Back to the Workplace Webinar Series
Part II: Testing Workers for Active Virus and Antibodies

Thursday, July 23, 2020
4 p.m. ET
Today’s Speakers

Moderators:

James Klein
President
American Benefits Council

Ilyse Schuman
Senior Vice President, Health Policy
American Benefits Council

Guest Speakers:

Wendi Mader
Executive Director and Commercial Leader
Quest Diagnostics

Peter Silvester
Senior Vice President and President, Life Sciences Solutions
Thermo Fisher Scientific
Our Response to COVID19 is a Powerful Example of Our Mission

Healthier
Supporting diagnostic testing and development of vaccines and treatments

Cleaner
Making hand sanitizer for colleagues and enabling increased production

Safer
Providing personal protective equipment for those on the front lines

We enable our customers to make the world healthier, cleaner and safer
## Types of COVID-19 Testing

<table>
<thead>
<tr>
<th>Sample Method</th>
<th>Test Setting</th>
<th>Timing of Results</th>
<th>Tests For:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Molecular (RNA qPCR)</td>
<td>Swab and Saliva Lab and Point of Care</td>
<td>Point of Care: one sample can take up to 30 mins</td>
<td>Acute Infection (Early Stage)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>No</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Immune to Infection</td>
</tr>
<tr>
<td>Antigen</td>
<td>Swab and Saliva Lab, Point of Care and at Home (in development)</td>
<td>Labs: can test hundreds to thousands of samples in several hours</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>No</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>No</td>
</tr>
<tr>
<td>Serology (IgM and IgG antibodies)</td>
<td>Blood</td>
<td>Depends on Test</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Unknown*</td>
</tr>
</tbody>
</table>

*Need clinical studies for each antibody test
COVID-19 Testing: Which Marker, When?

Molecular Diagnostics Tests

Immuno-Assay Testing

Antigen Tests

- IgM Antibody Tests
- IgG Antibody Tests
- Total Antibody (IgM, IgG, IgA) Tests

Portfolio of Tests for Different Uses, Leveraging a Mixture of Technologies
**How Capacity for Testing Has Scaled in the U.S.**

<table>
<thead>
<tr>
<th>THEN</th>
<th>NOW</th>
</tr>
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</table>

- Total testing in U.S.: 95\(^2\)
- CDC’s molecular test had only FDA Emergency Use Authorization (EUA)\(^5\)
  - 22 additional molecular EUAs by **end of March** but no other types of tests

- **Total testing in U.S.:** 32.3 million\(^3\)
- Three day rolling testing average: 594,000\(^4\)
  - Capacity at plateau and discrepancy between available test capacity and the actual utilization of the tests

- **FDA EUAs for Tests\(^5\)**
  - Molecular Tests including LDTs: 130
  - Antigen Tests: 1
  - Serology Tests: 23
  - Tests for Management of Patients: 1

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4. [https://covidtracking.com/data/us-daily](https://covidtracking.com/data/us-daily)
Examples of Barriers to Scale That Were Overcome

**Swabs**
- One of the first significant bottlenecks—lack of swabs to take samples
- April 2020-DOD awarded $75.5M through the Defense Production Act to Puritan Medical Products

**Viral Transport Media (VTM)**
- VTM tubes-holds the swab after a patient is sampled, preserving it for lab testing
- May 2020-partnered with HHS to provide up to 170M VTM tubes by December

**Test Kits**
- States needed additional molecular tests with assured supply
- May 2020-supplied Strategic National Stockpile with 7.4M test kits that were distributed to states
Case Study: Enabled Rapid Stand-Up of 4 Labs in the State of Ohio in 11 Days

**Actions**

1. Partnered with Ohio Dept. of Health and university/hospital directors to identify testing sites in four major metropolitan areas.


