Technical Release Bulletin QwikCheck™ Test Strips Quality Control Issue date: February 1st 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 <u>www.irisdiagnostics.com</u> 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 1st 2015

Authority: Dr. Lev Rabinovitch, CTO

Distribution: SQA-V and QwikCheck™ Test Strips users

