

## DIRECTIONS FOR USE OF THE:

### CariCult Oral Bacteria Detection System

# CariCult

#### GENERAL DESCRIPTION

The CariCult Oral Bacteria Detection System is used for the collection and screening of oral mutans streptococci by bacterial count, and is used as a validation test in the diagnosis of dental caries. The CariCult Culture Tube is

a disposable plastic tube, the inner surface of which is coated with a special selective culture medium. The cap is specially designed to minimize moisture loss and provide for needed gas exchange during culturing.

#### Prepare the Incubator .....

Prepare the CariCult Incubator as per the Incubator manual. The temperature should be set at 37 C

#### Prepare the Falcon Tube (step 1) .....

Add 2 mL of sterile Transfer Media to a 15 mL sterile blue-capped Falcon Tube.

#### Collect Sample (step 2) .....

Use a provided brush and utilize sterile techniques, that is to say be careful not to contaminate the brush with bacteria other than from the oral environment. **Firmly scrub** (inadequate scrubbing during this step can cause a false negative or low culture result) the brush across the lower anterior teeth back and forth 5 times on the buccal and then 5 times on the lingual surfaces to the mandibular incisors, or 4 alternate teeth.

#### Prepare Sample (step 3) .....

Place the brush containing the patient sample into the prepared Falcon Tube. Mix vigorously by shaking gently or tapping the bottom of the tube about 20 times with your finger (plunking).

#### Prepare Culture Tube (steps 4 & 5) .....

Transfer the liquid contents of the Falcon Tube into the Culture Tube. By carefully pouring the liquid into the Culture Tube, you can manage to leave the brush in the Falcon Tube. Cap the tube and slowly rotate 2 times to completely cover the walls of the tube. Pour out the contents of the Culture Tube into a waste container holding the tube at an angle for 10 seconds until the last drop falls. Recap the tube and prepare a label using tape to identify the patient information. Dispose of the specimen and recap the Falcon Tube containing the brush as infected waste.

#### Incubate Sample (step 6) .....

Place the Culture Tube into the incubator cap down. The tray that the tubes come in makes a great holder in the incubator. Incubate the sample at 37 C for 18-24 hours.

#### Read the Results (examples on back) .....

After incubation, examine the Culture Tube and compare the results to the standardized photographs of the tubes for low-moderate-high levels of Colony Forming Units (CFU's). Designate the sample for the patient as low, moderate, or high CFU.

#### Precautions and Warnings .....

After use, the CariCult Culture tubes should be handled and disposed of as biologic hazard materials. Do not use the product beyond the expiration date printed on the label. If a Culture Tube shows growth or excessive drying out prior to using the tube, discard tube. Use the CariCult system only in accordance with package insert and protocol instructions.

#### Limitations of the Procedure .....

As with any bacteria test method, antibacterials taken by the patient may affect test result. The results obtained by this kit yield valuable data that must be evaluated in light of the total clinical information obtained by the dentist. CariCult is a presumptive test. Identification of specific organisms requires subculture and appropriate testing.

#### Storage .....

Store in the sealed foil pouch in a cool place, not above 30 C (80 F). Do not freeze.

#### More Information .....

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

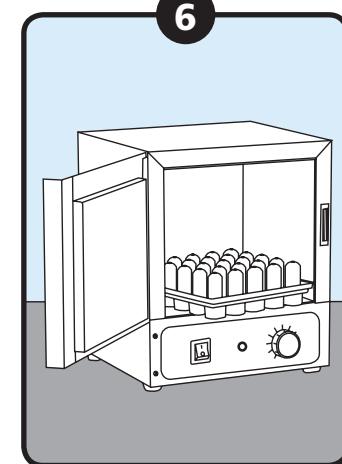
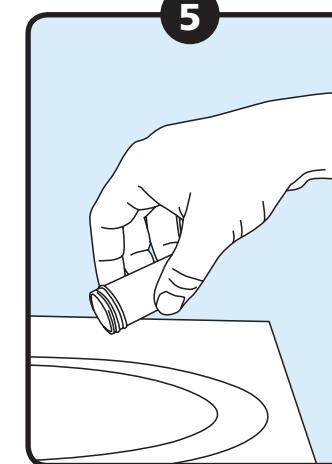
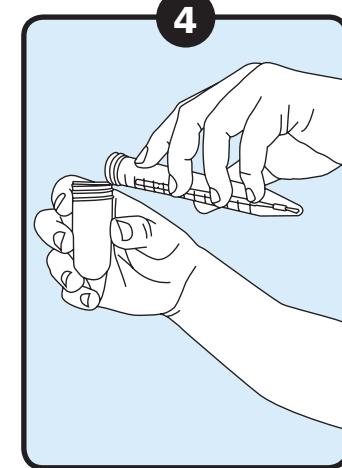
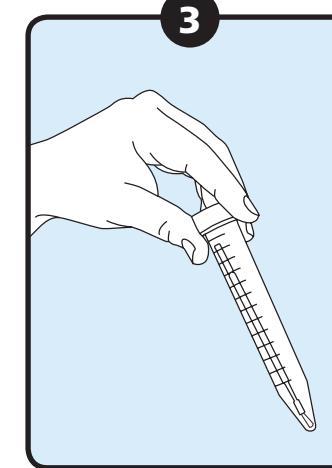
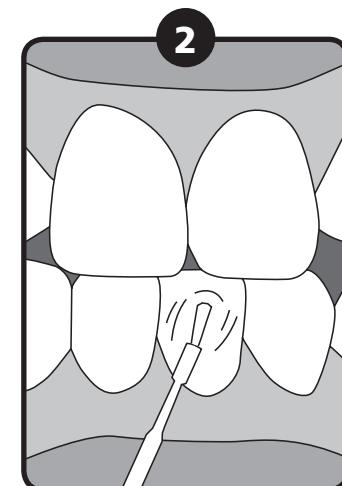
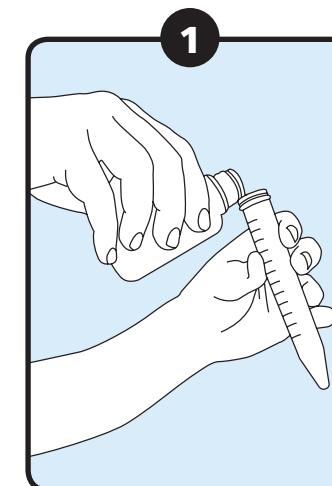
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MORE DIRECTIONS ON BACK ➔

