



Product Insert

INTRODUCTION AND INTENDED USE: QwikCheck™ Test Strips are used to determine the pH and leukocytes (WBCs) level in semen. They are for in vitro diagnostic use by professionals. Test results are determined by comparing the color of the test patches to the color chart provided on the bottle label. A blank pad may be seen between the WBC and pH pad .

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

STABILITY AND STORAGE CONDITIONS: The product has a shelf life of 18 months (closed bottle) and 90 days (open bottle). Note the expiration date on the bottle. Store at 15°C to 30°C (60-86°F) and humidity <30% (very important). Leave the desiccant in the bottle to absorb moisture. Keep away from direct sunlight and tightly cap the bottle when not in use. Do not touch the test pads. The product is stable and shows no loss of expected performance characteristics after transport/storage over a period of 72 hours at the temperature range of -20°C to +37°C (-4°F to +99°F).

INSTRUCTIONS FOR USE:

1. Test fresh semen, untreated, undiluted and within 1 hour of collection.
2. Remove only the required number of test strips from the bottle, and place horizontally on the lab bench. Do not remove the desiccant.
3. Mix the semen sample thoroughly.
4. Using a standard sample dropper (pipette), place one drop of the specimen on each test pad (pH and Leukocytes). Do not touch the test pad areas, and leave the test strip in the horizontal position.
5. Wait 1 **minute** to read leukocytes and pH.
6. Compare the color of the test pad to the appropriate color scale for pH and WBC on the bottle label.
7. 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 diagnostic value.

INGREDIENTS:

pH Pad	Methyl Red	0.05 mg.
	Bromothymol Blue	1.00 mg
Leukocytes Pad	3-Indoly-phenol ester	6.00 mg
	Benzendiazonium salt	0.40 mg

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 Leulocyte pad reports semi-quantitative results: NEG is < 1 M/mL and POSITIVE is ≥ 1 M/mL. Test results can be impacted by drugs or other chemical use.

EXTERNAL QC: For validating the QwikCheck™ Test Strips, use: IRISpec™ CA/CB Chemistry Controls or KOVA® Liqua-Trol™ . Follow manufacturer guidelines and refer to the bottle label for color charts.

REFERENCES: WHO laboratory manual for the examination and processing of human semen - 5th ed., WHO Press, 2010.