3. Fast-tracked help with instrumentation, supplies, installation, training, and validation.

**Results**

<table>
<thead>
<tr>
<th>Starting point (April 4, 2020)</th>
<th>Full implementation (April 14, 2020)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Only 2,000 samples/week</td>
<td>Enabled four high-throughput testing sites to achieve 20,000 samples/week</td>
</tr>
</tbody>
</table>

**Rapid lab transformation**

- Collaborated with Ohio National Guard to redeploy six Applied Biosystems™ 7500 Fast Dx Real-Time PCR Systems and three Thermo Scientific™ KingFisher™ Purification Systems

- Stood up testing centers at Cleveland Clinic, Ohio State University, and University Hospital of Cincinnati

**Testing is underway**

- Applied Biosystems™ TaqPath™ COVID-19 Combo Kits

- Six 7500 Fast Dx Systems

- KingFisher Purification Systems

**Quick expansion**

- Expanding into six additional sites throughout Ohio

- On track to achieve 120,000 samples/week (60x increased capacity)

Industry and government collaborated to exponentially increase testing capacity.
Case Study: Rapid Stand-Up of 3 Labs in the UK 0 to 100K samples per day in 6 weeks

**Actions**

1. Partnered with UK government to build and enable three centralized labs to run 100K COVID-19 tests per day
2. Facilitated gathering of required instrumentation from our UK customer network with 24/7 service engineers, application scientists for support/training to have labs up and running
3. Created a bespoke consumables supply chain support team to cover 3 centralized labs and wider UK network of testing labs

“Thermo Fisher’s expertise has been vital in our work from the outset”
-- Site Director of a UK Lighthouse Labs

**Results**

<table>
<thead>
<tr>
<th>Starting point (March 19, 2020)</th>
<th>Full implementation (April 30, 2020)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 samples per week</td>
<td>Enabled three high-throughput testing sites to achieve 100,000 samples/day combined</td>
</tr>
</tbody>
</table>

**Rapid lab creation**
- Facilitated Army/Navy/RAF to collect >100 Applied Biosystems™ 7500 Fast Dx Real-Time PCR Systems and >40 Thermo Scientific™ KingFisher™ Purification Systems from our customer network
- Labs created in Milton Keynes, Manchester and Glasgow

**Innovating to Solve Problems**
- Significant lab and supply chain logistics problem solving activities over many weeks with a cross divisional and functional teams
- Testing protocol updates implemented to enable product supply to match lab demand

**Continuing to Evolve and Collaborate**
- Additional instruments supply to balance unit ratios maximizing efficient workflows
- Preparing for phase 2 population monitoring, border control and back to work testing needs. Lab expansion and decreased volunteer workers.

Thermo Fisher Scientific and Government collaborated to rapidly build incredible testing capacity.
Different Types of Use Cases for Testing

<table>
<thead>
<tr>
<th>Symptomatic Patients</th>
<th>Population-Based Screening</th>
<th>Targeted Group Testing</th>
<th>Vaccine and Treatment Development</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Objective</strong></td>
<td></td>
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</tbody>
</table>
| • Quickly diagnose and treat | • On-going, systematic tracking and monitoring spread of virus | • Screen large but specific groups of people  
• Examples include back to work and back to school | • Screen for clinical trials for potential vaccine and therapeutics  
• Measure long term efficacy and immunity |
| **Type of Testing**  |                             |                        |                                  |
| • Molecular  
• Antigen | • Molecular  
• Antigen  
• Serology | • Molecular  
• Antigen  
• Serology | • Serology |
Challenges to Keeping the Economy Open

• COVID-19 will continue to be a threat until vaccines are fully scaled or therapies become available.
• The timeline for vaccine development may be 12 or more months away, and scaling vaccine penetration to sufficient levels will likely take multiple years.
• Asymptomatic carriers are a key concern: according to CDC, about 20 million Americans—nearly 6% of the population—have been infected. This is about 10 times the 2.3 million cases that have been confirmed.

