

TECHNICAL BULLETIN: New pH and WBC QwikCheck™ Test Strips
Updated Test Time for WBC Testing
September 7, 2020

BACKGROUND

The QwikCheck™ Test Strips supplied by Medical Electronic Systems (MES) are used to determine the pH and presence of leukocytes (WBCs) in semen. They are FDA cleared for semen testing only and are for in vitro diagnostic use by professionals. Test results are determined by comparing the color change in the test patches to the color chart provided on the bottle label.

PRODUCT UPDATE:

- In May 2020, a new vendor was qualified by MES to supply QwikCheck™ Test Strips.
- The first batch of test strips is batch #20B29_180520 (starting May 2020).
- An example of the two bottles is presented below:



New Reagent Test Strips Bottle: pH/WBC



OLD Reagent Test Strips Bottle: pH/WBC

TESTING PROCEDURE UPDATE/CHANGES: Noted in the product insert

- Leucocyte (WBC) testing: **Wait 2 minutes to read the leukocyte (WBC) test pad** (the prior test strips were read in 1 minute).
- pH testing: Wait 1 minute to read the pH (no change from the prior test strips)
- Intended use/Performance/Storage/Handling conditions: No change.

Compliance Date: Effective September 7th, 2020 **Authority:** Marcia Deutsch, CEO

Distribution: QwikCheck™ Test Strips users

