



# DISINTEK™ OPA

## TEST STRIPS

Test for  
Ortho-phthalaldehyde  
High-level Disinfectant  
in either CIDEX® OPA  
or MetriCide® OPA Plus™

### DESCRIPTION

Serim® DISINTEK™ OPA Test Strips are chemical indicators for use in determining whether the concentration of *ortho*-phthalaldehyde, the active ingredient in CIDEX® OPA Solution and MetriCide® OPA Plus™ Solution, is above or below the established minimum effective concentration (MEC) of 0.3%.<sup>1,2</sup>

It is recommended that the disinfectant be tested before each disinfection cycle to ensure that the *ortho*-phthalaldehyde is above the MEC.

The test strips are chemical indicators (as opposed to biological indicators) and, as such, cannot be used to verify the efficacy or completeness of the sterilization or disinfection process. Serim DISINTEK OPA Test Strips are not intended to replace microbiological determinations.

Do not use CIDEX OPA or MetriCide OPA Plus Solution beyond the manufacturer-recommended use-life of 14 days regardless of the test strip results.

DISINTEK OPA Test Strips should only be used with CIDEX OPA or MetriCide OPA Plus Solution.

### CHEMICAL PRINCIPLES OF THE TEST

The Serim DISINTEK OPA test is based on a two-step chemical reaction in which *ortho*-phthalaldehyde reacts with Reagent 1 to form a colorless addition product. Any OPA in excess of 0.3% then reacts with Reagent 2 to form a colored compound that results in a color change on the indicator pad of the test strip.

STEP 1:  
OPA (0.3%) + Reagent 1 → Colorless compound

STEP 2:  
OPA (excess of >0.3%) + Reagent 2 → Colored compound

### WARNINGS AND PRECAUTIONS

- Do not use this product other than as directed.
- The OPA sample to be tested **must** be between 20°C and 28°C.
- Do not remove test strips from the bottle 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 bottle) after the expiration date.
- Do not touch the indicator pad.
- Do not allow the indicator pad to come into contact with liquids or work surfaces that may be contaminated with potentially interfering substances.
- This is a single use device. After use, discard the test strip according to federal, state, and local regulations. The test strip cannot be kept as a permanent record.

### STORAGE

- Serim DISINTEK OPA Test Strips must be kept in the original bottle with the lid tightly closed.
- Do not remove desiccant packets.
- Do not remove test strips from the bottle until immediately before use.
- Protection against ambient humidity is essential to guard against adverse performance.
- Store at temperatures between 15°–30°C (59°–86°F).
- Do not use a test strip (from an opened or unopened bottle) after the expiration date.
- Expiration date and lot number are printed on the bottom of the bottle.
- Do not use any indicators which are no longer blue.

### MATERIALS REQUIRED

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

- Watch or timer
- Paper towel

### 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.

#### Test Procedure:

1. Immerse entire indicator pad of test strip into a solution of:
  - CIDEX OPA for a full twenty (20) seconds
  - or
  - MetriCide OPA Plus for a full five (5) seconds.
2. Remove strip and touch the long edge of the strip lightly on a paper towel to remove excess OPA solution.
3. Lay strip, pad side up, on paper towel.
4. Interpret results **at the appropriate read time** by comparing the color of the indicator pad to the color blocks on the bottle label:
  - CIDEX OPA - wait an additional 40 seconds after the 20 second immersion
  - or
  - MetriCide OPA Plus - wait an additional 55 seconds after the 5 second immersion.
5. After recording the results, discard the test strip according to OSHA, state and local regulations.

## Results:

The color developed on the Serim DISINTEK OPA Test Strip indicator pad indicates whether the concentration of *ortho*-phthalaldehyde in the disinfectant solution is above or below the MEC of 0.3%.

**FAIL** - the color of the indicator pad is blue (see FAIL color blocks on bottle label); indicating the concentration of *ortho*-phthalaldehyde is at or below the 0.3% MEC.

**PASS** - the color of the indicator pad is green (see PASS color blocks on bottle label); indicating the concentration of *ortho*-phthalaldehyde is **above** the 0.3% MEC.

## 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 for the appropriate OPA Solution.

### Preparation of Control Solutions:

Verify the OPA Solution is within the expiration date printed on the label.

- **Positive Control Solution:** Use full-strength CIDEX OPA or MetriCide OPA Plus Solution as the positive control. The indicator pad of the strip dipped into the positive control should develop a green color (see PASS color blocks on bottle label).
- **Negative Control Solution:**
  - For **CIDEX OPA** - Dilute one part of the Positive Control Solution with one part water (1:1). Mix thoroughly.
  - For **MetriCide OPA Plus** - Dilute one part of the Positive Control Solution with two parts water (1:2). Mix thoroughly.

The indicator pad of the strip dipped into the negative control should display a blue color (see FAIL color blocks on bottle label).

If the results from the control solutions are not as expected, do not use the remaining strips for testing disinfectant solutions. Retain the bottle of test strips and contact Serim Research Corporation at 1-800-542-4670 or your local Serim distributor to request technical support.

## PERFORMANCE CHARACTERISTICS

The performance characteristics of Serim DISINTEK OPA Test Strips are based on analytical studies using disinfectant samples with *ortho*-phthalaldehyde concentrations at and above the MEC.

OPA Solution	No. of Samples Tested per Concentration	Blind Study Results achieved at:	
		0.3% OPA	0.5% OPA
CIDEX OPA	170	100% FAIL	100% PASS
MetriCide OPA Plus	203	100% FAIL	100% PASS

As the MEC of the OPA solution is approached during use, the test strips will give some "PASS" and some "FAIL" results. This is due to a safety margin designed into the test strip.

Sensitivity and accuracy of the test strip depends on variability in color perception, lighting conditions and the possible presence of interfering substances.

## LIMITATIONS

- DISINTEK OPA Test Strips should only be used with CIDEX OPA Disinfecting Solution and MetriCide OPA Plus Solution.
- The DISINTEK OPA Test Strips should not be used with CIDEX OPA or MetriCide OPA Plus solution at temperatures above 28°C as the test may produce a false "PASS" result.
- The Serim DISINTEK OPA Test Strips indicate the *ortho*-phthalaldehyde 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 if the reaction time is extended beyond 60 seconds, therefore **it is important to read the results of the test at 60 seconds.**

## REFERENCES

<sup>1</sup> CIDEX OPA Solution Instructions for Use (IFU), ASP, 2006 LC-20390-008 Rev. D (FAX)

<sup>2</sup> MetriCide OPA Plus Solution Instructions for Use (IFU), Metrex Research Corporation, 70-6005-1 2140IN 8/07

CIDEX® OPA is a registered trademark of Advanced Sterilization Products, a Johnson & Johnson company.

MetriCide® OPA Plus™ is a registered trademark of Metrex Research Corporation, an indirect subsidiary of Sybron Dental Specialties, Inc.



© 2013 Serim Research Corporation  
P.O. Box 4002, Elkhart, IN 46514-0002  
Tel: (800) 542-4670 · FAX: (574) 266-6222  
Tel: (574) 264-3440  
E-mail: customerservice@serim.com  
Web site: www.serim.com