

**Technical Release Bulletin**  
**QwikCheck™ Test Strips Quality Control**  
**Issue date: February 1<sup>st</sup> 2015**

**Background:** To perform quality control of the QwikCheck™ Test Strips (WBC and pH) manufactured by Medical Electronic Systems please follow the instructions below:

**WBC Test Strip QC Procedure Using IRISpec CA and CB Urine Controls:**

**REAGENT PREPARATION**

**Materials required:**

- **IRISpec CA and CB** (Beckman Coulter [www.irisdiagnostics.com](http://www.irisdiagnostics.com) IRISpec CA/CB part #8000074 or IRISpec CA/CB/CC part # 8007702)

**WBC QC TEST PROCEDURE**

1. Thoroughly mix the sample in each IRISpec bottle.
2. For each test, use a separate QwikCheck™ Test Strip.
3. Pipette 12µl IRISpec CA (Negative) solution and place onto WBC area of the strip.
4. Wait for the color to develop per the QwikCheck™ Test Strip instructions.
5. Compare the color on the test strip pad to the IRISpec CA color chart on the QwikCheck™ Test Strip label.
6. Repeat steps 1-4 for IRISpec CB (Positive) sample
7. Compare the color on the test strip pad to the IRISpec CB color chart on the QwikCheck™ Test Strip label.

**pH Test Strip QC Procedure Using Standard pH Solutions:**

**REAGENT PREPARATION**

**Materials required:**

- pH 5.0 Buffer solution (ReAgent, cat. #BUSO-1137-20)
- pH 7.0 Buffer solution (ReAgent, cat. #BUSO-1139-20)

**pH QC TEST PROCEDURE**

1. Pipette 12µl of pH 5.0 Buffer solution and place onto the pH pad of the QwikCheck™ Test Strip.
2. Wait for the color to develop per time labeling on the kit container.
3. Compare the color on the pad vs. the pH color chart on the QwikCheck™ Test Strips container.
4. Repeat steps 1-3 with the pH 7.0 Buffer solution on a new test strip.

**pH QC PASS CRITERIA**

1. pH 5.0 Buffer solution: The color is equal to the color on the QwikCheck™ Test Strip container for pH 5.0.
2. pH 7.0 Buffer solution: The color is equal to the color on the QwikCheck™ Test Strip container for pH 7.0.

**Compliance Date:** Effective February 1<sup>st</sup> 2015  
**Authority:** Dr. Lev Rabinovitch, CTO  
**Distribution:** SQA-V and QwikCheck™ Test Strips users



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