## Survey: COV2103

A set of three unknown samples was sent to each testing laboratory/site. Laboratories were instructed on how to obtain the sample from the tube as to simulate a nasopharyngeal swab.

Samples were checked for stability for the duration of the survey until the last result set was reported.

Results were reported using CMPT data entry portal.

## Results

**Table 1.** Results obtained by the different testing sites.

| Test Method | Reported | COV2103-1 (Strong Positive) | COV2103-2 (Mid Positive) | COV2103-3 (Negative) |
|---|---|---|---|---|
| **Antigen** | Positive | 8 (Acceptable) | 3 (Acceptable) | 0 |
| | Negative | 2 (Unacceptable) | 7 (Unacceptable) | 10 (Acceptable) |
| | Inconclusive | | | |
| **Ag Total** | | **10** | **10** | **10** |
| **Nucleic Acid** | Positive | 12 (Acceptable) | 13 (Acceptable) | 0 |
| | Negative | | | 12 (Acceptable) |
| | Inconclusive | 1 (Unacceptable)* | | 1 (Ungraded)** |
| **NA Total** | | **13** | **13** | **13** |
| **Grand Total** | | **23** | **23** | **23** |

* No explanation given by lab for inconclusive result

** Acceptable explanation given by laboratory

## Commentary

This group of samples was randomly selected and randomly ordered from material pre-determined to be either Strongly Positive, Mid-Range Positive, or Negative (for RNA or Protein Antigen). The expected semi-quantitation was confirmed by internal Quality Control.

The samples were sent from CMPT to both Private and Public Sector laboratories. Within the Public Sector sites, the samples went first to a Health Authority Hub who in turn sent the samples onto individual testing sites.

The interval between the testing sites receiving the samples and testing the samples ranges from 0-6 days. The interval did not appear to have an impact on results determination.

The two predominant testing methods include Abbott ID Now (Nucleic Acid) and Abbott PanBio (Antigen). Additional methods were also used and included in the results but were present at a sufficiently low number that they could not be fairly analyzed by brand within the larger pool. As the number of test sites increases, the additional methods will be identified if their number increases.

The results indicate an overall acceptable performance for Rapid Antigen Testing of 21 out of 30 (70%) with all unacceptable performances reported as False Negative. No False Positive results were reported.

For detection of the presence of RNA, the results were better with acceptable performance reported in 27 out of 29 samples (93.1%). For two samples, they were reported as "inconclusive". One laboratory provided an explanation and the sample was ungraded. The other laboratory provided no explanation and was graded as unacceptable.

The results require a certain degree of closer examination, especially since this is the first round of testing and many of the results may not have been performed by laboratory trained personnel.

Tests performance needs to be considered by their clinical analytic sensitivity, the ability to detect clinically relevant samples, and also by detection limit, where the antigen may be present but below the level the test is capable to detect. (1)

The two levels of positivity selected for this round of EQA testing were well within the detection limit of the test. The high level of False Negative results was not due to the sample being below the detection limit of the Abbott Panbio test, provided that the sample was collected properly and the kit was used as specified by the manufacturer. It was noted that test errors were found with both High Positive (Strong) and Mid-Positive samples. While antigens may degrade if left at room temperature, it was noted that none of the False negative results were in the group that had sat untested for up to 6 days.

Another explanation may be that the visualization of the Mid Positive samples tested on lateral flow cartridges requires good lighting and may require the full fifteen minutes of incubation. The test instructions make it clear than any clear and distinct line regardless of intensity should be read as positive.

Another contributing factor could have been that the tester was required to collect the sample out of a conical shaped tube and onto a swab. Although the tubes had ample material, if the tester did not attempt to completely load the swab, then it is possible that there was insufficient material on the swab which resulted in a False Negative result. This would be the equivalent of

testing a swab sample that was not taken from the nasopharynx. Testers need to sweep the swab through the sample with the intent to get as much on the swab tip as possible.

Because of the multiplication of the target by molecular techniques, detection limits issues may not result in False Negatives, but may represent another type of problem with test interpretation

## In summary

Facilities using Rapid Antigen Testing had a greater number of False Negative results that could not be explained solely by the content of the test samples. This may suggest some concerns with respect to sample handling and/or testing technique.

## Reference

(1) Saah AJ, Hoover DR. "Sensitivity" and "specificity" reconsidered: the meaning of these terms in analytical and diagnostic settings. Ann Intern Med. 1997 Jan 1;126(1):91-4. doi: 10.7326/0003-4819-126-1-199701010-00026. PMID: 8992938.