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Virology Proficiency Testing Program

Restricted Category Direct Antigen Detection

May 2016

Summary of scores, responses, and statistics for Respiratory syncytial virus, and Influenza virus A & B

Disclaimer The use of brand and/or trade names in this summary does not constitute an endorsement of the products on the part of the Wadsworth Center or the New York State Department of Health

The New York State Proficiency Testing Program May 2016 Direct Antigen Detection Category Evaluation Reports are available on the Health Commerce System via EPTRS and can be printed for your records.

This summary is based on scores and responses in the Electronic Proficiency Test Reporting System submitted by laboratories holding a NYS CLEP Virology permit. All NYSDOH Proficiency Test samples were prepared from isolates of viruses cultured from clinical specimens received in the Virology Laboratory at the Wadsworth Center.

Sample Scoring and Validation

The scores and analyses for the May 2016 event can be found below. Federally mandated validation criteria require a sample to be correctly identified by at least 80% of participating laboratories. In this event, all five samples in the RSV and Influenza subcategories were validated. All sample identities in each event have also been confirmed by laboratories outside of the NYSDOH Proficiency Testing Laboratory.

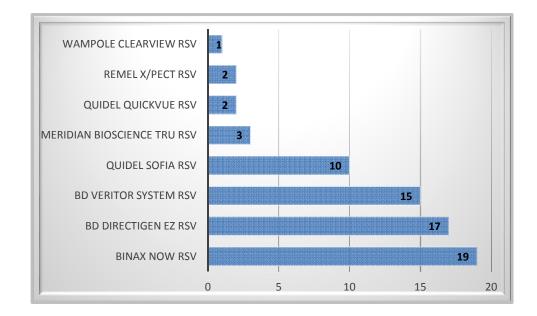
CLIA and CLEP have established a passing grade for participating laboratories to be 80%.

RSV Direct Antigen Proficiency Testing Panel RSV Scoring Analysis: 69 Laboratories in category

Sample #	1696	1697	1697	1699	1700
Sample Identification	RSV	RSV	No Virus	RSV	RSV
Titer (TCID ₅₀) Log 10 per ml	4.0	3.7	0	3.7	3.5
Laboratories Scoring 100%	69	69	69	69	69

RSV Grade Distribution

Total Score For Panel	100%	80%	60%	40%	20%	0%
Participating Laboratories	69	0	0	0	0	0



Number of Laboratories Using Each RSV Kit

RSV Scores by Test Kit

	# of labs and associated score					re
Test Kit/Method	100%	80%	60%	40%	20%	0%
Binax NOW RSV	19					
BD Directigen EZ RSV	17					
BD Veritor System RSV	15					
Quidel Sofia RSV	10					
Meridian Bioscience TRU RSV	3					
Quidel QuickVue RSV	2					
Remel X/Pect RSV	2					
Wampole Clearview RSV	1					

Influenza Direct Antigen Proficiency Testing Panel

Sample #	1701	1702	1703	1704	1705
Sample Identification	Influenza virus, type B	No Virus	Influenza virus, type A	Influenza virus, type B	Influenza virus, type A
Titer (TCID₅₀) Log 10 per ml	4.5	0	6.7	3.5	7.0
Laboratories Scoring 100%	99	99	99	99	99

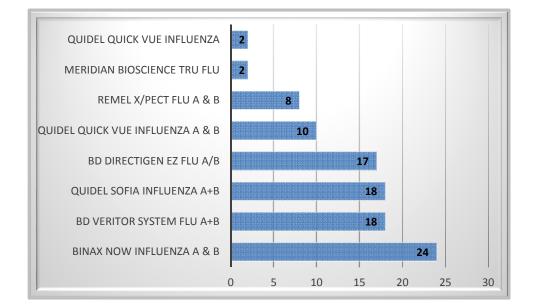
Influenza Scoring Analysis: 99 Laboratories in category

CDC Characterization

Sample 1701: Influenza B: B/MASSACHUSETTS/02/2012-LIKE Sample 1703: Influenza A: A/CALIFORNIA/07/2009-LIKE (H1N1)pdm09 Sample 1704: Influenza B: B/MASSACHUSETTS/02/2012-LIKE Sample 1704: Influenza A: A/TEXAS/50/2012-LIKE (H3N2)

Influenza Grade Distribution

Total Score For Panel	100%	80%	60%	40%	20%	0%
Participating Laboratories	99	0	0	0	0	0



Number of Laboratories Using Each Influenza Test Kit

Influenza Scores by Test Kit

Influenza	# of labs and associated score							
Test Kit/Method	100%	80%	60%	40%	20%	0%		
Binax NOW Influenza A & B	24							
BD Veritor System Flu A+B	18							
Quidel Sofia Influenza A+B	18							
BD Directigen EZ Flu A/B	17							
Quidel Quick Vue Influenza A & B	10							
Remel X/Pect Flu A & B	8							
Meridian Bioscience TRU FLU	2							
Quidel Quick Vue Influenza	2							

NOTES:

- September 2016 Influenza and Respiratory Syncytial Virus Direct Antigen Detection proficiency test date: September 13, 2016
- New York State Direct Antigen Detection proficiency test samples are not compatible with direct or indirect immunofluorescent microscopy detection methods. Laboratories using these methods are advised to perform alternative proficiency testing procedures.
- New York State Direct Antigen Detection proficiency test samples <u>are not</u> <u>intended</u> to be used with PCR detection methods.
- Generic worksheets and Instruction sheets can be found at: <u>http://www.wadsworth.org/programs/id/virology/pt</u>

For future proficiency test events:

- Please review your facility's influenza Test Specificity persistent data and update your entry. Make any necessary changes by selecting the correct test specificity from the drop down menu. The laboratory is responsible for selecting the correct test specificity for the test kit you are using. In this category, scoring is linked between test specificity and answer choice. This field must be filled in correctly or scoring for your laboratory will be adversely affected.
- Participants MUST enter responses in ALL fields when reporting electronically; scores may be adversely affected if there are blank fields.

EPTRS Notes:

- Participation in EPTRS is mandatory. Laboratories must submit test results electronically by logging into the Health Commerce System, navigating to EPTRS, entering results and clicking the "**Submit/Attest**" button on the EPTRS Summary Page.
- Please be sure to "Submit" test results. <u>Keeping results as "Saved" is</u> <u>considered non-participation for the event and will automatically result</u> <u>in a failing grade in the electronic system.</u>