

# Virology Proficiency Testing Program

## Restricted Category Direct Antigen Detection

September 2011

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 2011 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. Data includes that from laboratories holding a Virology Comprehensive 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 Virology Laboratory at the Wadsworth Center.

**Sample Scoring and Validation**

The scores and analyses for the September 2011 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 five sample identities in each event were also confirmed by reference laboratories.

CLIA and CLEP established a passing grade for participating laboratories at 80%.

**Rotavirus Direct Antigen Proficiency Testing Panel**

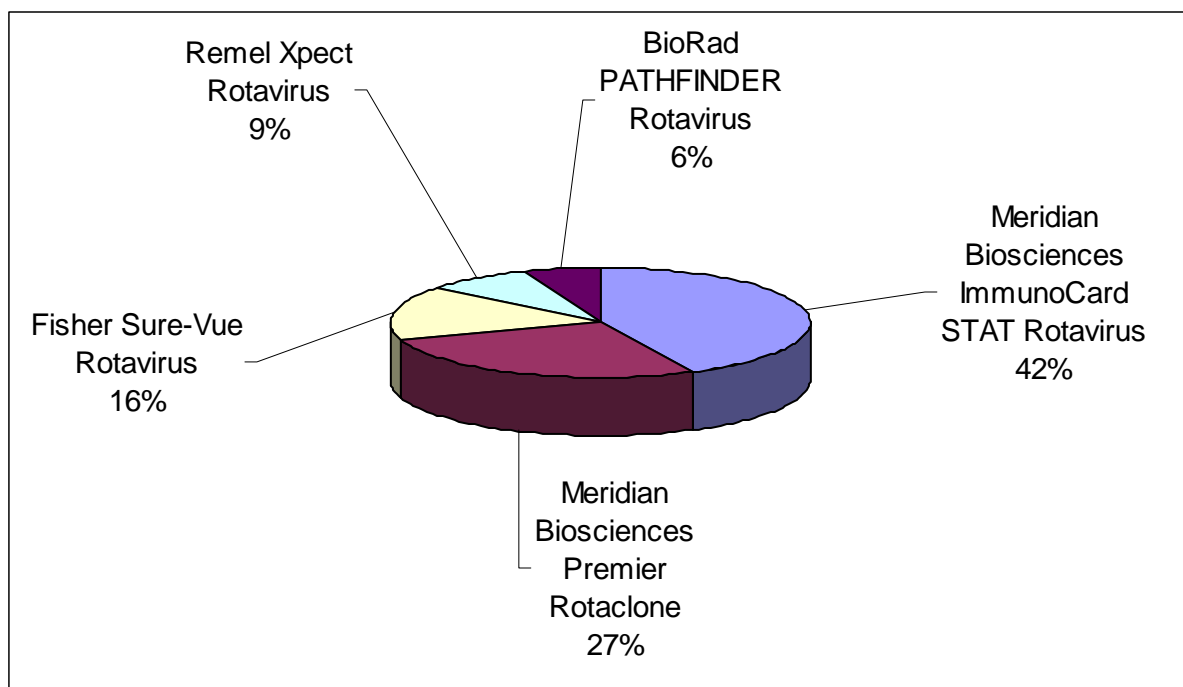
**Rotavirus Scoring Analysis:  
70 laboratories in category**

Sample #	1296	1297	1298	1299	1300
Sample Identification	Rotavirus	Rotavirus	Rotavirus	Rotavirus	No virus
Titer (TCID <sub>50</sub> ) Log 10 per ml	6.3	6.0	6.3	6.5	0
Laboratories Scoring 100%	70	69	69	69	69

## Rotavirus Grade Distribution

Total Score for Panel	100%	80%	60%	40%	20%	0%
Participating Laboratories	67	2	1	0	0	0

## Rotavirus Kits Used by Participating Laboratories



## Rotavirus Scores by Test Kit

Test Kit/Method	# of labs and associated score					
	100%	80%	60%	40%	20%	0%
Meridian Biosciences ImmunoCard STAT Rotavirus	28	1	1			
Meridian Biosciences Premier Rotaclone	18	1				
Fisher Sure-Vue Rotavirus	11					
Remel Xpect Rotavirus	6					
BioRad PATHFINDER Rotavirus	4					