• Temperature screening at the workplace provides false assurances—study highlighted 70% of patients sick enough to be hospitalized did not have fevers and it will miss at least 86% of infected individuals.2
• Even symptom screening done daily, identifies only about half of infected individuals, but days after they became contagious due to period from infection to symptoms.2

# How Can We Prepare for the Future

## Factors to Consider

<table>
<thead>
<tr>
<th>Factor</th>
<th>Consideration</th>
</tr>
</thead>
<tbody>
<tr>
<td>FDA Flexibility</td>
<td>Early engagement with the private sector and providing regulatory flexibilities are key to producing effective and scalable tests in the quickest amount of time.</td>
</tr>
<tr>
<td>Test Coverage</td>
<td>Strengthen coverage &amp; reimbursement, and ease ordering by eliminating the need for a physician’s signature.</td>
</tr>
<tr>
<td>Supplies</td>
<td>Ensure the adequate and sufficient supply of products for testing, treatments and vaccines.</td>
</tr>
<tr>
<td>Home Testing</td>
<td>Increase access to testing while eliminating potential exposure to other people.</td>
</tr>
<tr>
<td>Track and Trace</td>
<td>Quickly stand up effective contact tracing to significantly decrease infections.</td>
</tr>
<tr>
<td>Flu Season</td>
<td>Healthcare systems will need to prepare for the convergence of two life threatening infectious diseases that greatly impact the vulnerable populations.</td>
</tr>
</tbody>
</table>

Testing will continue to play a crucial role as we all try to get back to normal.
COVID-19 Testing: The science, the employer, and the reality

Wendi Mader, MA

July 23, 2020
COVID-19: Quest Diagnostics key milestones

MARCH 9
- Quest Diagnostics launches COVID-19 molecular test in two labs using our own lab-developed test (LDT)

MARCH 11
- World Health Organization (WHO) publicly characterizes COVID-19 as a pandemic

MARCH 16-20
- Quest raises testing capacity by offering a high-throughput test (Roche IVD) available across 12 lab locations.
- Quest receives EUA for LDT

May 27
- Quest granted EUA for nasal swab self-collection kits for molecular testing

FEBRUARY 29
- FDA announces independent labs can begin COVID-19 testing while pending Emergency Use Authorization (EUA) approval

APRIL 21
- Quest widely releases an IgG antibody test

July 18
- Quest granted EUA for pooling
Quest Diagnostics support in opening America up

Blueprint for testing

Identify positive COVID-19 cases

- Simplified specimen self-collection under supervision of an HCP
- Anterior nares and Mid Turbinate
- Unsupervised home collection
- Anterior nares
- High throughput molecular testing platforms

Public health reporting for rapid response program

- High-risk exposure contacts (e.g., close contacts)
- Healthcare worker contacts
- Contacts who work with or are part of a vulnerable population
- A high volume of low-risk contacts

Identify spread of virus

- Identify those who have already been infected by testing for presence of IgG antibodies
- Easy blood collection from our 2000 patient service centers

Return-to-work

- Medical Protocols & Testing
- Employee Safety & Wellness
- Office & Site Standards
- Employee Policies & Norms
- CDC Guidelines
- External Benchmarks
- State Directives
- Metrics
Testing considerations for the employer

Consider a customized solution

- Start with a customizable program aligned with CDC return-to-work guidance developed for healthcare workers
- This guidance includes
  - Time-based strategy of allowing employees to return to work 10 symptom-free days after a positive diagnostic test result, or
  - Test-based approach that includes 2 negative COVID-19 diagnostic tests completed at least 24 hours apart
- Elements such as antibody testing can be added based on specific company needs.

Not all SARS-CoV-2 (COVID-19) tests are high quality

- It isn’t enough to simply identify tests that have received FDA emergency use authorization (EUA)
- Clinician-guided care and interpretation is also important
- Remember: even in the best of circumstances, no test is 100% perfect

Effective testing requires a wrap-around solution

- You may need questionnaires for employees to take and/or contact tracing
- If offering on-site testing events, you may need to secure PPE and be well-versed in COVID-19 cleansing practices
- You may need to become familiar with technologies to provide SARS-CoV-2 test results securely to employees and required public health entities
- Providers that offer agile, comprehensive solutions are critical to creating effective programs
## Quest Return-to-work (RTW) solutions: scenarios for consideration

