

Technical Release Bulletin: QwikCheck Test Strips WHO 6th IFU and Label Update

BACKGROUND:

QwikCheck™ Test Strips are used to assay pH and WBC levels in semen.

UPDATES:

- IFU: WHO 6th revised labeling for semen pH NORMAL.
- Label: KOVA controls removed, a reference to QwikCheck Test Strip QC added
- Label: Content reorganized to improve the useability of the labeling

New IFU and LABEL:



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).


Product ~~Insert Test Strips Release~~ 08_DEC_2021



Reagent Strips for Semen Analysis

Contents: 100 strips for In Vitro Diagnostic Use Only

- Leukocytes
- pH



Medical Electronic Systems
REF 0700 CE IVD

TESTING TIMES & RESULTS COLOR CHART

pH: 1 min. 5.0 6.0 6.5 7.0 7.5 8.0 8.5

Leukocytes: 2 min. <1Mml >1Mml

STORAGE CONDITIONS: Store @ 15-30C (60-86F) and humidity <30%, away from direct sunlight. Keep the bottle tightly capped and avoid touching the test pads.

MFG DATE: 11_AUG_2021 LOT#: 80D82_110821


CLOSED VIAL EXP DATE: 11_FEB_2023

OPEN VIAL EXP = 90-DAYS: Opened _____

QUALITY CONTROL

NOTE: Compare MES QC against Results Color Chart above. For IRIS QC, use this color chart:

IRISpec CA IRISpec CB



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Distribution: All QwikCheck Test Strip users. All MES distributors

Effective Date: Immediate, December 22, 2021