

Technical Release Bulletin: QwikCheck™ Test Strips Quality Control

Re-Issue date: August 2, 2021

Background: QC of QwikCheck Test Strips (WBC and pH) can be effectively performed using IRISpec controls from Beckman Coulter. MES is currently working on an in-house Test Strip Quality Control alternative with an estimated release date of October 1, 2021. All customers will be contacted closer to the release date.

WBC & pH QwikCheck Test Strip QC Procedure Using IRISpec CA and CB Urine Controls

REAGENTS

IRISpec CA and CB are commercially available through Beckman Coulter and can be ordered through Beckman's Phone, Email, EDI, or eStore interfaces. For additional information please contact Beckman Coulter directly: 1-800-526-3821, Option 6. or email Askbeckman@beckman.com and reference part: [#800-0074 \(CA/CB CHEMISTRY CONTROLS\)](#)

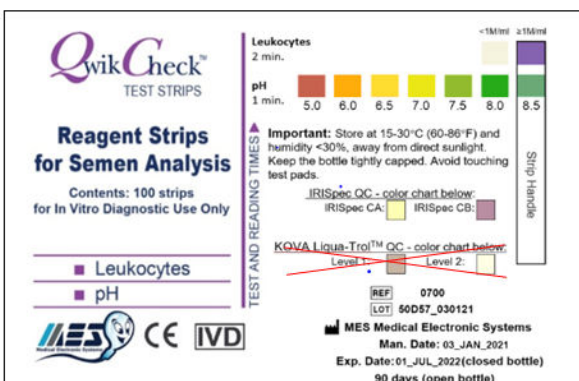
WBC & pH QC TEST PROCEDURE

1. Thoroughly mix the sample in each bottle and use a separate QwikCheck Test Strip for each test.
2. Pipette 10µl to 12µl IRISpec CA (Negative) solution and place onto the WBC pad of the QwikCheck Test Strip.
3. Repeat step 2 for pH pad.
4. Wait for the color to develop following the product insert instructions for wait time.
5. Compare the results to the IRISpec color chart on the QwikCheck Test Strip label.
6. Repeat steps 1-5 for IRISpec CB (Positive) sample.

PH QC PASS CRITERIA

- WBC CA: The color is equal or a bit different vs. the color on the QwikCheck Test Strip container for WBC < 1M/ml.
- WBC CB: The color is equal or darker vs. the color on the QwikCheck Test Strip container for WBC ≥ 1M/ml.
- pH CA & CB: The color is equal or a bit different vs. the colors on the QwikCheck Test Strip container for corresponding pH range:

ASSAY VALUES, VISUAL - TABLE OF ACCEPTABLE RESULT RANGES		
vChem Strips		
Parameter	IRISpec CA	IRISpec CB
Bilirubin	2 - 4 mg/dL 35 - 70 µmol/L (++) - (+++)	NEG.
Urobilinogen	NORM.	4 - 12 mg/dL 70 - 200 µmol/L (++) - (++++)
Ascorbic Acid	NEG.	NEG.
Protein	100 - ≥ 500 mg/dL 1 - ≥ 5 g/L (++) - (+++)	NEG.
Blood	0.03 - 0.2 mg/dL (5-10) - 50 RBCs/µL (+) - (++)	NEG.
pH	8 - 9	5 - 6
Nitrite	NEG.	POS.
Leukocytes	NEG.	75 - 500/µL
SG	1.000 - 1.005	1.030 - 1.035
Ketone	NEG.	25 - 100 mg/dL 2.5 - 10 mmol/L (+) - (++)
Glucose	500 - > 1000 mg/dL 28 - 56 mmol/L (+++)- (++++)	NEG.



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Authority: Marcia Deutsch, CEO
Distribution: SQA and QwikCheck Test Strip users



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