

RAPID INFLUENZA AND RSV BY PCR

Invalid Results work up and Internal control
validity

Process improvement project
By: Mariam Imsaiah

SIMPLEXA™

- The Simplexa™ Flu A/B & RSV direct assay is a real-time RT-PCR system that enables the direct amplification, detection, and differentiation of human influenza A (Flu A), human influenza B (Flu B) and RSV viral RNA from unprocessed nasopharyngeal swabs that have not undergone nucleic acid extraction.

RESULTS

- For each sample ID entered, software displays a result of “Detected”, “Not Detected”, “invalid”, “EC500”, or “EC505” for each analyte.

DETECTED/NOT DETECTED

Direct Amplification: Simplexa Flu A_B & RSV Direct _1 Segment Report

Assay Name	Simplexa Flu A_B & RSV Direct .5	Run Name	Run 02-25-2017 At 0457 KSK D
Test By	Beaumont Royal Oak	Report By	Beaumont Royal Oak
Lot Number	33533	Lot Expiration	01/2018
Instrument	Donald Duck - 100308	Software	6.0.0.2
Disc Id	B00403413	Test Date	2/25/2017 5:13:10 AM

Ct Values

Wedge	Sample Id	Sample Type	Flu A (FAM)	Flu B (JOE)	RSV (CFR610)	RNA IC (Q670)	QC Statement/Notes
3	742502080	Unknown	0	30.1	0	29.1	
4	742502875	Unknown	0	0	25.5	30	
5	742501089	Unknown	0	0	0	29.3	
6	742502870	Unknown	0	0	0	29.1	
7	742501003	Unknown	0	0	0	30.1	
8	742503071	Unknown	36.2	0	0	30.3	

Results

Wedge	Sample Id	Sample Type	Flu A (FAM)	Flu B (JOE)	RSV (CFR610)	RNA IC (Q670)	QC Statement/Notes
3	742502080	Unknown	Not Detected	Detected	Not Detected	Valid	
4	742502875	Unknown	Not Detected	Not Detected	Detected	Valid	
5	742501089	Unknown	Not Detected	Not Detected	Not Detected	Valid	
6	742502870	Unknown	Not Detected	Not Detected	Not Detected	Valid	
7	742501003	Unknown	Not Detected	Not Detected	Not Detected	Valid	
8	742503071	Unknown	Detected	Not Detected	Not Detected	Valid	

ERROR CODES (EC500, EC505, INVALID)

Direct Amplification: Simplexa Flu A_B & RSV Direct _1 Segment Report

Assay Name	Simplexa Flu A_B & RSV Direct .5	Run Name	Run 04-09-2017 At 0906 w A
Test By	RO Virology	Report By	RO Virology
Lot Number	33819	Lot Expiration	02/2018
Instrument	Aladdin - 100396	Software	6.0.0.2
Disc Id	B00426148	Test Date	4/9/2017 9:09:55 AM

Ct Values

Wedge	Sample Id	Sample Type	Flu A (FAM)	Flu B (JOE)	RSV (CFR610)	RNA IC (Q670)	QC Statement/Notes
5	760810872	Unknown	0	14.2	0	29.2	Flu B:EC500 - Data Quality
6	760903294	Unknown	0	0	0	28.1	

Results

Wedge	Sample Id	Sample Type	Flu A (FAM)	Flu B (JOE)	RSV (CFR610)	RNA IC (Q670)	QC Statement/Notes
5	760810872	Unknown	Not Detected	EC500	Not Detected	Valid	Flu B:EC500 - Data Quality
6	760903294	Unknown	Not Detected	Not Detected	Not Detected	Valid	