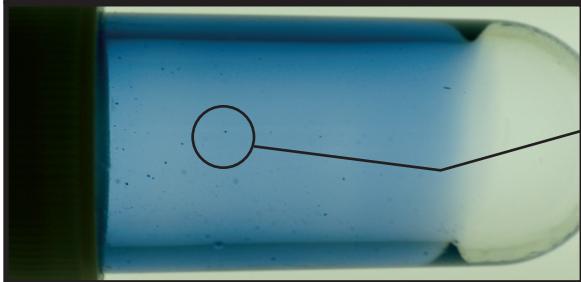
## Read the Results (continued) .....

After incubation, examine the Culture Tube and compare the results to the standardized photographs of the tubes for low, moderate, and high levels of Colony Forming Units (CFU's). Designate the sample for the patient as low, moderate, or high CFU.

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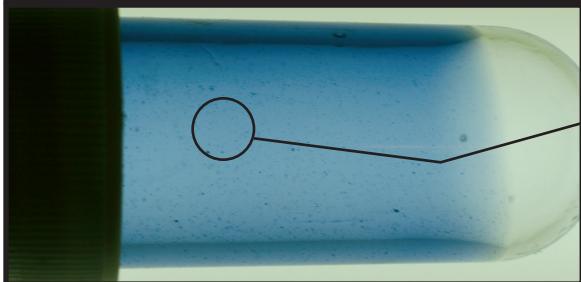
### LOW RISK SAMPLES



### LOW RISK SAMPLES

This sample portrays the culture from a low risk patient and correlates to less than  $10^5$  colony forming units (CFU's) of mutans streptococci from the patient's oral biofilm. It is recommended that this patient be placed into standard re-care protocols. CariFree Maintenance Rinse may be prescribed to help maintain non-cariogenic biofilm.

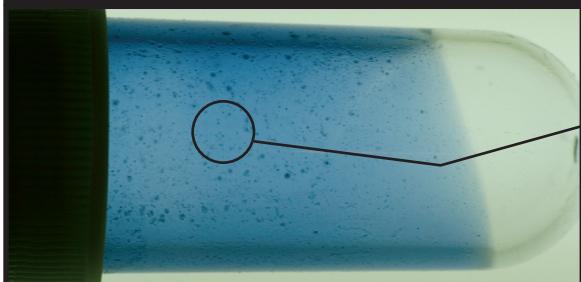
### MODERATE RISK SAMPLES



### MODERATE RISK SAMPLES

This sample portrays the culture from a moderate risk patient and correlates to  $10^5$  colony forming units (CFU's) of mutans streptococci from the patient's oral biofilm. It is recommended that this patient be prescribed one month of antimicrobial therapy with the CariFree Treatment Rinse (2 weeks) followed by the CariFree Maintenance Rinse (2 weeks) and then be re-cultured. Continued use of the Maintenance Rinse is recommended.

### HIGH RISK SAMPLES



### HIGH RISK SAMPLES

This sample portrays the culture from a high risk patient and correlates to greater than  $10^5$  colony forming units (CFU's) of mutans streptococci from the patient's oral biofilm. It is recommended that this patient be prescribed one month of antimicrobial therapy with the CariFree Treatment Rinse (2 weeks) followed by the CariFree Maintenance Rinse (2 weeks), and then be re-cultured. Continued use of the Maintenance Rinse is recommended.