Survey: COV2107

A set of four challenge 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.

Expected results

COV2107-1: Negative

COV2107-2: Positive

COV2107-3: Negative

COV2107-4: Negative

Results

Table 1. Results obtained by the different testing sites.

Method	Reported	COV2107-1	COV2107-2	COV2107-3	COV2107-4
Antigen	Positive		15 (Acceptable)		
	Negative	16 (Acceptable)	**1 (Unacceptable)**	16 (Acceptable)	16 (Acceptable)
Ag Total		**16**	**16**	**16**	**16**
RNA	Positive		14 (Acceptable)		
	Negative	15 (Acceptable)	**1 (Unacceptable)**	12 (Acceptable)	14 (Acceptable)
	Inconclusive*			**3 (Unacceptable)**	**1 (Unacceptable)**
RNA Total		**15**	**15**	**15**	**15**
Total		**31**	**31**	**31**	**31**

*No specific comments added.

Commentary

This group of samples was randomly selected and randomly ordered from materials pre-determined to be either Strong Positive, or Medium Positive or Negative (for RNA or Protein Antigen). Note in this panel of 4 samples, one was strong positive and three were negative. The expected semi-quantitation was confirmed by internal Quality Control by multiple testing by multiple testers.

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 0-7 days. The interval did not appear to have an impact on results determination.

The two predominant testing methods include Abbott ID Now (Nucleic Acid Amplification) and Abbott PanBio (Antigen Detection). 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 a good overall performance for Rapid Antigen Testing of 63 out of 64(98%) with only one unacceptable performance reported as False Negative.

For detection of the presence of RNA, the results also good with acceptable performance reported in 55 out of 60 samples (92%). There were five samples reported “Inconclusive”, all of them using the ID NOW system. None of the testing sites specify reasons for that report.

Note that the US Food and Drug Administration, (MAUDE Adverse Event Report: ABBOTT DIAGNOSTICS SCARBOROUGH, INC. ABBOTT ID NOW REAGENTS, 2019-NOVEL CORONAVIRUS NUCLEIC ACID: Last updated 07/31/2021) recommends the following: "an inconclusive result is most likely an indication of virus present near the limit of detection and should be treated as a result of detected". These four inconclusive results are considered as ***unacceptable*** and ***probable false positives***, with the cause of error undetermined. The possibility of contamination resulting from **COV2107-2** should be excluded.

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