A Clungene® COVID-19 antigén gyorsteszt kazetta használata

Allow the test device and specimens to equilibrate to room temperature (15–30 C) prior to testing.

The kit consists of Package Insert, Sterilized Swab, Work Station, Extraction Tube, Dropper Tip, Extraction Reagent and Test Cassette.

Test Procedure

Put extraction tube on the work station.

Unscrew the lid of an extraction reagent. Add all of the extraction reagent into an extraction tube.

Sample collection

Remove the swab from the package.

Orr-garatnyálkahártya kenet minta

Tilt patient’s head back about 70º.

Insert the swab through the nostil parallel to the palate (not upwards) until resistance is encountered or the distance is equivalent to that from the ear to the nostril of the patient.

Gently rub and roll the swab. Leave swab in place for several seconds to absorb secretions.

Slowly remove swab while rotating it.

Száj-garatnyálkahártya kenet minta

Insert swab into the posterior pharynx and tonsillar areas.

Rub swab over both tonsillar pillars and posterior oropharynx and avoid touching the tongue, teeth, and gums.

Insert the swab specimen into the extraction tube which contains extraction reagent.

Roll the swab at least 5 times while pressing the head against the bottom and side of the extraction tube.

Leave the swab in the extraction tube for one minute.

Remove the swab while squeezing the sides of the tube to extract the liquid from the swab.

Cover the extraction tube with a dropper tip tightly.

Remove the test cassette from the sealed pouch. Place the test cassette on a dry, flat surface.

Reverse the specimen extraction tube, holding the tube upright, transfer 3 drops (approximately 100uL) slowly to the specimen well of the test.

Start the timer and wait for colored lines to appear.

Interpret the test results at 15 minutes. Do not read results after 20 minutes.

Az eredmények értelmezése

Positive: Two lines appear.

One colored line appears at the control region (C), and another colored line appears at the test region (T), irregardless of the intensity of the test line.

Negative:

One colored line appears at the control region (C), and no line appears at the test region (T).

Invalid: Control line fails to appear.

Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test using a new test cassette.

MEDICAL WASTE

The used test cassette should be discarded according to federal, state and local regulations!

Limitations

- The product is limited to provide a qualitative detection. The intensity of the test line does not necessarily correlate to the concentration of the antigens in the specimens.

- Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions.

- A physician must interpret the results in conjunction with the patient’s history, physical findings, and other diagnostic procedures.