Sensitivity Results for the Abbott m2000 PCR Assay of SARS-CoV-2 at a Denver, Colorado Medical Center

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Background

- Abbott received an Emergency Use Authorization on March 18, 2020 for its RealTime SARS-CoV-2 assay for use on the m2000 system to detect SARS-CoV-2 nucleic acid in nasopharyngeal (NP) and oropharyngeal (OP) specimens.
  - Denver Health Medical Center's Department of Pathology and Laboratory Services validated this assay in late March 2020 for the same specimens.
- At this time, no published data exists on the performance characteristics of the assay.

Methods

- Denver Health serves >30% of Denver's population and includes a 550-bed public safety-net hospital.
- From Mar 19-Apr 21, testing was limited to inpatients and outpatients presenting with symptoms consistent with SARS-CoV-2.
- On Apr 22, universal testing began on all admitted patients, regardless of symptom presentation.
- On May 2, testing began of asymptomatic outpatients prior to time-sensitive urgent procedures.
- We evaluated the sensitivity and negative predictive value for tests conducted Mar 19 through Jul 14, using a surrogate method defined as:
  - False negative: person who had an initial negative test followed by a positive test within 7 days OR within 14 days
  - True negative: person who had two initial consecutive negative tests within 7 days OR within 14 days
  - True positive: person who had an initial positive test

Results

- There were 21,596 tests performed on 17,668 individuals during the study period.
  - 16,392 tests did not meet the criteria for a result category and were excluded.

Test Results Based on Surrogate Methodology

Test Result	7-Day Timeframe N (%)	14-Day Timeframe N (%)
False Negative	21/21,596 (0.1)	57/21,596 (0.3)
True negative	467/21,596 (2.2)	825/21,596 (3.8)
True positive	2464/21,596 (11.4)	2464/21,596 (11.4)

Results (concluded)

- Sensitivity (true positives/true positives plus false negatives):
  - 7-day timeframe: 99.2% (95% confidence interval [CI]: 98.9-99.5)
  - 14-day timeframe: 97.7% (95% CI: 97.1-98.3)
- Negative predictive (true negatives/true negatives plus false negatives):
  - 7-day timeframe: 95.7% (95% CI: 93.4-97.3)
  - 14-day timeframe: 93.5% (95% CI: 91.7-95.5)

Limitations

- Although PCR assays are known to have a low false positive rate, our assumption of no false positives may be incorrect. However, in the absence of a true gold standard comparator, we could not calculate test specificity.
- Testing asymptomatic patients may artificially inflate the true negative results and therefore the negative predictive value.
- Results are dependent upon the quality of specimen collection, preservation, transportation, and handling, and there could have been a breach in any of these steps for a given specimen.

Conclusions

- Accounting for repeat testing in a short, 7- or 14-day timeframe lends credibility to the sensitivity and negative predictive value results.
- Given lack of published gold standard data on SARS-CoV-2 PCR assays, we are confident that infection can be reliably ruled in and out using our surrogate methodology, allowing providers to confidently use the results to make clinical and infection prevention management decisions.