

Technical Release Bulletin: QwikCheck™ Test Strips (For SQA-V software version 2.43 through 2.49 Gold)

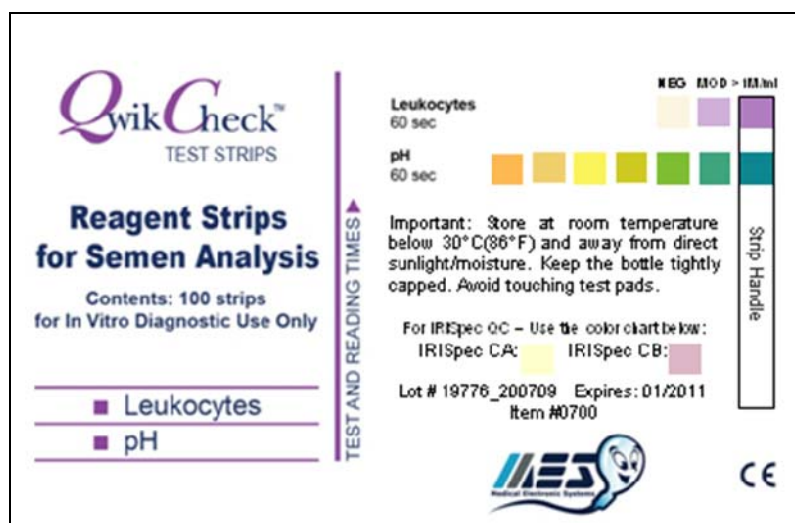
Issue date: Tuesday, January 12, 2010

Subject: QwikCheck™ Test Strips – change in testing time and product label

Background: QwikCheck™ Test Strips are used to assay pH and WBC levels in semen. The outside label provides ranges for pH and Leukocytes based on a color chart. The testing time for Leukocytes was 2 minutes/the pH 1 minute.

Update: Effective JULY, 2009 with LOT #19776_200709 and LOT # 20074_200709 the following change(s) was (were) made from previous lots:

- The testing time for Leukocyte testing changed from 2 minutes to 60 seconds (1 minute).
- Color pads were added to the outside label to reflect the IRISpec CA and CB quality control values.



- The package insert instructions reflect this change in the INSTRUCTIONS FOR USE section of the insert:

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.

Distribution: U.S. and on demand
Effective Date: Immediate
Approval: Dr. Lev Rabinovitch, CTO



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