UltrOx™ Test Strip

REF 610-2472

INTENDED USE:
The UltrOx Test Strip is a high-level disinfectant concentration monitor dedicated for use with UltrOx High-Level Disinfectant. The purpose of the UltrOx Test Strip is to determine whether the concentration of hydrogen peroxide, the active ingredient in UltrOx High-Level Disinfectant, is above the minimum recommended concentration (MRC) of 1.5%.

EXPLANATION OF THE TEST:
UltrOx Test Strip is designed exclusively for monitoring the minimum recommended concentration (MRC) of UltrOx High-Level Disinfectant. It is recommended that UltrOx High-Level Disinfectant solution be tested before each usage in order to guard against dilution which may lower the hydrogen peroxide concentration of the solution below its MRC of 1.5% hydrogen peroxide.

NOTE: Not all disinfectant solutions are available in all areas.

CHEMICAL PRINCIPLE:
The UltrOx Test Strip is based on a colorimetric sulfite-peroxide reaction, generating a blue/purple color. If sufficient hydrogen peroxide is present, initially after a test strip is immersed in the high-level disinfectant solution for 2 seconds and removed, the solution will turn the original yellow color of the test strip to a uniform blue/purple and will maintain its blue/purple color at the 60 second (1 minute) read time. When the solution is at or below its MRC, the test strip will show non-uniform areas of blue/purple and pink colors at the 60 second read time.

STORAGE:
Store UltrOx Test Strips in the original bottle with the cap tightly closed. Store at 6-30 °C (43-86 °F). Packaging contains an integral desiccant to prevent humidity inside the storage bottle. Store unused test strips in their bottle, and ensure lid is properly closed to prevent test strip deterioration. Do not store in a freezer.

EXPIRATION:
The expiration date for the unopened bottle is printed on the bottle label. When opening the bottle for the first time, record the date opened in the space provided on the bottle label. The shelf life after the first opening of the bottle is 180 days, or the labeled expiration date, whichever is sooner. Do not use this product beyond the expiration date.

PRECAUTIONS:
- Do not use any test strips 180 days after opening the bottle
- Store between 6-30 °C (43-86 °F)
- Protect test strips from exposure to light
- Protect test strips from exposure to oxidizing agents, strong acids/alkalis and detergents
- Packaging contains an integral desiccant. Return unused test strips to bottle, and ensure lid is properly closed to prevent test strip deterioration
- Use test strip immediately after removal from bottle
- Only read the test strip result from the 'front' of the test strip, i.e. the side having text on the handle
- Don the appropriate PPE per facility's policies and procedures

MATERIALS REQUIRED:
The following materials are not provided with the UltrOx Test Strip but will be needed for the test:
- Watch or timer
- Paper towel
- Clean container (if required) to hold the UltrOx High-Level Disinfectant

SPECIMEN COLLECTION AND PREPARATION:
UltrOx Test Strip can be used to test the high-level disinfectant solution directly in the secondary solution container (i.e. soaking basin, open architecture automated ultrasound transducer reprocessor or validated processing system). When this is not feasible, remove approximately 30 ml of the high-level disinfectant solution from the secondary container and place the solution into a clean container.

DIRECTIONS FOR USE:
1. Ensure that the high-level disinfectant solution to be tested has been dispensed according to label instructions.
2. Ensure the test strip reaches room temperature before testing.
3. Ensure that the high-level disinfectant solution is ≥ 20 °C (68 °F).

   CAUTION: THE TEST STRIP MAY NOT PERFORM PROPERLY IF USED WITH HLD SOLUTION BELOW 20 °C.
4. Remove a test strip from its bottle and close the bottle immediately. Hold the test strip such that the front side having the viewing 'window' for the indicator pad is facing you, as directed by the text on the handle.

5. Prior to each use, dip the indicator pad at the end of the test strip into the high-level disinfectant solution for 2 seconds and remove. Do not leave the test strip in the test high-level disinfectant solution for longer than 2 seconds or "stir" the test strip in the high-level disinfectant solution.

   NOTE: Incorrect dipping technique, such as leaving the test strip in the high-level disinfectant solution longer than the specified 2 seconds and/or swirling the test strip in the high-level disinfectant solution, may wash off the reagents in the test strip pad. This can cause an incomplete color formation (FAIL) when testing a solution that will normally test as PASS.
6. Remove excess solution from the indicator pad by touching the short edge of the indicator pad to a paper towel. Do not shake the test strip after removal. Immediately start a 60 second timer.

   NOTE: 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, which can again cause FAIL results for the high-level disinfectant solutions that will normally test as PASS.
7. The yellow pad will become blue/purple. Continue to allow any indicator pad color to develop and read the results of the color reaction present on the indicator pad in the viewing 'window' at 60 seconds.
   a. If the pad is completely blue/purple, this indicates that the hydrogen peroxide concentration in the high-level disinfectant solution being tested is above the MRC (PASS result).
   b. If any pink appears on the indicator pad or the pad is not completely blue/purple, the hydrogen peroxide concentration of the high-level disinfectant solution is at or below the MRC (FAIL result) and should be discarded per your facility's policies and procedures.

