NEW YORK STATE OF OPPORTUNITY. Department of Health

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Virology Proficiency Testing Program

Restricted Category
Direct Antigen Detection

September 2015

Summary of scores, responses, and statistics for
Rotavirus, 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 September 2015 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 (with the exception of rotavirus).

Sample Scoring and Validation

The scores and analyses for the September 2015 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 Rotavirus, 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%.

Rotavirus Direct Antigen Proficiency Testing Panel

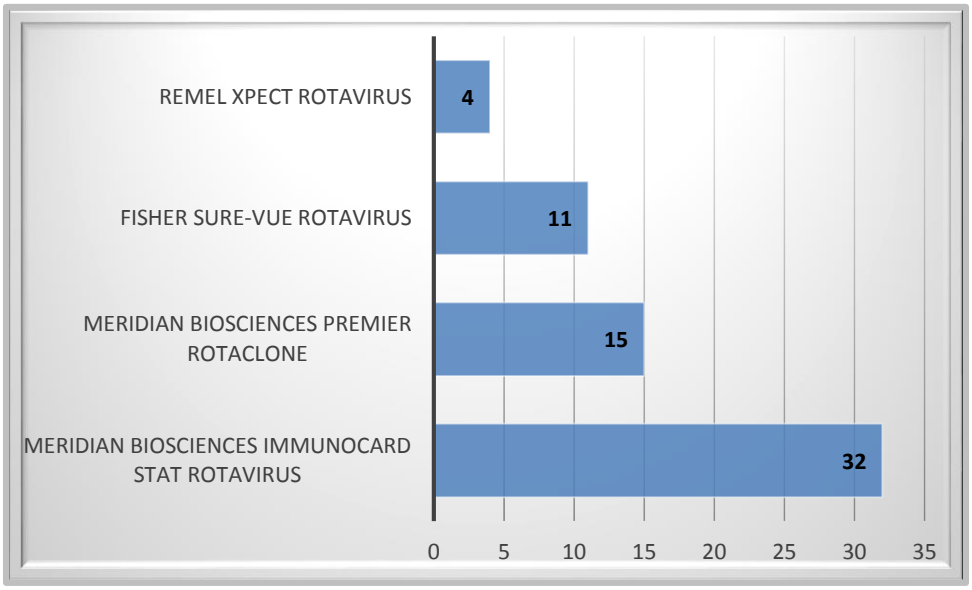
Rotavirus Scoring Analysis: 62 Laboratories in category

Sample #	1641	1642	1643	1644	1645
Sample Identification	Rotavirus	No virus	Rotavirus	Rotavirus	Rotavirus
Titer ($TCID_{50}$) Log 10 per ml	5.5	0	6.0	6.0	5.5
Laboratories Scoring100%	59	62	62	62	59

Rotavirus Grade Distribution

Total Score for Panel	100%	80%	60%	40%	20%	0%
Participating Laboratories	59	0	3	0	0	0

Number of Laboratories Using Each Rotavirus Test Kit



Rotavirus Scores by Test Kit

	# of labs and associated score					
Test Kit/Method	**100%**	**80%**	**60%**	**40%**	**20%**	**0%**
Meridian Biosciences ImmunoCard STAT Rotavirus	30		2			
Meridian Biosciences Premier Rotaclone	14		1			
Fisher Sure-Vue Rotavirus	11					
Remel Xpect Rotavirus	4					

RSV Direct Antigen Proficiency Testing Panel

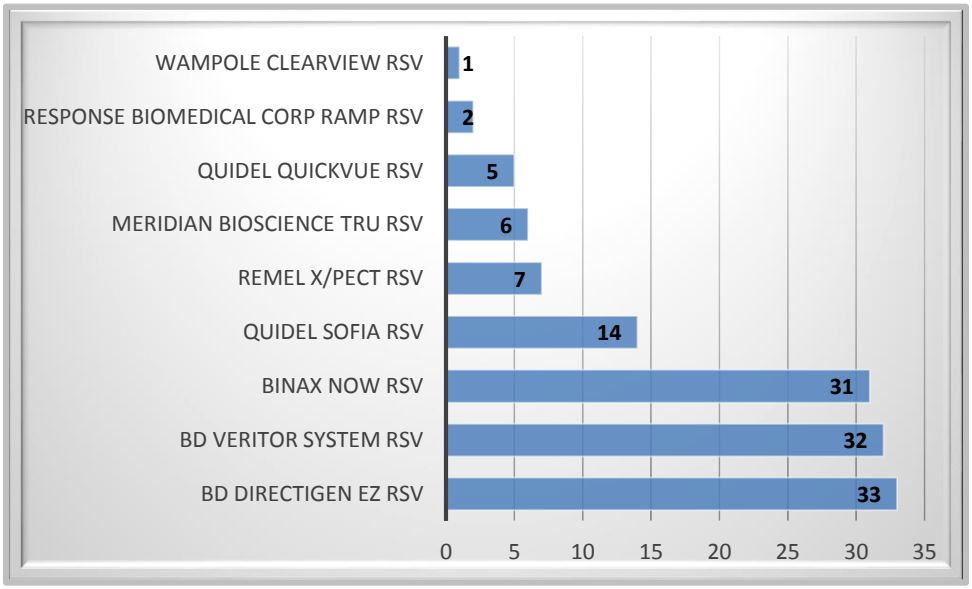
RSV Scoring Analysis:131 Laboratories in category

