

## 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 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 capped bottle and add exactly 5 ml of distilled water using a laboratory pipette (not supplied in the kit).
2. Attach the blue cap and close. Then mix contents vigorously in order to completely dissolve the powder.
3. Open the bottle cap and insert a dropper into the bottle. Push it snugly into place with the dropper side up. Place the cap on the bottle and close.
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 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 topped QC media on each of the pH and WBC test pads.
5. Wait **1 minute** before reading the WBC and pH 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 color chart for pH and WBC on the bottle of QwikCheck Test Strips.
7. WBC POS results should be equal to or darker than the WBC POS lavender labeling of the QwikCheck Test Strip kit. Any lighter color (pink, grey, white, etc.) is WBC NEG.
8. 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).
9. PLEASE NOTE: Test pads will grow DARKER if read after 1 minute. 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 - 5th edition, WHO Press, 2010.

