Antigen Testing Frequently Asked Questions

1) What is the name of the MAKO Antigen Test?

Answer: LIAISON® SARS-CoV-2 Ag

2) Who is the manufacturer of the MAKO Antigen Test?

Answer: DiaSorin

3) What instruments is the MAKO Antigen Test run on?

Answer: DiaSorin LIAISON XL utilizing chemiluminescence immunoassay (CLIA) technology

4) What is the sensitivity of the MAKO Antigen Test?

Answer: 97.1% out to 10 days of symptoms

5) What is the Specificity of the MAKO Antigen Test?

Answer: 100% out to 10 days of symptoms

6) What type of collection is required for the MAKO Antigen Test?

Answer: Nasal swab (NS) and nasopharyngeal swab (NPS)

7) What is the turnaround time for the MAKO Antigen Test?

Answer: 24 hours

8) What is the capacity for MAKO Antigen testing?

Answer: 100,000 per day and increasing

9) What is the CPT Code for the MAKO Antigen Test?

Answer: 87426

FAQ's Continued »

10) What does the MAKO antigen test look for?

Answer: Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen. Antigen is generally detectable in upper respiratory specimens during the acute phase of infection. A Negative result may occur if the sample was collected, stored or transported improperly.

11) What does a positive result mean?

Answer: Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. A Positive result does not rule out bacterial infection or co-infection with other viruses.

12) What does a negative result mean?

Answer: Negative results should be treated as presumptive and confirmed with a molecular assay, if necessary for patient management. Negative results do not rule out COVID-19 and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Negative results should be considered in the context of a patient's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19.

13) What is the intended use of this test?

Answer: Individuals suspected to have COVID-19 by their healthcare provider within the first ten days from the onset of symptoms.

14) What are the transportation requirements?

Answer: A dry swab must be used and placed into a MAKO supplied inactivation buffer and then kept at refrigerated temperatures of -2 to 8 degrees Celsius.

15) What is the LOD (limit of detection)?

Answer: LOD= 22.0 TCID50/ml.
It cannot be compared 1:1 to PCR but samples with cycle thresholds of up to 34 were positive (estimated 4,000 copies of Viral RNA) which indicates good sensitivity with low amount of virus.

FAQ's Continued »

16) What is TCID50?

Answer: Tissue Culture Infectious Dose 50%, the gold standard method for the evaluation of viral titers.

17) What are the concentration cutoffs for positive result?

Answer: A result above or equal to 200 TCID50/mL generally indicates presence of the SARS-CoV-2 antigen in the specimen.

18) What is the NPA (formerly, specificity) and PPA (formerly, sensitivity) of your Antigen test?

Answer:

Nasal Swabs

PPA: 97.1% (35 samples ≤10 days from onset of symptons)

NPA: 100% (112 samples)

Reference IFU section 15 for more information

Nasopharyngeal Swabs

PPA: 94.6% (37 samples ≤10 days from onset of symptons)

NPA: 99.5% (112 samples)

Reference IFU section 15 for more information

19) Why was the N-Protein used for Ag testing?

Answer: The nucleocapsid protein antigen is abundant and generally detectable in the upper respiratory specimens during the acute phase of infection.

20) What is the difference between the new LIAISON SARS-CoV-2 Ag and other rapid assays and molecular assays (like the DiaSorin COVID-19 assay available on the MDX)?

Answer: The LIAISON SARS CoV-2 Ag combines a highly accurate In-Lab Antigen test with a high-throughput instrument to support large scale screening of the active virus of COVID-19. Rapid test while faster on a single patient basis (<30mins.) have been seen as a lower accuracy, manual process and low throughput are its biggest disadvantages). These assays also typically do not have optimal performance. (clinical study results reported sensitivity at 56%) At home pregnancy test are an example of a lateral flow assay.

Molecular test, RT-PCR is considered to the Gold Standard, however they were designed for research purposes and are more expensive and don't have as high of throughput as our offering.