NEW YORK STATE OF OPPORTUNITY. Department of Health

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# Virology Proficiency Testing Program

# Restricted Category Direct Antigen Detection

## September 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 September 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 September 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

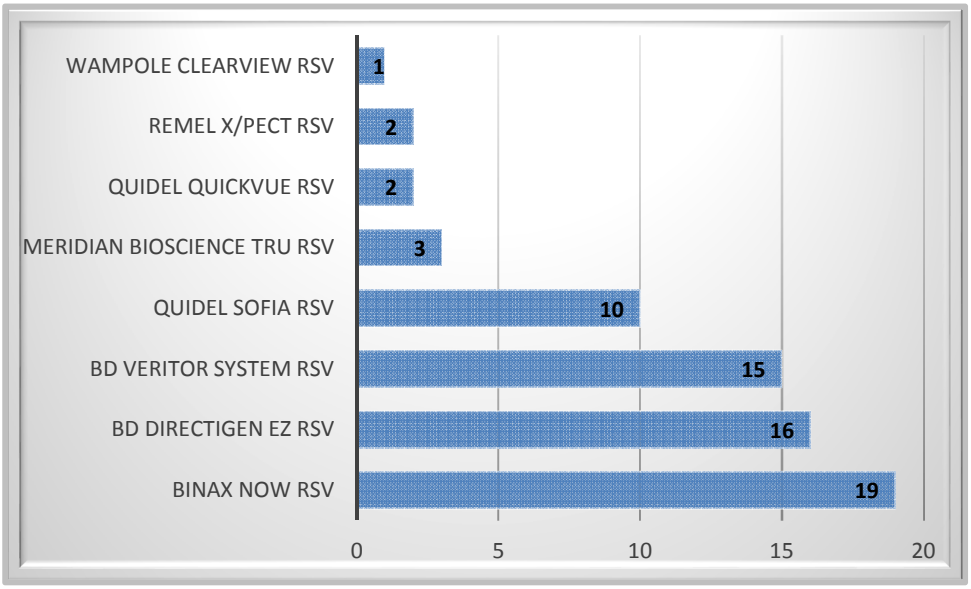
### RSV Scoring Analysis: 68 Laboratories in category

| Sample # | 1721 | 1722 | 1723 | 1724 | 1725 |
|---|---|---|---|---|---|
| Sample Identification | RSV | RSV | RSV | RSV | No Virus |
| Titer ($TCID_{50}$) Log 10 per ml | 4.0 | 3.7 | 3.0 | 3.5 | 0 |
| Laboratories Scoring 100% | 68 | 68 | 68 | 68 | 68 |

### RSV Grade Distribution

| Total Score For Panel | 100% | 80% | 60% | 40% | 20% | 0% |
|---|---|---|---|---|---|---|
| Participating Laboratories | 68 | 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%** |
| Binax NOW RSV | 19 | | | | | |
| BD Directigen EZ RSV | 16 | | | | | |
| 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

## Influenza Scoring Analysis:
## 98 Laboratories in category

| Sample # | 1726 | 1727 | 1728 | 1729 | 1730 |
|---|---|---|---|---|---|
| **Sample Identification** | No Virus | Influenza virus, type B | Influenza virus, type B | Influenza virus, type A | Influenza virus, type A |
| **Titer ($TCID_{50}$) Log 10 per ml** | 0 | 3.5 | 4.5 | 6.7 | 7.0 |
| **Laboratories Scoring 100%** | 98 | 97 | 98 | 98 | 98 |

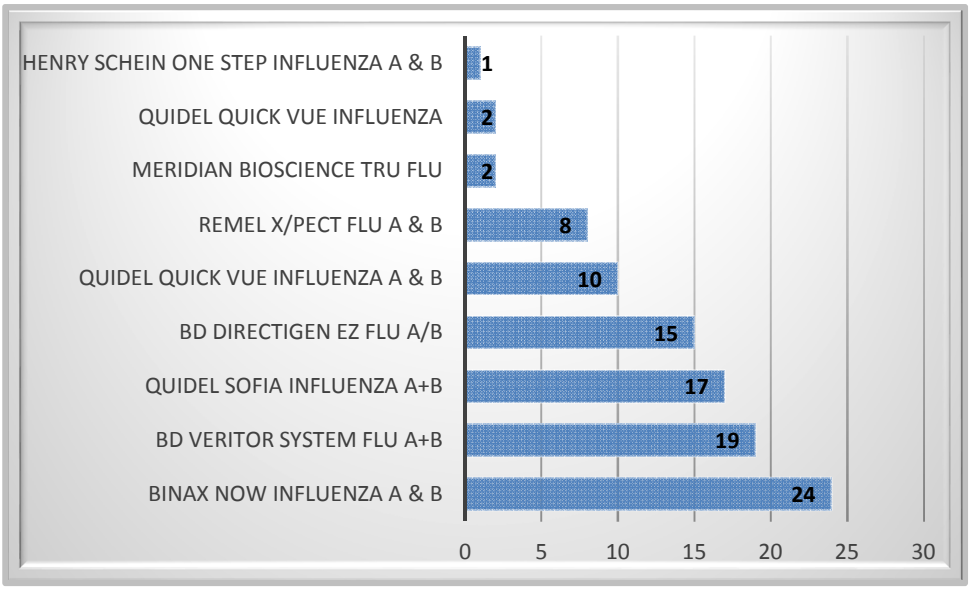
# CDC Characterization

Sample 1727: Influenza B: B/MASSACHUSETTS/02/2012-LIKE
Sample 1728: Influenza B: B/MASSACHUSETTS/02/2012-LIKE
Sample 1729: Influenza A: A/CALIFORNIA/07/2009-LIKE (H1N1)pdm09
Sample 1730: Influenza A: A/TEXAS/50/2012-LIKE (H3N2)

## Influenza Grade Distribution

| Total Score For Panel | 100% | 80% | 60% | 40% | 20% | 0% |
|---|---|---|---|---|---|---|
| **Participating Laboratories** | 97 | 1 | 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 | 19 | | | | | |
| Quidel Sofia Influenza A+B | 17 | | | | | |
| BD Directigen EZ Flu A/B | 15 | | | | | |
| Quidel Quick Vue Influenza A & B | 10 | | | | | |
| Remel X/Pect Flu A & B | 7 | 1 | | | | |
| Meridian Bioscience TRU FLU | 2 | | | | | |
| Quidel Quick Vue Influenza | 2 | | | | | |
| Henry Schein One Step Influenza A & B | 1 | | | | | |

## NOTES:

- As stated in a letter dated July 22, 2016 sent to Laboratory Directors, “Effective December 31, 2016, New York State will no longer provide clinical laboratory proficiency testing.”

- “ Note that all NYS PT requirements apply to PT offered by other providers. Requirements for permitted laboratories include but are not limited to:
  - Enroll in PT for tests offered by the laboratory that are described in 42 CFR 493 subpart H and subpart I.
  - Notify NYS of intended enrollment for required PT. There will be a notification process for 2017 in the fall of this year. Additional information about the notification process will be available in September, 2016.
  - Maintain satisfactory and successful performance for any formal PT event, whether or not the PT is required.
  - Perform corrective action and remediation for unsatisfactory and unsuccessful performance. Provide documentation to the Department when requested.”

- 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.