



STATE OF NEW YORK

DEPARTMENT OF HEALTH

*Virology Proficiency Testing Program*

## Virology

# Direct Antigen Detection Category

January 2010

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 January 2010 Direct Antigen Detection Category Evaluation Reports are available at: <https://commerce.health.state.ny.us/doh3/applinks/epters/> and can be printed for your records.

This summary is based on scores and responses in the Electronic Proficiency Testing Reporting System. Data includes that from laboratories holding a Virology General permit as well as laboratories holding Virology permits restricted to Direct Antigen Detection Only.

All NYSDOH Proficiency Test samples were prepared from isolates of viruses grown in the Virus Reference and Surveillance Laboratory at the Wadsworth Center.

## Sample Scoring and Validation

The scores and analyses for the January 2010 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 were also confirmed by reference laboratories. In the rotavirus event, all five samples were valid for laboratories that used test kits other than the ImmunoCard STAT! Rotavirus test kit where background staining issues were encountered. CLIA and CLEP establish a passing grade for participating laboratories at 80%.

## Rotavirus Direct Antigen Proficiency Testing Panel

### Rotavirus Scoring Analysis: 73 laboratories in category

Sample #	1171	1172	1173	1174	1175
Sample Identification	Rotavirus	Rotavirus	Rotavirus	Rotavirus	Rotavirus
Titer (TCID <sub>50</sub> ) Log 10 per ml	2.0	2.0	2.0	2.0	2.0
Laboratories Scoring 100%	41	41	41	38	39

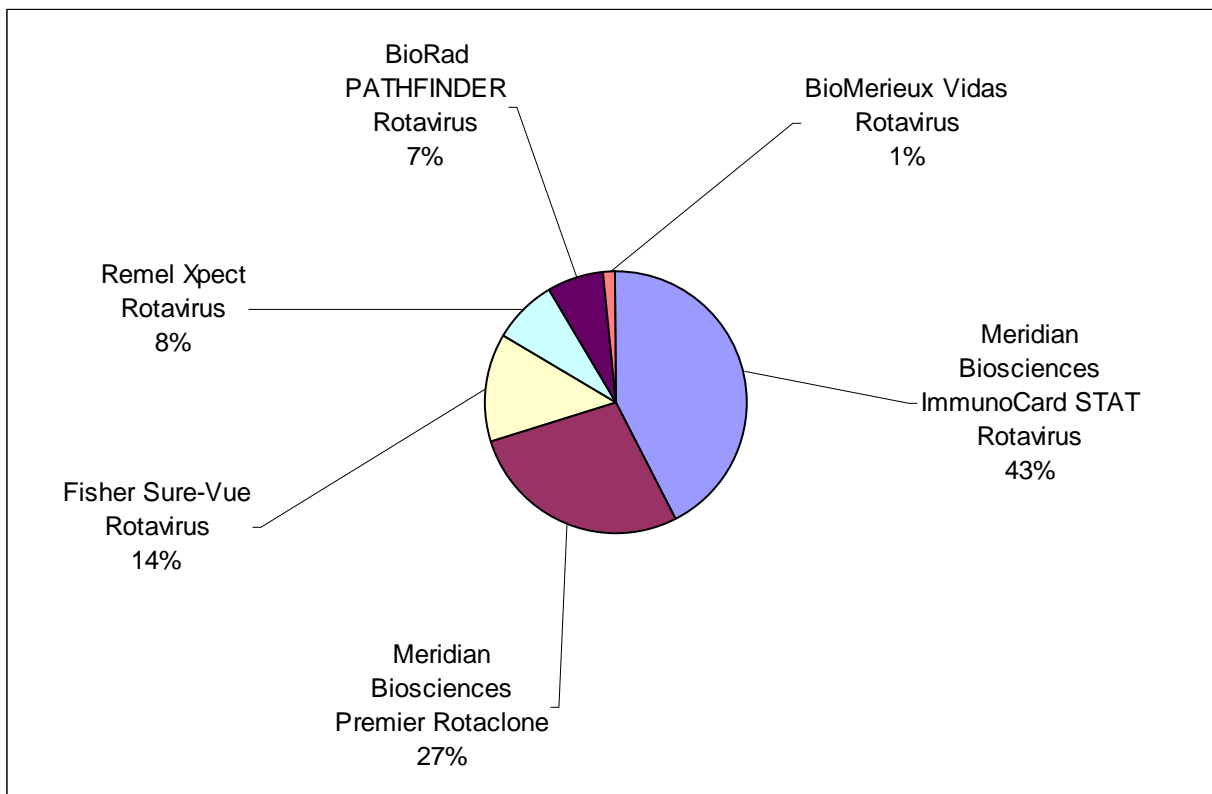
The above chart excludes all laboratories using the Meridian Bioscience ImmunoCard STAT! Rotavirus test kit due to background staining issues with the PT samples in this event.