## RSV Direct Antigen Proficiency Testing Panel

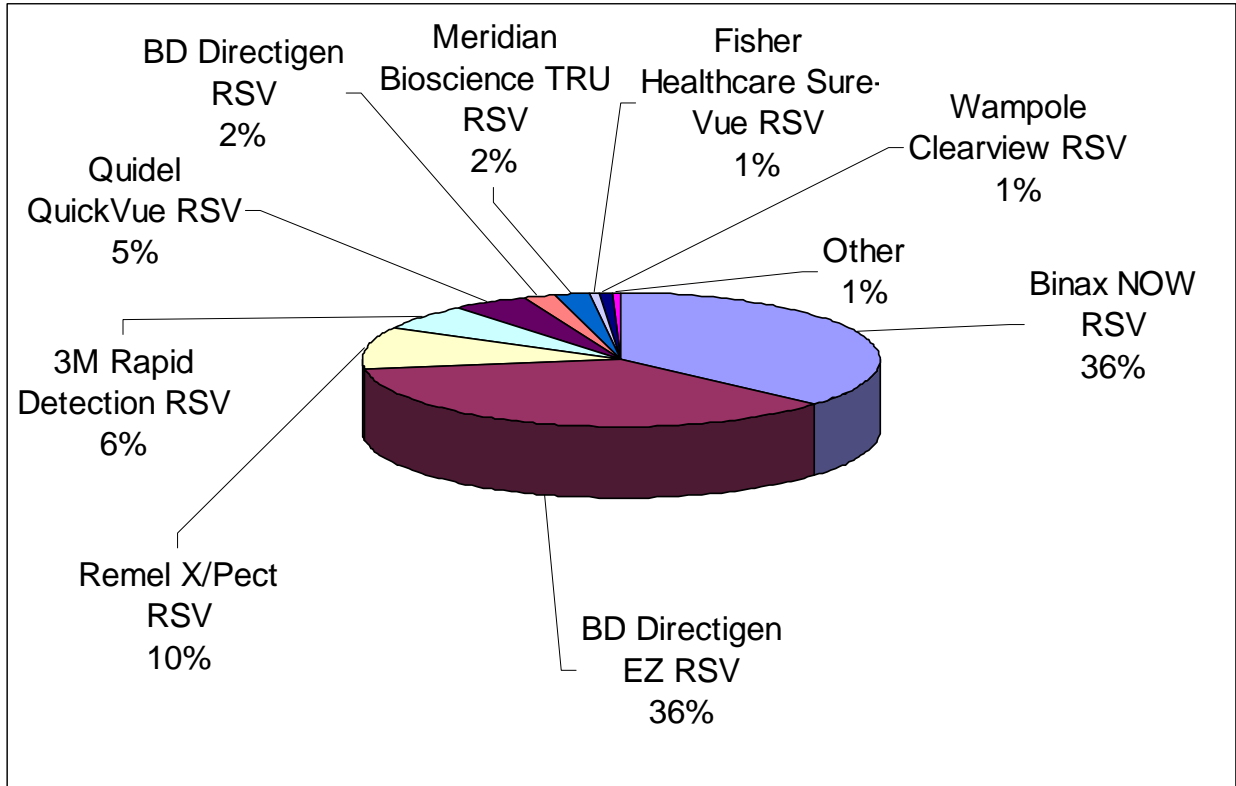
RSV Scoring Analysis:  
147 Laboratories in category

Sample #	1301	1302	1303	1304	1305
Sample Identification	No virus	RSV	RSV	No virus	RSV
Titer (TCID <sub>50</sub> ) Log 10 per ml	0	4.0	4.2	0	4.0
Laboratories Scoring 100%	146	147	147	146	147

### RSV Grade Distribution

Total Score For Panel	100%	80%	60%	40%	20%	0%
Participating Laboratories	145	2	0	0	0	0

## RSV Kits Used by Participating Laboratories



## RSV Scores by Test Kit

Test Kit/Method	# of labs and associated score					
	100%	80%	60%	40%	20%	0%
Binax NOW RSV	54					
BD Directigen EZ RSV	52	1				
Remel X/Pect RSV	15					
3M Rapid Detection RSV	9					
Quidel QuickVue RSV	7					
BD Directigen RSV	3					
Meridian Bioscience TRU RSV	2	1				
Fisher Healthcare Sure-Vue RSV	1					
Wampole Clearview RSV	1					
Other	1					

# Influenza Direct Antigen Proficiency Testing Panel

## Influenza Scoring Analysis: 224 Laboratories in category\*

Sample #	1306	1307	1308	1309	1310
Sample Identification	No virus	No virus	Influenza virus, type B	Influenza virus, type A	Influenza virus, type B
Titer (TCID <sub>50</sub> ) Log 10 per ml	0	0	5.3	4.2	5.5
Laboratories Scoring 100%	223	223	223	222	223

\* One participant scored 0% due to "Failure to submit results."

