McKESSON

OPA/28 Test Strips

Test Strips for the Concentration of
McKesson OPA/28 High-Level Disinfectant

MFR #
73-OPA28B

DESCRIPTION

McKesson OPA/28 Test Strips (MFR # 73-OPA28B) are chemical indicators for use in determining whether the concentration of *ortho*-phthalaldehyde (OPA), the active ingredient in McKesson OPA/28 Solution, is above or below the established minimum recommended concentration (MRC) of 0.35%.

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

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. McKesson OPA/28 Test Strips are not intended to replace microbiological determinations.

Do not use McKesson OPA/28 Solution beyond the manufacturer recommended use-life of 28 days regardless of the test strip results.

McKesson OPA/28 Test Strips should only be used with McKesson OPA/28 Solution

MATERIALS REQUIRED

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

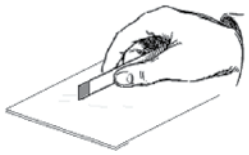
- Watch or timer
- Paper towel

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. Refer to the endoscope reprocessor's user manuals for instructions on how to take a sample of the disinfectant use solution.

Test Procedure

1. Initiate timer and immerse entire indicator pad of test strip into the McKesson OPA/28 Solution for a full three (3) seconds.
2. Remove strip and touch the long edge on a paper towel to remove excess McKesson OPA/28 Solution.



3. Lay strip, pad side up, on paper towel.
4. Compare indicator pad to the color blocks on the bottle at exactly ninety (90) seconds and interpret the result.
5. After recording the results, discard the test strip according to OSHA, state and local regulations.

Results

The color developed on the McKesson OPA/28 Test Strip indicator pad indicates whether the concentration of *ortho*-phthalaldehyde in the disinfectant solution is above or below the MRC of 0.35%.

FAIL – the color of the indicator pad is blue (see FAIL color blocks on test strip bottle label); indicating the concentration of *ortho*-phthalaldehyde is at or below the 0.35% MRC.

PASS – the color of the indicator pad is green (see PASS color blocks on test strip bottle label); indicating the concentration of *ortho*-phthalaldehyde is above the 0.35% MRC.

LIMITATIONS

- McKesson OPA/28 Test Strips should only be used with McKesson OPA/28 Solution.
- McKesson OPA/28 Test Strips should not be used with McKesson OPA/28 Solution at temperatures above 81°F (27°C) as the test may produce a false "PASS" result.
- The McKesson OPA/28 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 in color 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 with any other aldehyde-based disinfectants as it may result in false positive results.

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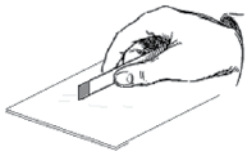

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FAIL – the color of the indicator pad is blue (see FAIL color blocks on test strip bottle label); indicating the concentration of *ortho*-phthalaldehyde is at or below the 0.35% MRC.

PASS – the color of the indicator pad is green (see PASS color blocks on test strip bottle label); indicating the concentration of *ortho*-phthalaldehyde is above the 0.35% MRC.

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- Hold strip motionless. **Do not** agitate the strip back and forth during immersion as reagents may be washed out of the indicator pad.
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- Do not use with any other aldehyde-based disinfectants as it may result in false positive results.

CUSTOMER STORAGE

- McKesson OPA/28 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 59–86°F (15–30°C).
- 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 in which the indicator pad is no longer blue.
- Test strips are good for 6 months once opened. The date opened should be written on the test strip bottle.

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 McKesson OPA/28 Solution is within the expiration date.

Positive Control Solution
Use full-strength McKesson OPA/28 Solution as the positive control.
The indicator pad of the strip dipped into the positive control should develop a color similar to or greener than the PASS color blocks on the bottle label.

Negative Control Solution
Dilute one part of the Positive Control Solution with one part reverse osmosis (RO) water (1:1). Mix thoroughly.
The indicator pad of the strip dipped into the negative control should display a blue color similar to the FAIL color blocks on the 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 call 1-800-722-1529 to request technical support.

CHEMICAL PRINCIPLES OF THE TEST

The McKesson OPA/28 Test Strip 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 0.35% 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 (0.35%) + Reagent 1 → Colorless compound

STEP 2: excess OPA (>0.35%) + Reagent 2 → Colored compound

WARNINGS AND PRECAUTIONS

- Do not use this product other than as directed.
- The McKesson OPA/28 sample to be tested must be between 68° and 81°F (20° and 27°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. 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.

PERFORMANCE CHARACTERISTICS

The performance characteristics of McKesson OPA/28 Test Strips are based on analytical studies using disinfectant samples with *ortho*-phthalaldehyde concentrations at and above the MRC.

No. of Samples Tested per Concentration	Blind Study Results achieved at	
	0.35% McKesson OPA/28	0.5% McKesson OPA/28
184	100% FAIL	100% PASS

As the MRC of the McKesson OPA/28 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.

General questions? Call 1-800-777-4908
Technical questions? Call 1-800-722-1529

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Richmond, VA 23228
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