### Rotavirus Grade Distribution

Total Score for Panel	100%	80%	60%	40%	20%	0%
Participating Laboratories	68*	2	2		1	

\*All laboratories using the Meridian Bioscience ImmunoCard STAT! Rotavirus test kit were defaulted to a 100% score due to background staining issues with the PT samples in this event.

## Rotavirus Kits Used by Participating Laboratories



## Rotavirus Scores by Test Kit

Test Kit/Method	Number of Labs and associated score <sup>a</sup>					
	100%	80%	60%	40%	20%	0%
Meridian Biosciences ImmunoCard STAT Rotavirus <sup>b</sup>	31					
Meridian Biosciences Premier Rotaclone	17	1	2			
Fisher Sure-Vue Rotavirus	8	1				
Remel Xpect Rotavirus	6					
BioRad PATHFINDER Rotavirus	5					
BioMerieux Vidas Rotavirus					1	

<sup>a</sup> This does not include laboratories that scored 0% due to non-participation

<sup>b</sup> All laboratories using the Meridian Bioscience ImmunoCard STAT! kit were defaulted to a 100% score due to background staining issues with the PT samples in this event.

# RSV Direct Antigen Proficiency Testing Panel

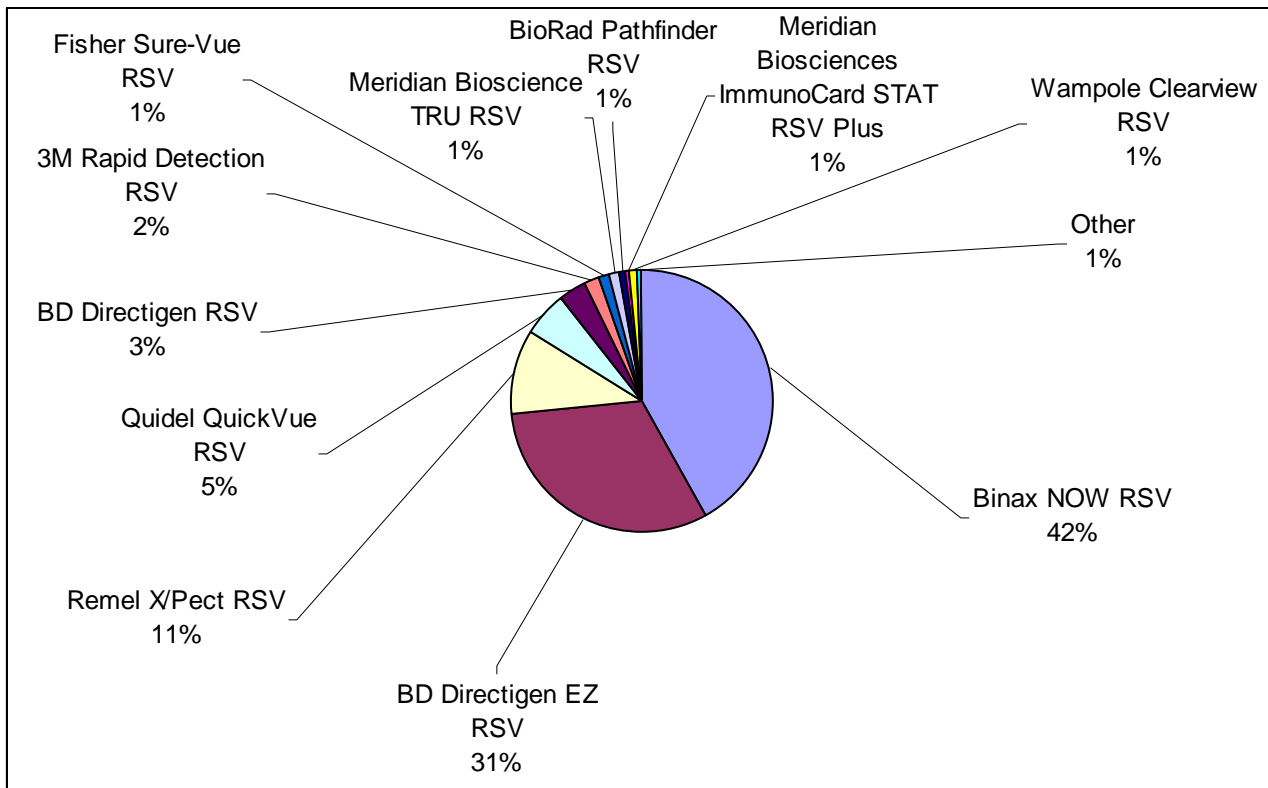
## RSV Scoring Analysis: 150 Laboratories in category

