f | ACC. NO. | M – F66931 |
| g | SAS | NW |
| h | FAPCR | NEG-MFDA – enter correct result below previous value**POS-MFDA** *Correction statement will automatically default* |
| i | FBPCR | POS-MFDA |
| j. | RSVR | NEG-MFDA |
| k. | ---- | Click  |
| l. | NAME | Enter name, last initial and credential |
| m. | ---- | Click OK, date and time stamp will default |
| n. | ACCEPT | A |

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**REFERENCES**

1. Laboratory for Windows User’s Guide, UD-1599/00-12-GL, Sunquest Information Systems
2. CAP Microbiology Checklist, Section Department: Molecular Diagnostics, MIC.64988, 04.21.2014, College of American pathologists, 325 Waukegan Rd, Northfield, IL 60093

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| **Historical Record** |  |
|  | **Version** | **Written/Revised by:** | **Effective Date:** | **Summary of Revisions** |
| 1 | Michelle Merryman, Julie Laramie | 03.11.2018 | Initial Version |
|  | 2 | J. Laramie | 04.01.2018 | Revised to reflect IQCP implementation – QC testing every 30 days and with new lot/shipment.  |