



Test Strips Product Insert

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

KIT CONTENTS: 100 and 50 test strip (limited distribution) bottles are available with the product use instructions enclosed.

STABILITY AND STORAGE CONDITIONS: The CLOSED bottle expiration date is printed on the product label, and the OPEN bottle stability is 90 days. The test strips can deteriorate rapidly in humid conditions, so store at 15° C to 30° C (60-86°F) and humidity <30% (important to maintain 90-day open-bottle stability.) After removing a test strip, immediately close the bottle's cap (do not remove the moisture absorbing desiccant from the bottle.) 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 it horizontally on the lab bench. Do not touch the test pads at any time during the 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 recommended timeframe. The color of the whole patch should be considered, not only colorations around the edges of the patch. Colors that develop after the recommended 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 ≥ 7.2 ; the pH pad reports a range of 5.0 to 8.5. Normal values for semen Leukocytes are < 1 M/ml; the Leukocyte pad reports NEG is <1M/mL and POSITIVE is ≥ 1 M/mL. Test results can be impacted by drugs or other chemical use.

QUALITY CONTROL: Medical Electronic Systems produces assayed Quality Control for the Test Strips. Contact us for details: www.mes-global.com/contact.

REFERENCES: WHO laboratory manual for the examination and processing of human semen, Sixth Edition, WHO 2021, pg. 18 (pH); pg. 112 (Leukocytes).

