

DIRECTIONS FOR USE:

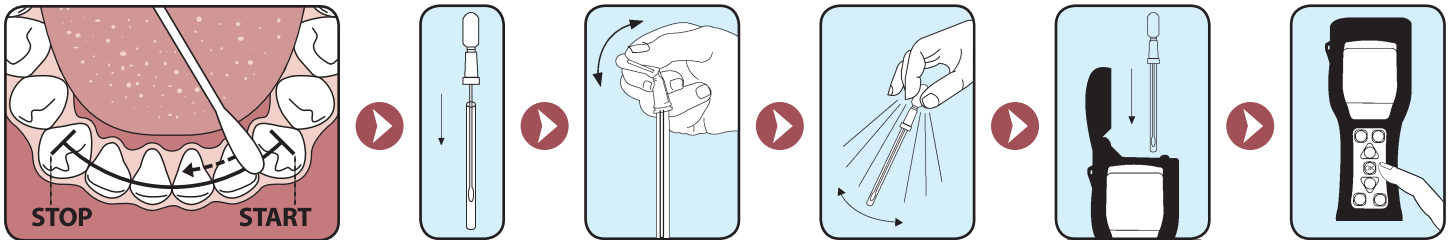
CariScreen Caries Susceptibility Testing Meter and Swabs



GENERAL DESCRIPTION

The CariScreen Swab sampling device is a self-contained ATP device for use with the CariScreen Caries Susceptibility Testing Meter. This system is used as a screening for the presence of dental caries. The CariScreen Meter, in conjunction with the CariScreen Swab, measures adenosine triphosphate (ATP), the universal energy molecule found in all animal, plant, bacterial, yeast,

and mold cells. When ATP is brought into contact with the unique liquid-stable luciferase/luciferin reagent within the CariScreen Swab sampling device, light is emitted in direct proportion to the amount of ATP present. The CariScreen Meter measures the amount of light generated and provides information about the potential levels of cariogenic bacteria present in the biofilm.



1 COLLECTING SAMPLE

When collecting a sample make sure to use aseptic techniques. Do not touch the swab or the inside of the sampling device with fingers.

Holding the swab tube, twist and pull the top of the swab out of the swab tube. The swab tip comes pre-moistened with a detergent. Condensation may be visible on the inside of the swab tube; this is normal. Carefully swab the mid-lingual surface of the lower anteriors from #22 to #27. **Use one firm swipe** across the lingual surface of these teeth, being sure not to contact the gingiva or any soft tissue with any part of the swab. After swabbing the desired test area, place swab back in swab tube. **Once activated, the sample must be read in the meter within 60 seconds.**

2 ACTIVATING DEVICE

To activate the device, hold the swab tube firmly and use the thumb and forefinger to break the snap valve by bending the bulb forward and backward. Squeeze the bulb twice, expelling all liquid down the swab shaft. Bathe the swab bud in liquid by gently shaking for 5–10 seconds.

3 READING RESULTS

Once the CariScreen has been turned on and has self-calibrated, insert the CariScreen Swab device into the CariScreen Meter and close the lid. Press the button labeled "OK," the meter will count down from 15, at the end of which the results can be read. Results should be read within one minute of activation of the CariScreen Swab device. Please refer to the CariScreen Meter manual for operating instructions.

4 INTERPRETING RESULTS

The reading will appear on the screen as a number of RLUs (Relative Light Units 1–9999). Record this number for the patient on the Caries Risk Assessment Form. Values correspond to level of risk as follows:

- 0–1500 = low risk
- 1501–9999 = at risk

5 PRECAUTIONS AND WARNINGS

- The CariScreen reading is one component of a complete caries risk assessment. It is a screening test only and represents just one data point for the patient. Caries diagnosis decisions should include all relevant data points including the caries risk assessment form, risk factors, caries history, bacterial culture results, oral exam, radiographic exam and professional judgment. For the ADA Council on Scientific Affairs risk category parameters for dental caries please refer to http://www.ada.org/prof/resources/pubs/jada/reports/report_fluoride/pdf.
- Hold the CariScreen Meter upright when taking readings.
- Hold the CariScreen Swab device upright when activating.
- Read the CariScreen Swab sampling device within one minute of activation.
- Keep the CariScreen Swab out of direct light when possible.

6 STORAGE

CariScreen Swab sampling devices must be refrigerated at 2–8 degrees C (35–46°F). Sample devices should be left out at room temperature for 2 to 5 minutes before being used.

Do not use if swab is expired.

7 MORE INFORMATION

If more information is required, please contact Oral BioTech at:

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