<table>
<thead>
<tr>
<th>Quest RTW Solution</th>
<th>SARS-CoV-2 (COVID-19) molecular (on-site or self-collected*)</th>
<th>SARS-CoV-2 (COVID-19) IgG Antibody (Serology)</th>
<th>On-site Services and Employee Safety</th>
</tr>
</thead>
</table>
| Basic RTW program  | ✓ Molecular for symptomatic and high-risk exposures       | ✓ IgG Serology for high-risk individuals (e.g., COPD, Chronic Disease, elderly in the home) | ✓ On-site temperature monitoring  
  ✓ Employee COVID application for triage into care  
  ✓ Physician oversight, telemedicine consult and state DOH reporting |
| RTW program with surveillance | ✓ Molecular mandatory for RTW  
  ✓ Periodic molecular surveillance based on risk / job category | ✓ IgG Serology for all employees (when prevalence in population is >5%) | ✓ Addition of contact tracing and infection control applications and analytics |
| Comprehensive RTW Program | ✓ Addition of antigen or molecular surveillance POCT  
  ✓ Mandatory molecular retesting surveillance | ✓ <5% Local Seroprevalence: consider use of >1 IgG test (2 different test antibodies on 2 separate occasions to improve True Positive rates of results) | ✓ Return-to-work playbook services |

*This at-home self-collection kit has not been FDA cleared or approved. This test has been authorized by FDA under an EUA for use by authorized laboratories.
SARS-CoV-2 (COVID-19) Return-to-work program – molecular testing

How does the program work?

- Employee is screened for SARS-CoV-2 risk/exposure via digital questionnaire
- If at risk, employee orders a SARS-CoV-2 self-collection kit
- Employee completes self-collection and receives results online
- If employee tests positive, they are contacted by our physician network and routed into care
- Employee who tested positive can be offered follow-up SARS-CoV-2 (COVID-19) testing after quarantine period is complete
- Employees who test negative are lower risk to return to work but still have some risk
  - All return-to-work policies are at the employer’s discretion; Quest Diagnostics does not provide suggestions for when employees should be deemed ready to return to work
  - This is one suggestion; the employer needs to consult their own experts in designing their program
SARS-CoV-2 molecular: potential protocol for reporting results

Getting participants the results as quickly as possible

- Positive results will receive a call from a PWNHealth physician
- Other results will be delivered online

- Routine confirmatory testing of positive samples by the CDC or state health labs is no longer required (unless requested by a PH agency).
- Our test has met FDA requirements for positive and negative sample comparison

- Results will automatically be sent to appropriate public health agencies

- Employees will receive results in the same way they typically receive results for other employer population health solutions
- Online access to a PDF of results
SARS-CoV-2 (COVID-19) Return-to-work program – antibody testing

How does the program work?

- Employee able to schedule SARS-CoV-2 IgG antibody testing at a Quest Patient Service Center (PSC)
- Employee attends PSC appointment for a venipuncture blood draw
- Employee receives results online and receives paper results report in the mail
- Employee who tests positive may be considered fit to return to work by the employer
  - All Return-to-work policies are at the employer’s discretion; Quest diagnostics does not provide suggestions for when employees should be deemed ready to return to work
- On-site testing available for employers with 500+ employees at the worksite
Return-to-work for any organization

Implementation
- Program design – analytics and consultation
- Program Consent
- Employee Questionnaire

Testing Solutions
- On-site Resources
- Community Events
- Medical Oversight
- PSC Access

Results
- Billing
- Employer Analytics
- Employee Results and Care
Return-to-work testing programs: examples

<table>
<thead>
<tr>
<th>Employer 1</th>
<th>Employer 2</th>
<th>Employer 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>20,000+ lives</td>
<td>750,000+ lives</td>
<td>45,000+ lives</td>
</tr>
</tbody>
</table>

- Biomedical Manufacturing and R&D
- Symptomatic employees offered self-collection kits
- Sales representatives required to return to hospitals offered self-collection kits
- Observed self-collection for manufacturing locations
- Antibody testing offered to all employees

- Distribution center model
- Employer-observed self-collections onsite
- Symptomatic individuals to start
- Moving to a surveillance program as workers are in proximity with each other on a regular basis & outbreak could cause a temporary facility closure