## CDC Characterization

Sample 1308: Influenza B: A/BRISBANE/60/2008-LIKE

Sample 1309: Influenza A: A/BRISBANE/10/2007-LIKE (H3N2)

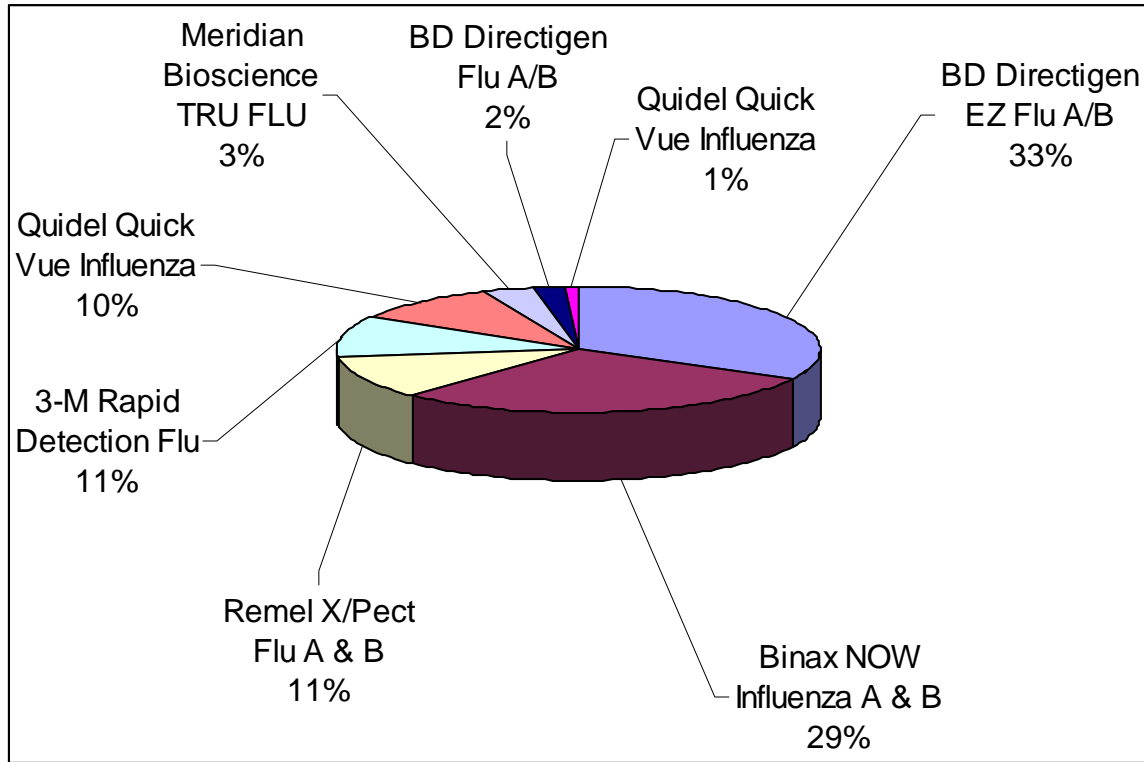
Sample 1310: Influenza B: B/BRISBANE/60/2008-LIKE

## Influenza Grade Distribution

Total Score For Panel	100%	80%	60%	40%	20%	0%
Participating Laboratories	222	1	0	0	0	1*

\* One participant scored 0% due to "Failure to submit results."

## Influenza Virus Kits Used by Participating Laboratories



Influenza Test Kit/Method	# of labs and associated score*					
	100%	80%	60%	40%	20%	0%
BD Directigen EZ Flu A/B	73					
Binax NOW Influenza A & B	65					
Remel X/Pect Flu A & B	25					
3-M Rapid Detection Flu A + B Test	24					
Quidel Quick Vue Influenza A & B	22					
Meridian Bioscience TRU FLU	7					
BD Directigen Flu A/B	5					
Quidel Quick Vue Influenza	1	1				

\* One participant scored 0% due to "Failure to submit results."

## Notes:

- Please take special note that in January 2012 and thereafter, Direct Antigen Detection samples will be sent as 1.5 ml aliquots in 2.0 ml cryovials. For those laboratories using the Meridian Bioscience ImmunoCard STAT! Rotavirus test kit, the instruction sheet will specify the amount of “ADD” to use for the rotavirus NYS PT samples.
- 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.**
- Each facility will receive an e-mail notice when the Virology PT shipping schedule for 2012 is to be posted on the Clinical Laboratory Evaluation Program website: (<http://www.wadsworth.org/labcert/clep/PT/ptindex.html> ).
- January 2012 Proficiency Test Dates:
  - Influenza Direct Antigen Detection: January 18, 2012
  - Comprehensive: January 25, 2012
  - Herpes Simplex Virus Testing: January 25, 2012
  - Rotavirus and Respiratory syncytial virus Direct Antigen Detection: January 24, 2012
- **Generic worksheets** can be found at:  
<http://www.wadsworth.org/divisions/infdis/virologyPT/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.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.**