STRYKER AG™

For Universities, Hospitality, Airports and ALL Businesses.

Enterprise Level Cloud Based POC to Client to Laboratory Automation System

FAST

ORAL RAPID

ACCURATE

ULTRA CAPACITY

- Laboratory Developed
- No Special Equipment Necessary
- Backed by Global Validations USA

ORAL RAPID ANTIGEN TEST

The STRYKER Lateral Flow Antigen (LFA) test is a Point-of-Care (POC) test intended for the qualitative detection of SARS-CoV2 antigen from oropharyngeal swabs collected by a healthcare provider, qualified and trained clinical laboratory personnel specifically instructed and trained in the techniques of collection and interpretation.

STRYKER AG is an in vitro diagnostic test that is manufactured by Covid Antibody Diagnostics, LLC.

CE Mark October 21st, 2020

USA Manufactured

For Immediate Export

The Test provides preliminary test results. Negative results don't preclude SARS-CoV-2 infection and they cannot be used as the sole basis for treatment or other clinical management decisions.

Box Contains:
20 Individually Sealed Cassettes
20Reagents
20 Oral Swabs

Capacity:
Oct 2020 - 500,000
Nov 2020 - 3,000,000
Dec 2020 - 9,000,000
Jan 2021 - 27,000,00
Feb 2021 - 54,000,000

SENSITIVITY 91.3% SPECIFICITY 100.0%

STATISTIC	VALUE	95% CI
Sensitivity	95.45%	77.16% to 99.88%
Specificity	100.00%	93.28% to 100.00%
Positive Likelyhood Ratio		
Negative Likelyhood Ratio	0.05	0.01 to 0.31
Disease Prevalence (*)	4.00%	
Positive Predictive Value (*)	100.00%	
Negative Predictive Value (*)	99.81%	98.73% to 99.97%
Accuracy (*)	99.82%	94.84% to 100.00%
Total Positive Patients	21/23	

True Positive	21/23
False Negative	1/22
False Positive	0/21
True Negative	1/53
Total Negative Patients (Negative Tested) 118 115/118	

(*) Values are dependent on disease prevalence

This test has not been FDA cleared or approved. Ongoing clinical evaluation and other information is available upon request. The test has not been authorized by the FDA for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens of in vitro diagnostic tests for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1).

RAPID ANTIGEN TEST

ORAL POINT-OF-CARE

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