

Technical Release Bulletin: QwikCheck™ Vitality Kit QC / Proficiency
May 14, 2018

To validate the QwikCheck Vitality Kit please follow this QC procedure:

1. Collect 1 fresh Human semen sample with >50% Motility and Volume >1 ml.
2. Wait for full liquefaction.
3. Split the liquefied sample into two equal aliquots in two separate vials. Label the vials Sample #1 and Sample #2.
4. Sample #1: Use as is.
5. Sample #2: Kill the cells by freezing the vial for 20 minutes or by placing it into liquid nitrogen for 10 minutes. Before testing, bring Sample #2 to room temperature.
6. Thoroughly mix sample #1.
7. Place 5 µl of sample #1 on a standard slide.
8. Add 5 µl of **QwikCheck Vitality** solution, mix with a pipette tip swirling the sample on the same slide.
9. Cover the slide with a 22 mm x 22 mm coverslip and wait for the sample to stop drifting.
10. Count 200 sperm cells to assess the Vitality: Live spermatozoa have white or light pink heads and dead spermatozoa have heads that are stained red or dark pink. If the stain is limited to only a part of the neck region, and the rest of the head area is unstained, this is considered a “leaky neck membrane”, not a sign of cell death. These cells should be assessed as alive.
11. Calculate the percent of vital “live” cells from the total sperm counted.
12. Repeat step 6-11 for Sample #2.

For Proficiency Challenge (not for QC):

- Sample #1 only: In a blind manner, repeat steps 6-11 above with a different operator.

QC Pass criteria:

- **PASS:** % Vitality of Sample #1 > % Vitality of Sample #2.
- **FAIL:** Deviation from PASS criteria, or no stained cells.

Proficiency Pass criteria:

- Establish Allowable Target Range between operators:
 - Mean vitality value for sample #1 of both operators +/- 3 standard deviations or 25% whatever is greater (please refer to the link below):
 - http://www.mes-global.com/_blog/MES_Service_Blog/tag/Acceptable_Ranges_for_Semen_Analysis/
- **PASS:** The vitality values of both operators fall inside the Allowable Target Range.

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