NEW YORK STATE OF OPPORTUNITY. Department of Health

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Virology Proficiency Testing Program

Restricted Category
Direct Antigen Detection

January 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 January 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 January 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

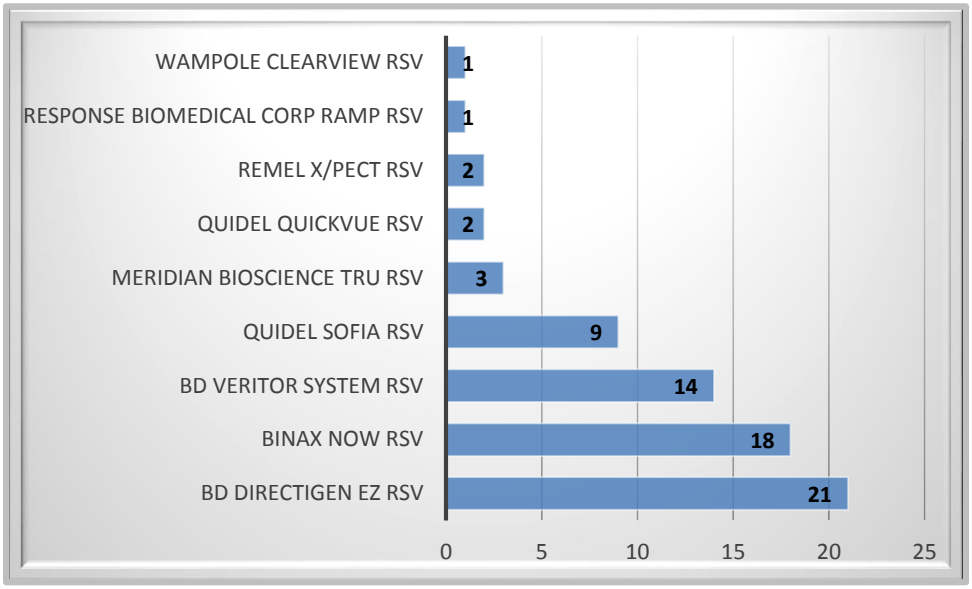
RSV Scoring Analysis: 71 Laboratories in category

Sample #	1671	1672	1672	1674	1675
Sample Identification	No Virus	RSV	RSV	RSV	RSV
Titer ($TCID_{50}$) Log 10 per ml	0	4.0	3.7	4.0	3.7
Laboratories Scoring 100%	71	71	71	71	71

RSV Grade Distribution

Total Score For Panel	100%	80%	60%	40%	20%	0%
Participating Laboratories	71	0	0	0	0	0

Number of Laboratories Using Each RSV Kit



RSV Scores by Test Kit

	# of labs and associated score					
Test Kit/Method	**100%**	**80%**	**60%**	**40%**	**20%**	**0%**
BD Directigen EZ RSV	21					
Binax NOW RSV	18					
BD Veritor System RSV	14					
Quidel Sofia RSV	9					
Meridian Bioscience TRU RSV	3					
Quidel QuickVue RSV	2					
Remel X/Pect RSV	2					
Response Biomedical Corp RAMP RSV	1					
Wampole Clearview RSV	1					

Influenza Direct Antigen Proficiency Testing Panel

Influenza Scoring Analysis:
104 Laboratories in category

Sample #	1676	1677	1678	1679	1680
Sample Identification	Influenza virus, type A	Influenza virus, type A	Influenza virus, type B	Influenza virus, type B	No Virus
Titer ($TCID_{50}$) Log 10 per ml	7.0	6.7	3.5	4.5	0
Laboratories Scoring 100%	104	104	100	103	104

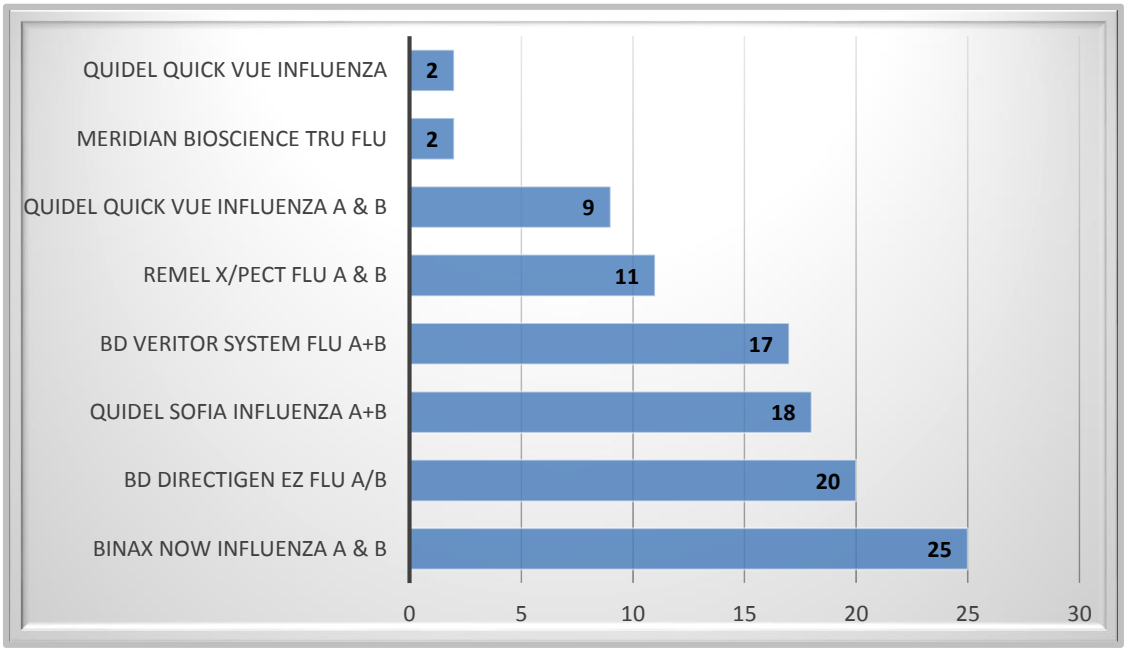
CDC Characterization

Sample 1676: Influenza A: A/TEXAS/50/2012-LIKE (H3N2)
Sample 1677: Influenza A: A/CALIFORNIA/07/2009-LIKE (H1N1)pdm09
Sample 1678: Influenza B: B/MASSACHUSETTS/02/2012-LIKE
Sample 1679: Influenza B: B/MASSACHUSETTS/02/2012-LIKE

Influenza Grade Distribution

Total Score For Panel	100%	80%	60%	40%	20%	0%
Participating Laboratories	99	5	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	25					
BD Directigen EZ Flu A/B	20					
Quidel Sofia Influenza A+B	13	5				
BD Veritor System Flu A+B	17					
Remel X/Pect Flu A & B	11					
Quidel Quick Vue Influenza A & B	9					
Meridian Bioscience TRU FLU	2					
Quidel Quick Vue Influenza	2					

NOTES:

- May 2016 Influenza and Respiratory Syncytial Virus Direct Antigen Detection proficiency test dates: May 3, 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 **are not intended** to be used with PCR detection methods.

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.**

- **Generic worksheets** can be found at:
  http://www.wadsworth.org/programs/id/virology/pt

  Generic worksheets can also be printed by logging onto the HPN and navigating to EPTRS, Results page, Print Optional Worksheet.

- **Instruction sheets** can be found at:
  http://www.wadsworth.org/regulatory/clep/pt/categories

- 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. **Keeping results as "Saved" is considered non-participation for the event and will automatically result in a failing grade in the electronic system.**