

A. Intended Use

The CIDEX® OPA Solution Test Strips are semi-quantitative chemical indicators for use in determining whether the concentration of *ortho*-phthalaldehyde, the active ingredient in CIDEX® OPA Solution, is above or below the minimum effective concentration (MEC) established for CIDEX OPA Solution.

CIDEX OPA Solution Test Strips cannot be used to validate the disinfection process.

B. Explanation of the Test

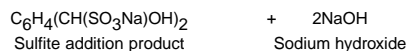
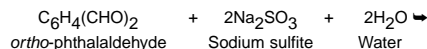
CIDEX OPA Solution Test Strips are developed exclusively for monitoring the minimum effective concentration (MEC) of CIDEX OPA Solution. It is recommended that CIDEX OPA Solution be tested before each usage with the CIDEX OPA Solution test strips in order to guard against dilution, which may lower the *ortho*-phthalaldehyde level of the solution below its MEC of 0.3%.

WARNING: Do not use CIDEX OPA Solution beyond its maximum 14 day use life.

C. Chemical Principle of the Test Procedure

ortho-Phthalaldehyde reacts with sodium sulfite in the test strip to form a sulfite addition product and an equivalent amount of base (STEP 1). If sufficient *ortho*-phthalaldehyde is present, the increase in pH causes a color change in the pH indicator (STEP 2).

STEP 1



STEP 2



When the concentration of *ortho*-phthalaldehyde is sufficient, a color change from light blue to purple occurs on the reagent pad at the end of the strips.

D. Reagents/Storage

The reagent pad at the end of the test strip is composed of paper impregnated with two reactive agents, sodium sulfite and pH-sensitive dye.

Store CIDEX OPA Solution Test Strips in the original bottle with the cap tightly closed. Store at controlled room temperature, 15°-30°C (59°-86°F), and in a dry place.

The shelf life (expiration date) for the unopened CIDEX OPA Solution Test Strips is stamped on the immediate container label. When opening the bottle for the first time, record the date opened in the space provided on the label.

PRECAUTIONS:

- Do not use any remaining strips 90 days after opening the bottle. Do not leave the test strip bottle open for more than 30 minutes. Improper storage or use of test strips may result in false readings.
- To properly seal the test strip bottle, press down firmly with the palm of your hand on the lid. Please make sure that the bottle is closed completely.
- Do not refrigerate or freeze.
- Protect strips from exposure to light, heat, and moisture.
- Tightly re-cap test strip bottle after each use to minimize exposure to humidity.

E. Specimen Collection and Preparation

CIDEX OPA Solution Test Strips can be used to test CIDEX OPA Solution directly in the tray, bucket or other container holding the solution. When this is not feasible, remove a sufficient volume (~30 ml) of CIDEX OPA Solution to fully submerge the CIDEX OPA Solution Test Strip indicating pad area, and place into a clean plastic container (polyethylene or polypropylene). Appropriate safety precautions should be taken according to label instructions and the Material Safety Data Sheet.

F. Directions for Use

1. Ensure that the solution to be tested has been dispensed according to labeling instructions.
2. Always note the date the bottle was opened and the “do not use after” date in the space provided on the bottle.
3. Ensure that appropriate safety precautions are observed when testing CIDEX OPA Solution, refer to product labeling and the Material Safety Data Sheet for CIDEX OPA Solution.
4. Remove one Test Strip from the bottle and replace the bottle cap immediately.
5. Use a watch or timer to monitor the following steps.
6. Timing control is critical to accurate reading.
7. **Completely Submerge** indicating pad at the end of the test strip into the container of the solution being tested. Hold for **one second and remove**. Do not leave the strip in the test solution for longer than one second or “stir” the test strip in the solution. Incorrect dipping technique, such as swirling the test strip vigorously in the solution, will wash off the reagents in the test strip pad. This can cause a lack of purple color formation (FAIL) when testing a solution that will normally test as PASS.
8. **Remove** excess solution from the indicating pad by standing the strip upright on a paper towel. Do not shake the strip after removal. When removing excess solution, incorrect technique, such as violently shaking the test strip and/or blotting the test strip with the pad face down against a paper towel, can remove the reagents and solution. This can cause FAIL results for solutions that will normally test as PASS.
9. **Read** the results of the color reaction present on the indicating pad at **90 seconds after the test strip is removed from the solution**. If read in less than 90 seconds, the color change may be incomplete and may be interpreted incorrectly. If read past 90 seconds, color will gradually change to indicate “FAIL”.

LC-20392-003 Rev. F
Cidex® OPA Solution Test Strips IFU
Enlarged 125%

Size: 72 x 582mm
Colors: Black

Date: 9/9/04

To indicate an effective concentration of the solution, the indicating pad will be completely purple. Any shade of purple is acceptable; the intensity will vary due to concentration variation. **If any blue** appears on the indicating pad apart from the top line, the solution is below the MEC of 0.3% and should be discarded. Refer to the color chart on the test strip bottle for interpretation of test results. Record the result of the test in a suitable log book.

See Section I, Test Results Interpretation, for additional important information on the use of this product.

10. **Dispose** of the used Test Strip in a waste bin or per hospital policy.

G. Materials Required

The following materials are not provided with the CIDEX OPA Solution Test Strips but will be needed for the test:

- watch or timer
- paper towel
- a clean polyethylene or polypropylene container will be required to hold the solution sample if the solution cannot be tested directly in the tray, bucket or container in which it is being held.

