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ANTIGEN TEST COMPARATOR STUDY

Tests for SARS-CoV-2, the virus that causes CoVid-2 disease, are classified as either diagnostic or screening. The definitive "gold standard" diagnostic test is performed by polymerase chain reaction (PCR) performed in a clinical laboratory setting. Screening tests for the detection of vital antigen provide results within 15-20 minutes. The INDICAID™ COVID-19 Rapid Antigen Test was evaluated and compared to definitive PCR test results and to the BinaxNOW™ and *CareStart*™ rapid antigen tests.

Five hundred specimens (250 positive and 250 negative), previously tested by PCR, were selected and run on three different antigen tests. Compared to PCR results, the specificity (true negative results) was 100% for all antigen tests. The sensitivity (true positive results) was 92.2% for INDICAID™, 78.8% for BinaxNOW™, and 61.2% for *CareStart*™. This data is summarized in the table below. In addition to the tests' performance, several other differences that affect operational feasibility are noted. As a result of this study it was concluded that the INDICAID™ test is superior and compares favorably to a PCR test.

	INDICAID™ COVID-19 Rapid Antigen Test		***CareStart*™ COVID-19 Antigen Home *Test***		**BinaxNOW™ COVID-19 Ag Card**	
Breakout Quantities of Samples Tested	*Positive 239*	*Negative 261*	*Positive 186**	*Negative 307***	*Positive 218*	*Negative 282*
Acceptable Sensitivity (>90%)	✓	92.2%	✗	61.2%	✗	78.8%
Specificity (100%)	✓	100% PPA 84.4%, NPA 96.3%	✓	100% PPA 87%, NPA 98%	✓	100% PPA 75%, NPA 92%
Collection Method: Anterior Nasal Swab	✓		✓		✓	
Capable of Sample Batching	✓	Run within 2 hours	✓	Run within 4 hours	✗	Run immediately
Buffer Suitable for Additional Testing	✓		✓		✗	Buffer inactivates virus particles
Simple Storage	✓	2-30°C	✓	1-30°C	✗	2-30°C 15-30°C 1hr before collection

*Seven invalid specimens **Three invalid specimens
2% of the tests performed with the *CareStart*™ kit in this study resulted as "invalid" and were not included in the statistical calculations.

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