Survey: COV2201

A set of four 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.

Expected results

COV2201-1: Positive

COV2201-2: Positive

COV2201-3: Negative

COV2201-4: Negative

Results

Table 1. Results obtained by the different testing sites.

Method	Reported	COV2201-1	COV2201-2	COV2201-3	COV2201-4
Antigen	Positive	52 (Acceptable)	41 (Acceptable)		3 (Unacceptable)
	Negative	1 (Unacceptable)	12 (Unacceptable)	53 (Acceptable)	50 (Acceptable)
	No report	2 (Unacceptable)	2 (Unacceptable)	2 (Unacceptable)	2 (Unacceptable)
Ag Total		**55**	**55**	**55**	**55**
RNA	Positive	32 (Acceptable)	32 (Acceptable)		
	Negative			34 (Acceptable)	34 (Acceptable)
	Inconclusive	3 (Unacceptable)	3 (Unacceptable)	1 (Acceptable)*	1 (Acceptable)*
RNA Total		**35**	**35**	**35**	**35**
Total		**90**	**90**	**90**	**90**

* Lab that reported "inconclusive" due to lack of RNaseP.

Commentary

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

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 0-8 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 a good overall performance for Rapid Antigen Testing of 196 out of 212 (92%). Most of the issues with the Rapid Antigen group continue to be the detection of a medium positive sample; there was a 24% of false negative reported. For the first time there were 3 false positives reported in this group.

For detection of the presence of RNA, the results were really good with acceptable performance reported in 134 out of 140 samples (96%). There were three positive samples reported “Inconclusive”, all of them using the ID NOW system. Various explanations were given for inconclusive results, like “query procedural control fail”, “likely technique error”, “short sample”, or “unknow issue”.

One lab reported the two negative samples as “inconclusive”. This report was graded “Acceptable” as the methodology used by this lab detects RNAse P gene as a test indicator for sample integrity. CMPT samples for COVID-19 testing include human epithelial cells as source of the gene. Some commercial kits have difficulty measuring the presence of this gene at the levels present in CMPT samples. CMPT will not downgrade an indconclusive answer based on lack of detection of human RNAse P gene

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