H. Quality Control Procedures

1. **Preparation of Control Solutions**
To prepare positive and negative control solutions for testing, first verify that the labeled expiration date for the solution is appropriate. This solution may be used as a positive control. To prepare a negative control, dilute one part of full strength solution with one part of water. Label each control solution appropriately.
2. **Testing Procedure**
Following the Directions for Use, submerge three test strips in each of the above freshly prepared solutions for one second each. Remove. The three strips dipped in the full strength positive control solution should exhibit a complete purple color on the indicating pad at 90 seconds. The three strips dipped in the diluted negative control should either remain completely blue or exhibit an incomplete color change to purple when read at 90 seconds. Refer to the color chart on the test strip bottle for interpretation of results.
3. **Testing Frequency**
It is recommended that the testing of positive and negative controls be performed on each newly opened test strip bottle of CIDEX OPA Solution Test Strips. After this initial testing, it is recommended that testing of freshly prepared positive and negative controls be performed on a regular basis as established by your own quality control procedures and program. This testing program will serve to minimize errors between different users, use of outdated materials or product that has been improperly stored or handled.
4. **Unsatisfactory QC Test Performance**
If the results obtained from using the positive and negative controls indicate the test strip is not functioning properly, discard the remaining strips. **Do Not Use Strips.** For technical product information, contact Advanced Sterilization Products at 1-888-783-7723.

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I. Test Results Interpretation

Following the one second submersion in the CIDEX OPA Solution being tested, remove excess solution from the pad by standing the strip upright on a paper towel. The CIDEX OPA Solution Test Strip should then be compared to the color chart provided on the test strip bottle at 90 seconds. The entire indicating pad must be completely purple to pass the test indicating an effective concentration of the solution. If any blue appears on the indicating pad apart from the top line, this is a failure, verifying the solution is below MEC and should be discarded.

As the MEC of CIDEX OPA Solution is approached during its use life, the test strip will give some PASSES and some FAILS. This is due to the safety margin provided by the test strip.

The solution must be discarded if the Test Strip indicates FAIL.

J. Limitations

Although CIDEX OPA Solution Test Strips may give a color reaction with *ortho*-phthalaldehyde and glutaraldehyde-based disinfectants from other manufacturers, their use is limited to the CIDEX OPA Solution. Disinfectants from other manufacturers may claim different MECs which will lead to inaccurate test results using CIDEX OPA Solution Test Strips.

CIDEX OPA Solution Test Strips will not work with CIDEX® Activated Dialdehyde Solution or CIDEX PLUS® Solution.

K. Performance Characteristics

The performance characteristics of CIDEX OPA Solution Test Strips are based on testing the strips using samples of CIDEX OPA Solution with known concentrations of *ortho*-phthalaldehyde at the MEC and above the MEC. The analytical method used to determine the *ortho*-phthalaldehyde concentrations in these samples utilized High Pressure Liquid Chromatography with UV detection. The performance of CIDEX OPA Solution Test Strips has been designed to indicate FAIL 100% of the time at the MEC of *ortho*-phthalaldehyde shown below:

TEST STRIP/SOLUTION	MEC (% <i>ortho</i> -phthalaldehyde)
CIDEX OPA Solution	0.3%

Since the accuracy and sensitivity limit of CIDEX OPA Solution Test Strips is approximately +0.05% at concentrations of 0.05% above the MEC, the test strips will indicate FAIL about 50% of the time and PASS about 50% of the time. This provides the user with a high margin of safety. The solution must be discarded if the test strip indicates FAIL.

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L. Warnings & Precautions

1. Always follow the Instructions for Use.
2. THIS PRODUCT IS MOISTURE SENSITIVE AND WILL NOT PERFORM PROPERLY IF STORED INCORRECTLY. If the container is left open for more than 30 minutes, discard the Test Strips and use a fresh bottle of new Strips.
3. Test Strips should not be returned to the bottle after being removed due to their moisture sensitivity - dispose of any unused Test Strips.
4. Keep out of reach of children.
5. Do not ingest the Strip and/or expose it to the eye.
6. Chemical indicators such as CIDEX OPA Solution Test Strips cannot be relied upon as a means of validating the sterilization or disinfection process. Chemical indicators can only verify if the MEC is present.
7. Each Test Strip must be discarded after use and not reused.
8. Ensure that appropriate safety precautions are observed when testing CIDEX OPA Solution, refer to product labeling and the Material Safety Data Sheet for CIDEX OPA Solution.

M. Disposal

Dispose of used or expired Test Strips and their bottle in a waste bin or per hospital policy.

N. Bibliography

1. Advanced Sterilization Products
Standard Test Method Number
TP-45078-001 (available upon request).

O. How Supplied

PRODUCT CODES	DESCRIPTION	PACKAGE INFORMATION
20392	CIDEX® OPA Solution Test Strips	60 Strips/Bottle 2 Bottles/Shipper
20393	CIDEX® OPA Solution Test Strips	15 Strips/Bottle 2 Bottles/Shipper

Marketed By:

 **ADVANCED STERILIZATION PRODUCTS®**
a *Johnson & Johnson* company
Division of Ethicon, Inc.

33 Technology Drive, Irvine CA 92618-9824
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Made in UK
For technical information
call 1-888-783-7723.

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Cidex® OPA Solution Test Strips



Composition: CIDEX® OPA Solution Test Strips consist of sodium sulfite and dyes impregnated and dried on filter paper.

STORAGE

IMPORTANT: Keep cap tightly closed.

Store bottle at controlled room temperature 15°-30°C (59°-86°F) and in a dry place. **CAUTION:** Do not use after 90 days of opening the bottle.

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