Sample #	1176	1177	1178	1179	1180
Sample Identification	RSV	RSV	No virus	RSV	RSV
Titer (TCID <sub>50</sub> ) Log 10 per ml	3.5	5.5	0	3.7	3.5
Laboratories Scoring 100%	150	150	150	150	149

## RSV Grade Distribution

Total Score For Panel	100%	80%	60%	40%	20%	0%
Participating Laboratories	149	1	0	0	0	0

## RSV Kits Used by Participating Laboratories



## RSV Scores by Test Kit

Test Kit/Method	Number of Labs and associated score*					
	100%	80%	60%	40%	20%	0%
Binax NOW RSV	63					
BD Directigen EZ RSV	47					
Remel X/Pect RSV	15	1				
Quidel QuickVue RSV	8					
BD Directigen RSV	5					
3M Rapid Detection RSV	3					
Fisher Sure-Vue RSV	2					
Meridian Bioscience TRU RSV	2					
BioRad Pathfinder RSV	1					
Meridian Biosciences ImmunoCard STAT RSV Plus	1					
Wampole Clearview RSV	1					
Other	1					

\*This does not include laboratories that scored 0% due to non-participation

## Influenza Direct Antigen Proficiency Testing Panel

### Influenza Scoring Analysis: 231 Laboratories in category\*

Sample #	1181	1182	1183	1184	1185
Sample Identification	Influenza virus, type B	Influenza virus, type A	No virus	Influenza virus, type A	Influenza virus, type B
Titer (TCID <sub>50</sub> ) Log 10 per ml	1.0	3.6	0	1.0	1.5
Laboratories Scoring 100%	225	228	228	228	227

\*One participant reported "Test temporarily suspended", one participant reported "Test no longer offered." and one participant scored 0% due to "Non Participation."

## CDC Characterization

Sample 1181 and 1185: Influenza B: B/FLORIDA/04/2006-LIKE

Sample 1182: Influenza A: A/SOLOMON ISLANDS/03/2006-LIKE (H1N1)

Sample 1184: Influenza A: A/WISCONSIN/67/2005-LIKE (H3N2)