Sample #	1646	1647	1648	1649	1650
Sample Identification	RSV	No virus	RSV	No virus	RSV
Titer ($TCID_{50}$) Log 10 per ml	3.0	0	2.7	0	2.7
Laboratories Scoring 100%	131	131	131	131	131

RSV Grade Distribution

Total Score For Panel	100%	80%	60%	40%	20%	0%
Participating Laboratories	131	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	33					
BD Veritor System RSV	32					
Binax NOW RSV	31					
Quidel Sofia RSV	14					
Remel X/Pect RSV	7					
Meridian Bioscience TRU RSV	6					
Quidel QuickVue RSV	5					
Response Biomedical Corp RAMP RSV	2					
Wampole Clearview RSV	1					

Influenza Direct Antigen Proficiency Testing Panel

Influenza Scoring Analysis:
189 Laboratories in category*

Sample #	1651	1652	1653	1654	1655
Sample Identification	Influenza virus, type B	Influenza virus, type A	Influenza virus, type B	No virus	Influenza virus, type A
Titer ($TCID_{50}$) Log 10 per ml	4.5	6.3	3.5	0	6.5
Laboratories Scoring 100%	188	187	185	186	188

* One laboratory scored 0% due to Non-Participation.

CDC Characterization

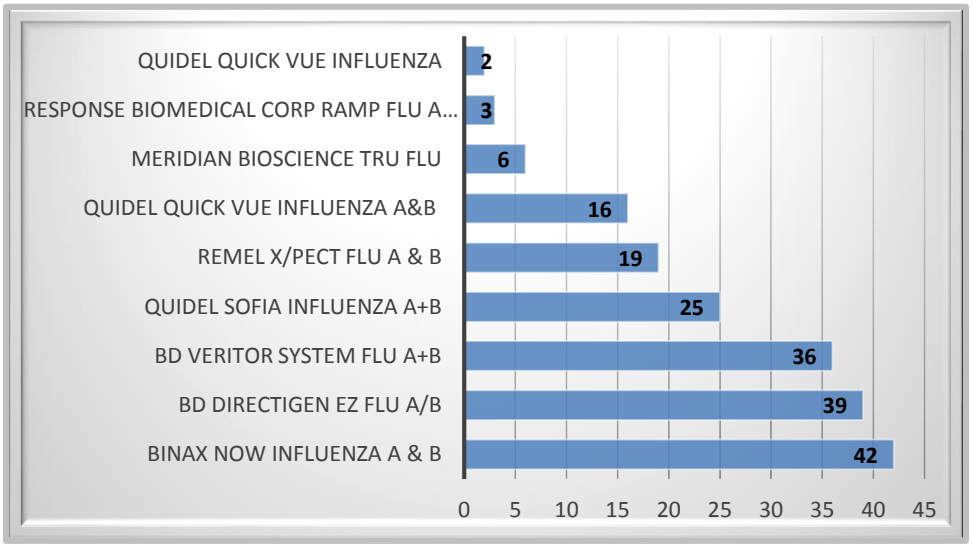
Sample 1651: Influenza B: B/WISCONSIN/01/2010-LIKE
Sample 1652: Influenza A: A/CALIFORNIA/07/2009-LIKE (H1N1)pdm09
Sample 1653: Influenza B: B/BRISBANE/60/2008-LIKE
Sample 1655: Influenza A: A/VICTORIA/361/2011-LIKE (H3N2)

Influenza Grade Distribution*

Total Score For Panel	100%	80%	60%	40%	20%	0%
Participating Laboratories	182	6	0	0	0	1

* One laboratory scored 0% due to Non-Participation.

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	42					
BD Directigen EZ Flu A/B	37	2				
BD Veritor System Flu A+B	36					
Quidel Sofia Influenza A+B	24	1				
Remel X/Pect Flu A & B	17	2				
Quidel Quick Vue Influenza A & B	16					
Meridian Bioscience TRU FLU	6					
Response Biomedical Corp RAMP Flu A & B	2	1				
Quidel Quick Vue Influenza	2					

NYS Virology Proficiency Testing Notice

- **The September 2015 Rotavirus Direct Antigen Detection panel is the last rotavirus panel New York State will be sending to permitted laboratories.** As discussed in previous letters to NYS CLEP permitted laboratories, numerous proficiency test (PT) panels have been eliminated from the 2016 CLEP test menu. Please refer to the August 14, 2015 letter sent to all Laboratory Directors stating, "Beginning January 1, 2016, laboratories that are currently enrolled in these NYS PT programs must be enrolled in another CMS-approved PT program that satisfies the same CLIA PT requirements."

- If you have any questions, please contact:

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NOTES:

- January 2016 Influenza and Respiratory syncytial virus direct antigen detection proficiency test dates:
  Influenza Direct Antigen Detection, January 12, 2016
  Respiratory Syncytial Virus, January 20, 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 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/divisions/infdis/virologyPT/instruction_worksheets.shtml

  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/divisions/infdis/virologyPT/instruction_worksheets.shtml

- 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.**