



## Test Strips Product Insert

**INTRODUCTION AND INTENDED USE:** QwikCheck™ Test Strips are an FDA cleared, in vitro diagnostic strip for the determination of pH and leukocytes (WBCs) in semen. Test results are determined by comparing the color of the test patches to the color chart provided on the bottle label. For professional use only.

**KIT CONTENTS:** 100 and 50 test strip bottles are available with the product use instructions enclosed.

**STABILITY AND STORAGE CONDITIONS:** Note the expiration date on the label for both closed and open bottle. The test strips can deteriorate rapidly in humid conditions so store at 15° C to 30° C (60-86°F) and humidity <30% (very important). After removing a test strip, immediately close the cap (which contains the desiccant for moisture absorbance). Keep away from direct sunlight. Do not touch the test pads before or during testing.

### **INSTRUCTIONS FOR USE:**

1. Test fresh semen, untreated, undiluted and within 1 hour of collection.
2. Remove a test strip from the bottle and place horizontally on the lab bench. Do not touch the test pads at any time during entire testing process.
3. Mix the semen sample thoroughly.
4. Place one drop of semen on each test pad (pH and Leukocytes) using a pipette.
5. Wait time: Leukocyte (WBC) pad: **2 minutes** / pH pad: **1 minute**
6. PLEASE NOTE: Test pads will grow DARKER if read after the timeframe. 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 diagnostic value.

### **REAGENTS:**

pH Pad	Bromothymol Blue	55.0% w/w
	Bromocresol Green	3.3% w/w
	Non-reactive ingredients	41.7% w/w
Leukocytes Pad	Pyrrrole Amino Acid Ester	4.3% w/w
	Diazonium Salt	0.4% w/w
	Buffer	92.6% w/w
	Non-reactive ingredients	2.7% w/w

**CLINICAL INFORMATION:** Normal values for semen pH are generally 7.1 to 8.0; the pH pad reports a range of 5.0 to 8.5. Normal values for semen Leukocytes are < 1 M/ml; the Leulocyte pad reports semi-quantitative results: NEG is <1M/mL and POSITIVE is ≥1 M/mL. Test results can be impacted by drugs or other chemical use.

**REFERENCES:** WHO Laboratory Manual for the Examination of Human Semen and Sperm-Cervical Mucus Interaction, 5<sup>th</sup> Edition, Cambridge University Press, 2010 pg. 16 (pH); pg. 107 (Leukocytes).