- Large commercial airline
- Onsite IgG antibody testing & PCR in combined setting at 3 terminals
- Plan to implement a PCR collection program at all major hubs for ongoing testing of symptomatic employees

**Questions to ask as you plan your Return-to-work testing strategy:**

- What type of testing is best for your organization?
- How do employees qualify for a test?
- Are you/your testing vendor(s) compliant with local and state reporting guidelines?
- Do you have the proper consent in place prior to test for EHS/HR to receive employee results?
- Do you have an outline of when employees can return to the office based on different test results and scenarios?
Experience:
- 20 years of experience collaborating with thousands of employers
  - Work with 5,500 employers and screen over 3.5M individuals each year
  - Currently working with nearly 600 employers on COVID-19-related Return-to-work solutions
  - Strategic partnerships for health intervention programs and data integration

Expertise:
- A medical and scientific staff of more than 600 MDs and PhDs
  - Quest LDT and commercial platforms for SARS-CoV-2 molecular testing
  - Independent verification of IgG antibody tests
  - As of June 22, Quest has completed more testing than any other lab provider across our network of laboratory processing facilities nationwide: over 5 million COVID-19 diagnostic tests and over 2 million antibody tests
For more information on SARS-CoV-2 (COVID-19) testing and employer population health solutions, visit https://www.QuestForHealth.com
SARS CoV-2 (COVID-19) molecular (NAAT) from Quest:
Analytical sensitivity, clinical performance, and specificity for Test code 39448

<table>
<thead>
<tr>
<th></th>
<th>Quest LDT</th>
<th>Roche IVD</th>
<th>Hologic Panther® Fusion IVD</th>
<th>Hologic Panther® IVD</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Analytical sensitivity:</strong> Limit of detection (LOD)*</td>
<td>• 136 copies/mL for both N1 and N3 targets</td>
<td>• Target 1 - 0.009 TCID50/mL</td>
<td>• 0.01 TCID50/mL</td>
<td>• 0.01 TCID50/mL</td>
</tr>
<tr>
<td>Use 20 replicates</td>
<td>*The lowest concentration at which 19/20 replicates are positive (95%)</td>
<td>*The lowest concentration at which 19/20 replicates are positive (95%)</td>
<td>*The lowest concentration at which 19/20 replicates are positive (95%)</td>
<td>*The lowest concentration at which 19/20 replicates are positive (95%)</td>
</tr>
<tr>
<td><strong>Clinical performance</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PPA</td>
<td>NPA</td>
<td>PPA</td>
<td>NPA</td>
<td>PPA</td>
</tr>
<tr>
<td>30/30= 100%</td>
<td>30/30= 100%</td>
<td>50/50= 100%</td>
<td>100/100= 100%</td>
<td>69/69= 100%</td>
</tr>
<tr>
<td></td>
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<td></td>
<td></td>
<td>109/109 =100%</td>
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<td></td>
<td>50/50= 100%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>55/54= 98%</td>
</tr>
<tr>
<td><strong>Specificity:</strong> no cross-reactivity with other respiratory pathogens</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
</tr>
</tbody>
</table>

Note: Positive Percent Agreement (PPA) and Negative Percent Agreement (NPA)

Self-collection for SARS-CoV-2 (COVID-19) molecular (NAAT) to provide a consumer-friendly, scalable testing solution

- Self-administered sample collection
- Nasal (anterior nares) foam swab
- Room temperature shipping
- Implemented with provider observation nationwide
- Available for un-observed consumer collection (pending FDA authorization)
- Integration with telemedicine services and reporting

Anterior Nares Swab, Self-Collection Kit for COVID-19

Instructions sample

Welcome to Self-Collection


**Read First for your Safety**

- Do not use if you are under the age of 18 years old without adult supervision, on blood thinners, or have had a previous trauma to your nose.
- Read the instructions carefully before starting.
- Once the swab is inserted, your nose may feel very taut. If you feel pain at any time during your collection, stop and call your doctor to guide you with your collection.
- Do not use the liquid in the tube to treat the swab, or to lubricate your nose. Do not drink the liquid.
- Do not touch the swab tip with your finger or with anything else except your nose and the tube liquid. If the swab tip touches anything, then contact Quest Diagnostics at 1-800-332-2013 for another swab.
- Do not use swabs on more than one person. Sharing a swab with someone else can cause an infection.

