

Technical Release Bulletin

QwikCheck™ Test Strips Quality Control Color Change for Pos/Neg WBC

Issue date: April 26th, 2022

BACKGROUND: To perform quality control on MES QwikCheck™ Test Strips (WBC and pH) it is recommended to use the QwikCheck™ Test Strips QC Kit manufactured by Medical Electronic Systems.

INTRODUCTION AND INTENDED USE: QwikCheck™ Test Strip QC is used to validate QwikCheck Test Strips that assess pH and leukocyte (WBC) levels in human semen. The QC results are determined by placing the QC media onto the QwikCheck Test Strip's pH and WBC patches and comparing the developed strip colors to the color chart on the QwikCheck Test Strips. QwikCheck Test Strip QC is for in vitro diagnostic use only by professionals.

STABILITY AND STORAGE CONDITIONS: The product shelf life is 12 months (closed bottle) and 45 days (open bottle after mixing). Store at room temperature (20-25°C; 68-77°F).




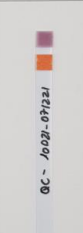
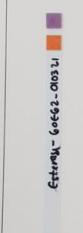
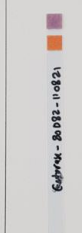
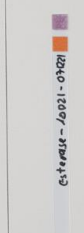


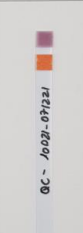
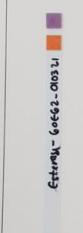
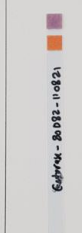
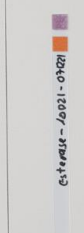


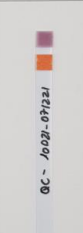
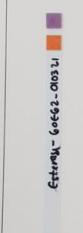
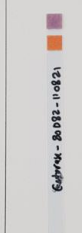
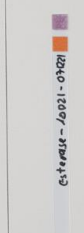
REPORTED CONCERN(S):

- The QwikCheck Test Strip QC testing time for WBC was not in line with the QwikCheck Test Strip WBC testing time.
- The color of the Test Strip QC WBC POS was lighter than the WBC POS Test Strips.

UPDATED INSTRUCTIONS FOR USE:

Modified instructions for Test Strips batches: **60E62_010321, 80D82_110821, 10D21_071221** include the following:

- **Follow these updated "Mixing" instructions when creating the controls:** Attach the cap and close. Mix contents vigorously using a vortex or a strong shaking motion in order to completely dissolve the powder. No powder residue should be seen after mixing.
- Wait **TWO minutes** (not ONE minute as previously specified) before comparing the Test Strip WBC Patch to the RESULTS COLOR CHART shown in the table below.
- WBC Positive: Close to or darker than the WBC ≥ 1 M/mL lavender test strip color chart shown below.
- WBC Negative: Any color lighter than WBC ≥ 1 M/mL lavender test strip color chart (white, pink, grey, etc.)
- Use the WBC ≥ 1 M/ml (POS) color patch below as the color reference for the TEST STRIP batches noted above and below. Interpretation: WBC Positive is close to or DARKER; WBC Negative is lighter (pink, grey, or no reaction) to the WBC ≥ 1 M/ml (POS) patch below.

WBC ≥ 1 M/ml (POS)	WBC (above) and pH (below) QC of Test Strips (different batches)																								
	<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th colspan="3" style="text-align: center;">Test-Strips QC kit WBC POS control</th> <th colspan="3" style="text-align: center;">Esterase + Seminal Plasma (Final conc. of 1.5mg/ml - the most concentrated)</th> </tr> <tr> <th style="font-size: small;">Batch #</th> <th style="font-size: small;">Batch #</th> <th style="font-size: small;">Batch #</th> <th style="font-size: small;">Batch #</th> <th style="font-size: small;">Batch #</th> <th style="font-size: small;">Batch #</th> </tr> <tr> <th style="font-size: x-small;">60E62_010321</th> <th style="font-size: x-small;">80D82_110821</th> <th style="font-size: x-small;">10D21_071221</th> <th style="font-size: x-small;">60E62_010321</th> <th style="font-size: x-small;">80D82_110821</th> <th style="font-size: x-small;">10D21_071221</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">  </td> <td style="text-align: center;">  </td> <td style="text-align: center;">  </td> <td style="text-align: center;">  </td> <td style="text-align: center;">  </td> <td style="text-align: center;">  </td> </tr> </tbody> </table>	Test-Strips QC kit WBC POS control			Esterase + Seminal Plasma (Final conc. of 1.5mg/ml - the most concentrated)			Batch #	Batch #	Batch #	Batch #	Batch #	Batch #	60E62_010321	80D82_110821	10D21_071221	60E62_010321	80D82_110821	10D21_071221						
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- NOTE: Future batches of Test Strips and Test Strip QC will include updated instructions based on the information included in this Technical Bulletin.

Compliance Date: Effective April 25th 2022

Authority: Marcia Deutsch, CEO; Eric Carver, General Manager

Distribution: SQA-Vision, SQA-V and QwikCheck™ Test Strip users



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