EC500, EC505, INVALID

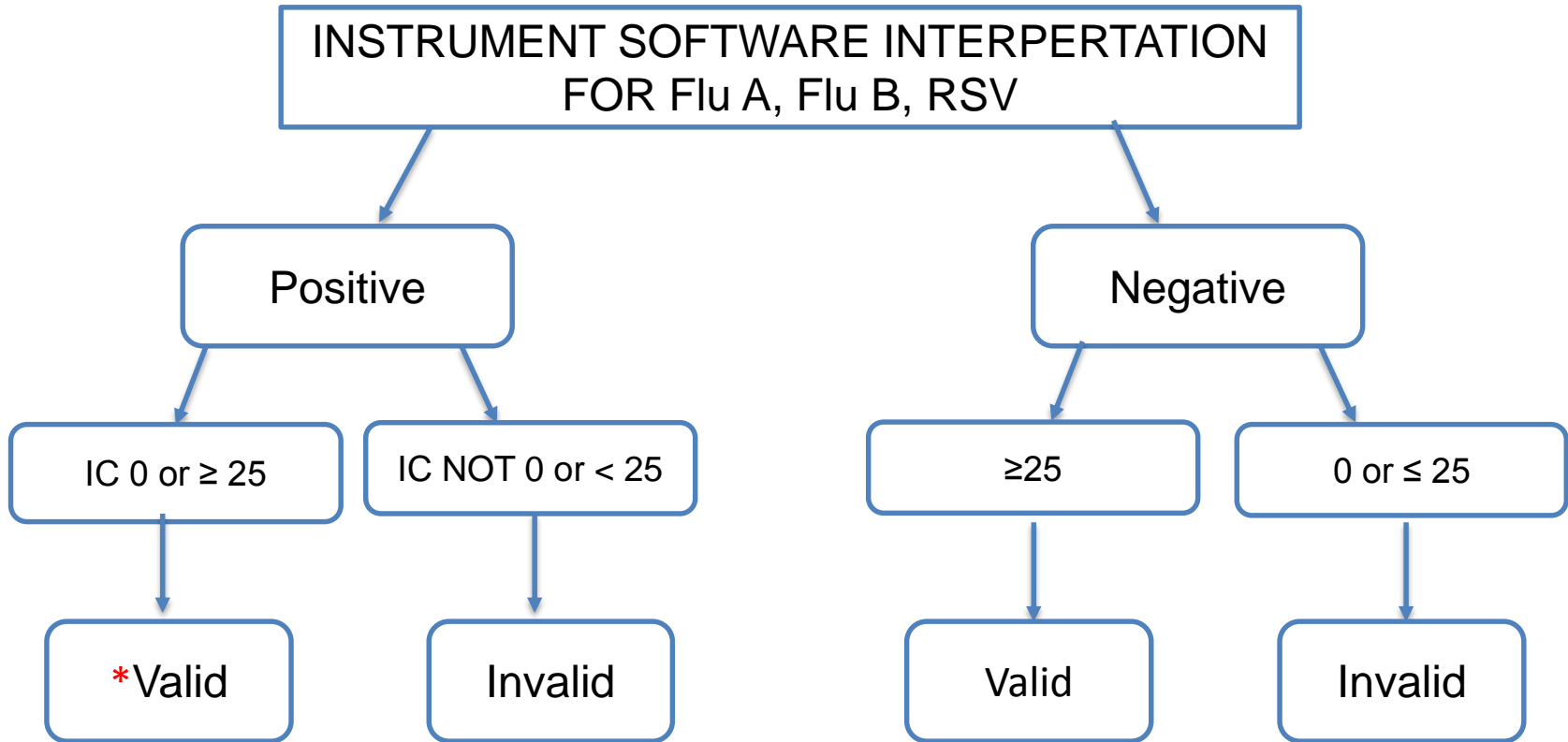


Invalid result resolution protocol



- a. Centrifuge (2500 x g for 10-15 min) the original viral transport media specimen (no need to remove swab if present).
- b. After centrifugation, transfer 300 µL of the supernatant (do not disturb the cellular pellet) into an appropriately labeled microcentrifuge tube.
- c. Perform a freeze-thaw cycle:
 - i. Place microcentrifuge tube in a freezer (-70oC x 10-15 min).
 - ii. Remove microcentrifuge tube and allow it to thaw.
 - iii. Use 50 µL for the Simplexa Rapid Influenza and RSV by PCR test.
 - iv. If the problem is unresolved, result the affected target as indeterminate.
- v. Notify the Medical/Technical Director and notify ordering physician.**

VALID VS INVALID INTERNAL CONTROL RESULTS



*Internal control can be 0 due to the positive specimen that used up all of the reagent. **0 IC is valid for positive results.**

Examples of Valid Internal Control

Scenario	Flu A Result	Flu B Result	RSV Result	IC Result
	0	0	0	35
	15	0	0	38
	0	25	0	0
	0	0	14	0

Examples of Invalid Internal Control

Scenario	Flu A result	Flu B result	RSV result	IC result
	15	0	0	20
	0	20	0	17
	0	0	17	14

NOW THAT YOU HAVE COMPLETED THE POWER
POINT, PLEASE TAKE THE QUIZ