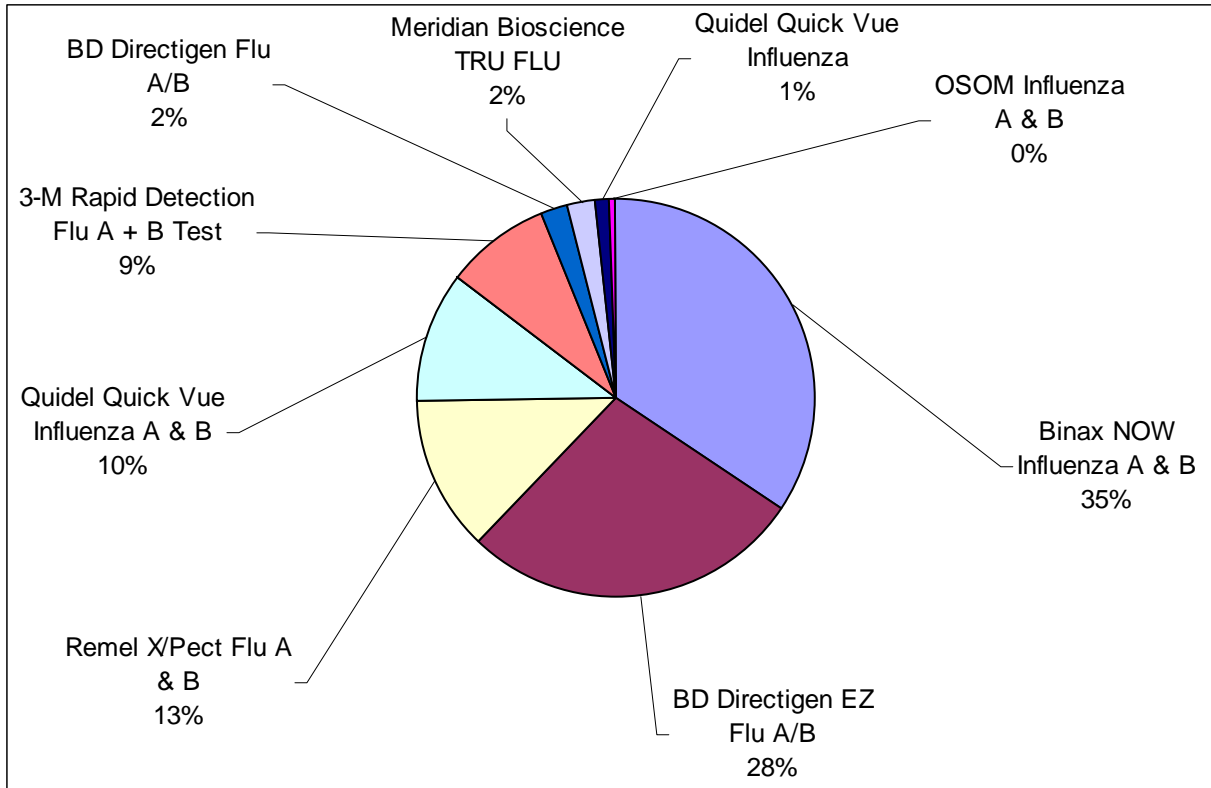
## Influenza Grade Distribution

Total Score For Panel	100%	80%	60%	40%	20%	0%
Participating Laboratories	225*	2	1	0	1	1**

\* One participant granted an exclusion, due to "Test temporarily Suspended."

\*\*One participant failed due to "Non participation."

## Influenza Virus Kits Used by Participating Laboratories



Influenza Test Kit/Method	Number of Labs and associated score*					
	100%	80%	60%	40%	20%	0%
Binax NOW Influenza A & B	78	1				
BD Directigen EZ Flu A/B	62	1				
Remel X/Pect Flu A & B	29		1			
Quidel Quick Vue Influenza A & B	23				1**	
3-M Rapid Detection Flu A + B Test	20					
BD Directigen Flu A/B	5					
Meridian Bioscience TRU FLU	5					
Quidel Quick Vue Influenza	3					
OSOM Influenza A & B					1	

\* This does not include laboratories that scored 0% due to non-participation

\*\*Participant selected Test Specificity inconsistent with Test Method (kit). EPTRS scoring is directly linked to test specificity.

