# 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 room  Area/Room 2: Processing room  Area/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; clickAccept | | |  | | |
|  |  | 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 MEM  Worksheet: **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 MEM  Worksheet: **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 MEM  Worksheet: **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 MEM  Worksheet: **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 | |

**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. |