

## TEST STRIPS

### Test for the concentration of Ortho-Phthalaldehyde in OPAL™ High Level Disinfectant

ARTG No: 206283

#### DESCRIPTION

OPAL™ Test Strips (Product Code 303 019) are chemical indicators for use in determining whether the concentration of Ortho-Phthalaldehyde (OPA), the active ingredient in OPAL™ Instrument Grade – High Level Disinfectant, is above or below the Minimum Recommended Concentration (MRC) of 0.35%. It is recommended the OPAL™ solution be tested before each disinfection cycle to ensure the concentration of OPA is above the MRC.

OPAL™ Test Strips are chemical indicators (as opposed to biological indicators) and, as such, cannot be used to verify the efficacy or completeness of the disinfection process. OPAL™ Test Strips are not intended to replace microbiological determinations.

Prior to each use, the concentration of OPA in the OPAL™ solution must be verified using OPAL™ Test Strips to be above the MRC of 0.35%. The decanted OPAL™ solution must be discarded after 28 days, even if the test strips indicate a concentration above the 0.35% MRC. DO NOT use OPAL™ beyond the 28 day reuse period or the labelled expiration date.

OPAL™ TEST STRIPS SHOULD ONLY BE USED WITH OPAL™ HIGH LEVEL DISINFECTANT.

#### CHEMICAL PRINCIPLES OF THE TEST

The OPAL™ Test Strips are based on a two-step chemical reaction in which OPA reacts with Reagent 1 to form a colourless addition product. Any OPA in excess of 0.35% then reacts with Reagent 2 to form a coloured compound that results in a colour change on the indicator pad of the test strip.

STEP 1: OPA (0.35%) + Reagent 1 → Colourless compound  
STEP 2: Excess OPA (>0.35%) + Reagent 2 → Coloured compound.

#### WARNINGS AND PRECAUTIONS

- Do not use this product other than as directed.
- Do not test OPAL™ Solution at temperatures above 25°C.

- Do not remove test strips from the container until immediately before use.
- Replace cap immediately and tightly after removing a strip as the strips must be protected from humidity.
- Do not remove desiccant pack.
- Do not use a test strip (from an opened or unopened container) after the expiration date.
- Do not touch the indicator pad.
- Do not allow the indicator pad to come into contact with any liquids or work surfaces that may be contaminated with potentially interfering substances.
- This is a single use device. Discard used or expired test strips in accordance with federal, state and local laws. The reacted test strip cannot be kept as a permanent record, as the green colour will continue to develop.
- Use OPAL™ Test Strips within 6 months of opening. The date opened must be written on the OPAL™ Test Strip container.
- The OPAL™ solution must be discarded after 28 days, even if the test strips indicate a concentration above the 0.35% MRC.
- Do not use any indicator strip in which the indicator pad is no longer blue.

#### STORAGE

- OPAL™ Test Strips must be kept in the original container with the lid tightly closed.
- Protection against ambient humidity is essential to guard against adverse performance.
- Store at temperatures between 15°C-30°C.
- Do not remove desiccant pack from the container as it assists in humidity control.

#### MATERIALS REQUIRED

The following materials are required for the test but are not supplied:

- Watch or timer
- Paper towel
- Thermometer

## TEST STRIPS

### DIRECTIONS FOR USE

Prior to routine use, practice with control solutions (described in the QUALITY CONTROL section of this insert) to become familiar with proper testing technique and interpretation of results. Refer to the endoscope reprocessor's user manuals for instructions on how to take a sample of the disinfectant test solution.

#### Test Procedure:

1. Initiate timer and immerse entire indicator pad of test strip into the OPAL™ solution for a full three (3) seconds.
2. Remove strip and touch the long edge on a paper towel to remove excess OPAL™ solution.
3. Lay strip, pad side up, on paper towel.
4. Compare indicator pad to the colour blocks on the container at exactly ninety (90) seconds and interpret the result.
5. After recording the results, discard the test strip according to federal, state and local regulations.

**Results:** The colour developed on the OPAL™ Test Strip indicator pad indicates whether the concentration of OPA in the disinfectant solution is above or below the MRC of 0.35%.

**FAIL** - the colour of the indicator pad is blue (see FAIL colour blocks on test strip container label); indicating the concentration of OPA is at or below the 0.35% MRC and the solution is ineffective and should be discarded.

**PASS** - the colour of the indicator pad is green (see PASS colour blocks on test strip container label); indicating the concentration of OPA is above the 0.35% MRC and the solution is acceptable.

### LIMITATIONS

- OPAL™ Test Strips should only be used with OPAL™ Solution.
- Do not test OPAL™ Solution at temperatures above 25°C.
- The OPAL™ Test Strips indicate the OPA concentration only, and therefore do not confirm disinfection.
- Failure to immerse the indicator pad in the disinfectant for the full immersion time indicated in the DIRECTIONS FOR USE may produce a false 'FAIL' result. Immersing the

indicator pad longer than directed may increase the chance of a false 'PASS' result.

- Hold strip motionless. Do not agitate the strip back and forth during immersion as reagents may be washed out of the indicator pad.
- Indicator pads can become greener in colour if the reaction time is extended beyond 90 seconds, therefore it is important to read the results of the test at exactly 90 seconds. **DO NOT USE RESULTS FROM THE TEST STRIP AFTER 90 SECONDS.**
- Do not use with any other aldehyde-based disinfectants as it may result in false positive results.

### QUALITY CONTROL

Implementing routine use of control solutions will increase user proficiency, minimize procedural errors and protect against the inadvertent use of outdated product or product that is deteriorated due to improper storage or handling. Each facility should establish its own Quality Control procedures. Perform quality control testing by following DIRECTIONS FOR USE and testing a positive and a negative control solution.

#### Preparation of Control Solutions:

Verify the OPAL™ Solution is within the expiration date.

#### Positive Control Solution

Use full-strength OPAL™ Solution as the positive control. The indicator pad of the strip dipped into the positive control should develop a colour similar to or greener than the PASS colour blocks on the container label.

#### Negative Control Solution

Accurately dilute one part of the Positive Control Solution with one part potable water (1:1). Mix thoroughly. The indicator pad of the strip dipped into the negative control should display a blue colour similar to the FAIL colour blocks on the container label.

If the results from the control solutions are not as expected, do not use the remaining strips. Retain the container of test strips and contact Whiteley Medical +61 2 4961 9333 to request technical support.