

QwikCheck™ Test Strip QC Instructions for Use

INTRODUCTION AND INTENDED USE: QwikCheck™ Test Strip QC is used to validate QwikCheck Test Strips that assess pH and leukocyte (WBC) levels in human semen. The QC results are determined by placing the QC media onto the QwikCheck Test Strip's pH and WBC patches and comparing the developed strip colors to the color chart on the QwikCheck Test Strips. QwikCheck Test Strip QC is for in vitro diagnostic use only by professionals.

KIT CONTENTS:

- **Four 5cc bottles with green caps: pH 5.0-6.0 + WBC negative (NEG, WBC < 1 M/ml)**
- **Four 5cc bottles with Blue/ Purple caps: pH 7.0-8.0 + WBC positive (POS, WBC ≥ 1 M/ml)**
- **8 droppers**
- **Instructions for Use (Product Insert)**

STABILITY AND STORAGE CONDITIONS: The product has a shelf life of 12 months (closed bottle) and 45 days (open bottle after mixing). Store at room temp (20-25°C; 68-77°F). Note the 45 day open vial expiration date on the bottles after mixing and on the table provided inside the box.

INSTRUCTIONS FOR USE:

How to mix / dissolve the QC powder (reconstitute only one set of POS and NEG bottles of reagent at a time)

1. Open one Blue/ Purple capped bottle and add exactly 5 ml of distilled water using a laboratory pipette (not supplied in the kit).
2. Insert a dropper into the bottle. Push it snugly into place with the dropper side up. Place the cap on the bottle and close.
3. Mix contents vigorously using a vortex or a strong shaking motion in order to completely dissolve the powder. No powder residue should be seen after mixing.
4. Write down the open bottle expiration date (45 days from mixing) on the bottle. Place the bottle into the box in the forward most position.
5. Repeat steps 1 through 6 for the green capped bottle.

How to Run QwikCheck Test Strip QC:

1. Place two QwikCheck Test Strips on a flat surface.
2. Shake both the blue/ purple and green capped bottles of QwikCheck Test Strip QC material.
3. On one QwikCheck Test Strip, place one drop of the Green topped QC media on each of the pH and WBC test pads.
4. On the other QwikCheck Test Strip, place one drop of the Blue/ Purple topped QC media on each of the pH and WBC test pads.
5. Wait **1 minute** for reading pH and **2 minutes** for reading the WBC results without touching the test pads or moving the test strips from the flat surface.
6. Compare the color of each test strip pad to the **RESULTS COLOR CHART at the top of the bottle.**
7. WBC Positive results should be close to or darker than the WBC >= 1 M/mL lavender labeling.
8. Any color lighter than WBC >= 1 M/mL lavender labeling (white, pink, grey, etc.) is considered as WBC Negative < 1 M/mL.
9. pH results should fall into the range specified by the QC Kit labeling when compared to QwikCheck Test Strip color chart (5.0-6.0 and 7.0 to 8.0).
10. PLEASE NOTE: Test pads will grow DARKER if read after defined above reading time. The color of the whole patch should be considered, not just colorations around the edge of the patch. Colors that develop after the testing cycle have no validation value.

REFERENCE: WHO laboratory manual for the examination and processing of human semen, Sixth Edition, WHO 2021.