## Influenza Direct Antigen Detection Educational Samples E3 and E4

Sample #	E-3	E-4
Sample Identification	Influenza A 2009 H1N1	Influenza A 2009 H1N1
Titer (TCID <sub>50</sub> )	5.5	5.5

### CDC Characterization

Sample E-3: A/CALIFORNIA/07/2009-LIKE (H1N1)v

Sample E-4: A/CALIFORNIA/07/2009-LIKE (H1N1)v

The educational samples were prepared from isolates of viruses grown from clinical respiratory specimens received in the Virus Reference and Surveillance Laboratory at the Wadsworth Center. Both isolates were sent to the CDC for antigenic characterization by hemadsorption inhibition and were reported to be A/CALIFORNIA/07/2009-LIKE (H1N1)v. Additionally, the viral genomes in both primary clinical samples were amplified by whole influenza virus amplification (Zhou et al. 2009, J. Virol. 83: 10309-13) and forwarded to the J. Craig Venter Institute for sequencing. The entire genomic sequences can be accessed via the following links:

E3:

<http://www.ncbi.nlm.nih.gov/sites/entrez?db=nucleotide&cmd=Search&dopt=DocSum&term=txid664127%5BOrganism%3Anoexp%5D>

E4:

<http://www.ncbi.nlm.nih.gov/sites/entrez?db=nucleotide&cmd=Search&dopt=DocSum&term=txid679774%5BOrganism%3Anoexp%5D>

### Reported Responses in EPTRS 231 Laboratories in Category

Responses	E-3	E-4
	# of Laboratories	# of Laboratories
Influenza A Positive	222	223
Negative	2	1
Influenza Positive (untyped)	3	3
Educational sample not tested	1	1

*Total number of responses does not include: one "Non-participant," one "Temporary Suspension" participant, and one "Test deleted" participant.*

Each participant reported using the same Test Method (kit) for the Educational samples and NYS proficiency test samples (see above chart for **Influenza Virus Kits Used by Participating Laboratories**). Two influenza A 2009 H1N1 samples were included in the January 2010 Influenza

Direct Antigen Detection panel as educational samples to collect information on rapid antigen detection kit performance with this subtype. The low sensitivity of rapid influenza diagnostic tests has been discussed in recent literature (see references below). Given the reported poor sensitivities of these rapid tests for 2009 H1N1 detection, the results for these two educational samples were encouraging.

Evaluation of Rapid Influenza Diagnostic Tests for Detection of Novel Influenza A (H1N1) Virus---United States, 2009, MMWR Weekly, August 7, 2009/58(30); 826-829.

Hurt et al (2009): Performance of influenza rapid point-of-care tests in the detection of swine lineage A (H1N1) Influenza viruses. Influenza and Other Respiratory Viruses. 3: 171-76.

Chan et al (2009): Analytical sensitivity of rapid influenza antigen detection tests for swine-origin influenza virus (H1N1). J Clin Virol. 45: 205-7.

Ginocchio et al (2009): Evaluation of multiple test methods for the detection of the novel 2009 influenza A (H1N1) during the New York City outbreak. J Clin Virol 45: 191-5

## Notes:

- Carefully select the correct Test Specificity for the test kit you are using. Influenza Direct Antigen Detection participants MUST enter responses in the *Test Specificity* and *Test Method (kit)* fields on the reporting page. You are 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. Therefore, it is imperative that this field is filled in correctly or scoring for your laboratory will be adversely affected.**
- The NYS Virology Proficiency Testing laboratory recently re-located to the David Axelrod Institute. Our new US Postal Service address is:
  - Virology Proficiency Testing Program, David Axelrod Institute, Wadsworth Center, NYS Department of Health, PO Box 22002, Albany, NY 12201-2002.
  - Telephone 518-474-0140 and fax 518-473-4336.
- The Virology PT shipping schedule for 2010 is posted on the Clinical Laboratory Evaluation Program website (<http://www.wadsworth.org/labcert/clep/PT/ptindex.html> ).
- Generic worksheets are provided for your optional use. Please do not return these worksheets to the program. Generic worksheets can also be printed via the HPN (<https://commerce.health.state.ny.us/doh3/applinks/epters/>).
- 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 in to: <https://commerce.health.state.ny.us/doh3/applinks/eptrs/> entering their 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.**