



**Tristel™**

**TEST  
STRIPS**



**USER GUIDE**

**SEMI-QUANTITATIVE  
CHEMICAL INDICATORS  
FOR USE WITH  
TRISTEL ULT**

## INTENDED USE

The Tristel Test Strips are semi-quantitative chemical indicators used to determine whether the concentration of the Tristel ULT high level disinfectant foam is above or below the minimum recommended concentration (MRC) (~90% v/v / ~280 ppm).

## MATERIALS REQUIRED

The following materials are needed for the test:

- Timer/stopwatch/clock with second hand
- Clean polyethylene or polypropylene container with a lid (e.g. specimen cup)
- A measure to determine a 10ml volume of water (e.g. measuring cylinder or a clean syringe)

## SHELF LIFE/EXPIRY

The expiration date for the unopened Tristel Test Strips is printed on the test strip vial label in the format YYYY/MM/DD.

When opening the vial for the first time, record the date opened in the space provided on the label. Once opened use Tristel Test Strips within 6 months.

Check that this does not extend past the expiration date.

## PRECAUTIONS

- Always follow the Directions for Use.
- Wear clean dry gloves when removing Tristel Test Strips from the vial.
- THIS PRODUCT IS MOISTURE SENSITIVE AND WILL NOT PERFORM PROPERLY IF STORED INCORRECTLY. To properly seal the vial, press down firmly with the palm of your hand on the lid. Make sure that the vial is closed completely. Close immediately after each use.
- Protect strips from exposure to light, heat, and moisture.
- Do not refrigerate or freeze.
- If the test strip vial is left open overnight, discard and open a new vial.
- Once removed, do not return the test strips to the vial. Dispose of any unused test strips.
- Do not store used test strips for later reference.
- Keep out of reach of children.
- Do not ingest the strip. If swallowed or ingested seek medical attention.
- Chemical indicators such as Tristel Test Strips cannot be relied upon as a means of validating the sterilization or disinfection process. Chemical indicators can only verify the MRC.
- Color blind users will need assistance to recognize the color.
- Test strips are single use. Do not reuse.
- Do not use after the expiry date.
- Do not use past 6 months after opening.

## DIRECTIONS FOR USE

### Step 1.

#### Wear gloves.

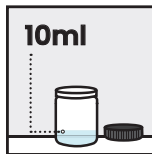
Check the expiry date on the Test Strips vial.  
Check the date the vial was opened.  
Record the date of opening on the vial label, if using for the first time.



### Step 2.

Use a 10ml syringe, or another 10ml measure, to add **10ml of room temperature water** into a lidded container.

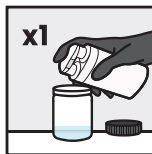
Get a timer ready for use in next steps.



### Step 3.

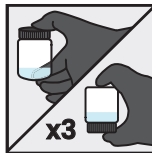
Press Tristel ULT pump 4 times to prime. Contain the foam dosed in priming on a wipe and dispose to waste.

Dispense **1 dose** of Tristel ULT Foam into a container with water. Close the lid tightly and start the timer for 2 minutes. Immediately continue to step 4.



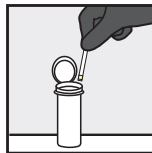
### Step 4.

Gently invert the container, then return to its original upright position. Repeat **3 times** in total. **Do not shake.** Keep container closed and proceed to step 5.



### Step 5.

Ensure your gloves are dry. Open the vial of Tristel Test Strips and take one test strip. To prevent contamination to the test strip, do not place the test strip on a wet surface.



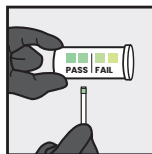
### Step 6.

When the timer reads 1 minute 45 seconds, open the container with test solution and tilt slightly. At 2 minutes fully submerge the indicator pad of the test strip, face up, without stirring, into the test solution for **2 seconds**. Remove. Hold the test strip against the color chart for no more than 10 seconds and allow the color to develop.



### Step 7.

Read the color of the indicator pad against the color chart on the vial label. If the pad is the same or darker green compared to the PASS section of the color chart, this indicates that the Tristel ULT is at or above the MRC. Refer to page 5 for more information on interpreting the test results.



### Step 8.

Discard the used test strip to general waste. Do not store used test strips for later reference. The tested solution can be flushed with water down the sink.



## TEST RESULTS INTERPRETATION

The test strip indicator pad color will change from light yellow to green when chlorine dioxide concentration is sufficient.

The shade of the green color is proportional to the concentration of chlorine dioxide.

Use the color chart on Tristel Test Strips vial label. The color chart is included here for reference only.

If the test strip is the same or darker green compared to the PASS section of the color chart, this indicates that the chlorine dioxide concentration of the Tristel ULT high level disinfectant foam is at or above the MRC.

### COLOR CHART:



**PASS** - green or darker



**FAIL** - lime green, yellow or lighter

If the test strip indicator pad is lime green, yellow or lighter this indicates that the tested Tristel ULT is below the MRC.

Repeat testing with a new dose of Tristel ULT. If the test strips indicate a FAIL again, follow quality control (QC) procedure to confirm the test strips are effective. If test strips pass the QC, mark the Tristel ULT as faulty and report to supplier or to Tristel.