**Read all instructions before starting your COVID-19 Self-Collection.**

Failure to follow instructions may lead to incorrect test results.

**Before you begin**

Visit fedex.com/labelreturn to view drop box locations. Be sure to bring your sample to a drop box on the same day you collect it before 3:00 PM. DO NOT drop sample into a drop box on Saturday or Sunday.

If you have any questions, please call 1-855-332-2531.

**Kit contents**

![Image of kit contents]

- **Test requisition (pre-printed)**
- **Swab (in a wrapper)**
- **Bag (containing a dehydrant)**
- **Box**
- **Tube (containing liquid)**
- **FedEx® label (pre-printed) and white bag**

**Read all instructions before starting.**

1. **Open the kit. Lay all the materials on a clean surface.**

2. **Locate and sign the test requisition. Verify your name and barcode are correct, and call 1-855-332-2013 if anything is incorrect. Complete the Date and Time Collected lines on the test requisition. Your sample may be rejected if you fail to complete date and time on the requisition.**

3. **Wash and dry your hands.**

4. ** Peel off the label with your name and date of birth from the bottom of the test requisition and place it on the tube.**

5. **Remove the swab from the package and do not touch the tip of the swab. Open the specimen tube, holding it in one hand and the swab in the other hand. Do not split or drip the liquid.**

6. **Insert the swab into one nostril, about one inch. Rotate the swab in a circular motion around the entire inside edge of the nostril. Do this 2 times and then keep it in place for 15 seconds. Repeat the same process in the other nostril using the same swab.**

7. **Insert the swab into the tube (tip first) until it reaches the bottom. Then pull the swab handle against the side of the tube at perpendicular breaks point.**

8. **Screw the cap onto the tube and place the tube into the bag. Treat the bag; important; Do not remove the desiccant (white sheet) from the bag.**

9. **Place the collection bag and test requisition in the box and close the lid. Place the box into the white return shipping bag, seal it, and apply the FedEx® label to the outside of the bag. DO NOT cover the UN3373 marking.**

10. **Drop the postage-paid FedEx return bag at a drop box location the same day you collect it, before 3:00 PM. DO NOT drop your specimen package in a drop box on a Saturday or Sunday.**

The Quest, Roche and Hologic tests and the self-collection kit (together the “molecular tests”) have not been FDA cleared or approved;

- The molecular tests have been authorized by FDA under an EUA for use by authorized laboratories;
- The molecular tests have been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens; and,
- The molecular tests are only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner. 
**Quest tests offered for SARS-CoV-2 IgG are extensively validated by the manufacturer and verified by Quest R&D**

FDA EUA, lab-based, high-throughput immunoassays that are highly sensitive and specific

<table>
<thead>
<tr>
<th>Sensitivity</th>
<th>Specificity</th>
<th>PPV @ 5% prevalence</th>
<th>NPV @ 5% prevalence</th>
</tr>
</thead>
<tbody>
<tr>
<td>100%</td>
<td>100%</td>
<td>93%</td>
<td>100%</td>
</tr>
<tr>
<td>90%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
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<tr>
<td>88%</td>
<td>100%</td>
<td>100%</td>
<td>99.3%</td>
</tr>
</tbody>
</table>

**Utilize platforms from manufacturers that demonstrate robust manufacturer validation data**

- Quest verifies the performance characteristics of the platforms by doing CLIA/CAP-required in-laboratory validations using stringent acceptability criteria for precision, reproducibility, accuracy, method comparison, cross-reactivity, and clinical performance before starting patient testing.

- 100% qualitative concordance, and % coefficient of variance (CV) <15% for the positive specimens.

- Specificity of 100% by testing a panel of specimens positive for other respiratory infections.