   CAUTION: If read in less than 60 seconds, the color change may be incomplete and may be interpreted incorrectly. Do not read the test strip after 60 seconds.

   CAUTION: An indicator with a PASS result at 60 seconds could demonstrate a FAIL result beyond the 60 second read time.
8. Refer to the visual standard on the test strip bottle for interpretation of test results. See section Interpretation of Test Results for additional important information on the use of this product.

INTERPRETATION OF TEST RESULTS:
When reading the results of the test, the color of the UltrOx Test Strip should be compared to the color chart provided on the test strip bottle label. The entire indicator pad in the viewing 'window' must be completely blue/purple at 60 seconds to achieve a PASS result, indicating that the concentration of hydrogen peroxide is above the MRC.

If any pink or other color appears on the indicator pad at 60 seconds, the test outcome is a FAIL result, verifying that the concentration of hydrogen peroxide in the high-level disinfectant solution is at or below the MRC and the solution should be discarded per your facility's policies and procedures.

During the reuse life of the high-level disinfectant solution, the test must be performed according to the Directions for Use in order to determine the concentration of hydrogen peroxide in the high-level disinfectant solution.

LIMITATIONS:
The UltrOx Test Strip is to be used exclusively with UltrOx High-Level Disinfectant.

QUALITY CONTROL (QC) PROCEDURES:

1. **Testing Frequency**
   It is recommended that the testing of positive and negative controls be performed on 1 bottle of UltrOx Test Strip for each lot received by the department. It is recommended that the testing of positive and negative controls be performed as new shipments of UltrOx Test Strip bottles are received.
2. **Preparation of Control Test Solutions**
   To prepare positive and negative control test solutions for testing, obtain an unopened bottle of high-level disinfectant. Verify that the labeled expiration date for the solution is within expiration.
   2.1. The full strength solution is used as a Positive Control Test Solution 30ml.
   2.2. To prepare a Negative Control Test Solution, dilute one part of full strength high-level disinfectant 15ml with one part of water 15ml.
   2.3. Label each control solution appropriately.
3. **QC Testing Procedure**
   Test solutions must be ≥ 20 °C (68 °F).
   CAUTION: THE TEST STRIP MAY NOT PERFORM PROPERLY IF USED WITH HLD SOLUTION BELOW 20 °C.
   Following the Directions for Use, individually test 3 test strips in each of the above freshly prepared solutions.
   PASSING QC TEST:
   The 3 test strips tested in the positive control test solution must show PASS results and the 3 test strips tested in the negative control test solution must exhibit FAIL results. Refer to the visual standard on the test strip bottle for interpretation of results.
   FAILING QC TEST:
   A failure to meet the positive control or negative control testing requirements demonstrates unsatisfactory QC test performance. This happens when 1 or more positive control test strip(s) show FAIL results or 1 or more negative control test strip(s) show PASS results. Refer to the visual standard on the test strip bottle for interpretation of results.
4. **Failing QC Test Performance**
   If the QC test failed, do not use. Always follow your facility's policies and procedures.

PERFORMANCE CHARACTERISTICS:
The performance characteristics of UltrOx Test Strip were established by testing the test strips using UltrOx High-Level Disinfectant with known concentrations of hydrogen peroxide under worst case conditions of germicide composition. The indicator exhibited no false positives in solutions containing 1.5% hydrogen peroxide when the testing was performed according to the Directions for Use. A false positive is a PASS result for a solution at or below 1.5% hydrogen peroxide.

WARNINGS & PRECAUTIONS:

- Discard used or expired test strips in a trash receptacle in accordance with national, federal, state and local laws
- Keep out of reach of children
- Do not ingest the test strip and/or expose to the eye
- This device is single use. DO NOT REUSE TEST STRIPS
- Test strips such as UltrOx Test Strip cannot be relied upon as a means of validating a disinfection process. Test strips can only establish exposure to specific conditions within the specified performance limits established for the test strip
- Serious incidents that have occurred in relation to this medical device should be reported to the manufacturer and competent authority in the country where the incident occurred

WARNING: THIS PRODUCT IS MOISTURE SENSITIVE AND WILL NOT PERFORM PROPERLY IF STORED INCORRECTLY. Bottle should be closed immediately following removal of each test strip.

HOW SUPPLIED:

Product	UltrOx Test Strip
Description	Chemical Indicators for monitoring of UltrOx High-Level Disinfectant
Codes	610-2472 (60 test strips per bottle; 2 bottles per box)

CIVCO

Manufactured for
CIVCO Medical Solutions
102 First Street South
Kalona, IA 52247 USA
319.248.6757
WWW.CIVCO.COM

610-2472-20r01