Use a new bottle of Tristel ULT and perform the MRC check with Tristel Test Strips.

## LIMITATIONS

Although Tristel Test Strips may give a color reaction with chlorine dioxide disinfectants from other manufacturers, their use is limited to Tristel ULT only. Disinfectants from other manufacturers may claim different MRCs which may lead to confusion in interpreting results.

Do not use Tristel Test Strips with other high level disinfectants.

## PERFORMANCE CHARACTERISTICS

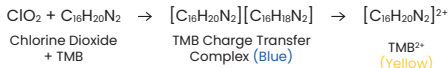
Tristel Test Strips have been validated based on testing the test strips using samples of Tristel ULT, with known concentrations of chlorine dioxide at and above the MRC and below the MRC. The analytical method used to determine the chlorine dioxide concentration in these samples utilized a spectrophotometer.

## CHEMICAL PRINCIPLE

Chlorine dioxide reacts with 3,5,3',5'-tetramethylbenzidine (TMB) in the test strip to form two colored complexes. The equilibrium between the two complexes is related to the amount of chlorine dioxide present.

When the concentration of chlorine dioxide is sufficient, a color change from light yellow to green occurs on the reagent pad at the end of the strips. The shade of the green color is proportional to the concentration of chlorine dioxide present.

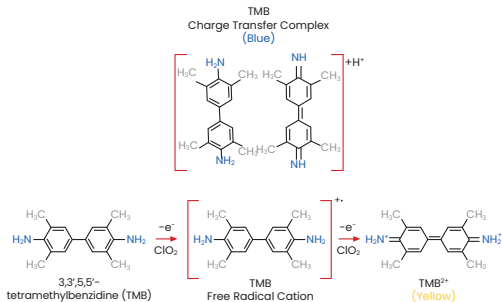
## CHEMICAL EQUATION



Blue complex + Yellow complex → Green color

## REACTION DIAGRAM

Figure 1 – oxidation reaction of 3,5,3',5'-tetramethylbenzidine<sup>1</sup>



## REAGENTS

The reagent pad at the end of the test strip is composed of paper impregnated with 3,5,3',5'-tetramethylbenzidine, a reactive agent.

## STORAGE

Store Tristel Test Strips in the original vial with the cap tightly closed. Store at room temperature (15-25°C/59-77°F) in a dry place. Keep out of direct sunlight.

## DISPOSAL

Dispose of used or expired Tristel Test Strips and the vial in a waste bin in accordance with national, federal, state laws and facility policies.

## HOW SUPPLIED

PRODUCT CODE	DESCRIPTION	CASE CONTENTS
45-13	Tristel Test Strips starter pack: A vial/bottle of 50 test strips. Stopwatch. Polyethylene container. 10ml measure syringe. User Guide.	1
45-10	Tristel Test Strips: A vial/bottle of 50 test strips. User Guide.	1

## Distributed in the USA by:

Parker Laboratories, Inc.,  
4 Sperry Road, Fairfield, New Jersey 07004 USA.  
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## QUALITY CONTROL (QC) PROCEDURE

### 1. Testing Frequency

The QC testing of positive and negative controls is recommended to be performed when the department receives a new lot/batch of Tristel Test Strips. Test one vial per lot/batch.

### 2. Preparation of Control Solutions

Verify that the Tristel ULT selected is within the expiration date, and within the use by date if using an open Tristel ULT. Use Tristel ULT to prepare the positive and negative control test solutions.

### 3. Testing Procedure

For the positive control test: use the full strength test solution prepared by adding 1 dose of Tristel ULT to 10ml of water. Follow the Tristel Test Strips Direction for Use. Test three test strips. Submerge them one by one in the prepared test solution. The three strips should exhibit a PASS.






For the negative control test: Prepare a dilute Tristel ULT test solution by adding 1 dose of Tristel ULT foam to 20ml of water (negative control test solution). Follow the Tristel Test Strips Direction for Use. Test three test strips. Submerge them one by one in the prepared negative control test solution. The three strips should exhibit a FAIL.<sup>2</sup>

Refer to the color chart on the test strips vial label for the interpretation of the results.

### 4. Unsatisfactory QC Test Performance

If the results obtained from using the positive and negative controls indicate the Tristel Test Strips do not meet testing requirements, mark the tested vial of Tristel Test Strips as faulty. Do not use. Report QC test fail to supplier or Tristel. Take a new vial and repeat QC procedure.

## LABEL SYMBOL GLOSSARY

SIGNS	DESCRIPTION
	Keep away from sunlight
	Consult instructions for use (USER GUIDE)
	Wear gloves
	Do not use if package is damaged
	Manufacturer

#### Bibliography:

- The Horseradish Peroxidase-catalyzed Oxidation of 3,5,3',5'-Tetramethylbenzidine FREE RADICAL AND CHARGE-TRANSFER COMPLEX INTERMEDIATES (Received for publication, September 21, 1981) P. David Josephy, Thomas Eling, and R. P. Mason -From the Laboratory of Pulmonary Function and Toxicology and the Laboratory of Environmental Biophysics, National Institute of Environmental Health Sciences, Research Triangle Park, North Carolina 27709.
- QTM042

# Tristel™

WE HAVE CHEMISTRY



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