

Technical Release Bulletin: QwikCheck™ Test Strips Quality Control

Issue date: March 9, 2021

Background: QC of QwikCheck Test Strips (WBC and pH) can be effectively performed using IRISpec controls from Beckman Coulter. KOVA controls will no longer be supported for QwikCheck Test Strips because the level of the reagent sensitivity required to identify WBC in semen is not always effective using KOVA controls. QwikCheck Test Strip labeling after batch # 50D57_030121 Exp Date July 2022 will no longer include KOVA as a QC option. MES is currently working on an in-house Test Strip Quality Control alternative with an estimated release date of JULY 1, 2021.

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

REAGENTS

IRISpec CA and CB are commercially available on the Beckman Coulter site under product code 800-0074

<https://www.beckmancoulter.com/search?query=CA%20CB&index=0&size=25&languages=English&type=products>

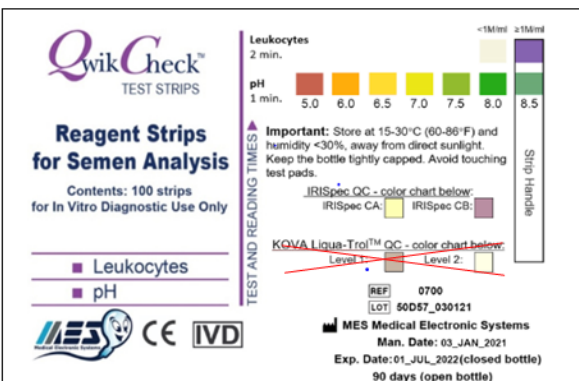
WBC & pH QC TEST PROCEDURE

1. Thoroughly mix the sample in each bottle and use a separate QwikCheck Test Strip for each test.
2. Pipette 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
Billirubin	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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