آغا خان یونیورسٹی ہسپتال
The Aga Khan University Hospital

THE AGA KHAN UNIVERSITY HOSPITAL
CLINICAL LABORATORIES

UPDATE
SARS-CoV2 Automated Antigen Test

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INTRODUCTION
The SARS-CoV2 automated antigen detection test can improve efficiency of the testing strategy by reducing the turnaround time of results. In hospital settings, automated antigen tests can identify infected patients rapidly, leading to rapid segregation at triage and isolation. This test identifies the presence of the SARS-CoV2 in the specimen through the detection of *nucleocapsid protein antigen,* which is detectable in upper respiratory specimens during the acute phase of infection.

TEST PRINCIPLE:
The SARS-CoV-2 Automated Antigen Test is a direct two-step sandwich chemiluminescence immunoassay (CLIA) for the qualitative detection of nucleocapsid antigens of SARS-CoV2 present in the human upper respiratory tract in individuals suspected of having COVID-19 infection.

Performance Characteristics:
The clinical performance of the LIAISON SARS-CoV-2 Ag on symptomatic and asymptomatic subject was established using a comparator method (RT-PCR) by the manufacturer. The sensitivity established for SARS-CoV2 rapid antigen test using nasal swab was 98%, (95% CI: 93.1 - 99.5%); and specificity was 99.5%, (95% CI: 97.4 - 99.9%) *.

SPECIMEN TYPE:
- Nasal swab collected in inactivation buffer (white cap 1 ml tube)

SPECIMEN COLLECTION, STORAGE AND TRANSPORT:
Nasal swab should be collected from both nostrils using swabs available at the AKUH laboratories. The Nasal swab sample collected in inactivation buffer tube should be transported to AKUH laboratories at 15-25 oC up to 24 hrs. If delay is anticipated, samples should be transported at 2-8 ºC for up to 72 hrs.

Testing Strategies:
- As a Diagnostic test: nucleocapsid antigen in a symptomatic patient, implies current viral infection.
- As a screening test: can be used as a screening test to determine if the individual is infected with SARS-CoV-2 or not, or whether a person who previously was diagnosed with COVID-19 remains infectious.
- For congregate care settings, use of rapid antigen testing may be advised for overall infection control with a rapid turnaround time.

LIMITATIONS:
- A negative result may occur if the concentration of antigen in a sample is below the detection limit of the test or if the sample was collected or transported improperly.
- A negative test result in a symptomatic patient should be confirmed by PCR test.

REJECTION CRITERIA:

- Sample received without inactivation buffer.
- Sample not transported on required temperature.

SCHEDULE AND REPORTING TIME:
For outside referrals: The test will be performed daily (Monday to Sunday) with same day reporting (Cut-off 11 am).
For AKUH in-patient: 4 hours after the sample is received in the Lab.

* LIAISON® SARS-CoV-2 Ag (Diasorin)

PLEASE FILE FOR QUICK REFERENCE