

**Technical Release Bulletin**  
**QC and proficiency testing of QwikCheck™ Vitality Kit**  
**Compliance date: May 11, 2018**

**Purpose of this document:**

To provide instructions for how to QC the QwikCheck Vitality product and test staff proficiency

**Preparing and testing semen samples:**

1. Collect 1 fresh Human semen sample that meets the following criteria:
  - % Motility > 70%.
  - Volume > 1ml
2. Wait for full liquefaction.
3. Mix the semen sample well.
4. Split the liquefied sample into two equal volume aliquots. Label Sample #1 and Sample #2.
5. Sample #1: Keep at Room Temperature.
6. Sample #2: Kill the cells by placing them into a standard freezer for 20 minutes, then allow sample to recover to Room Temp.
7. Thoroughly mix each sample.
8. Place 5 µl of each sample on a separate 1" x 3" lab slide.
9. Add 5 µl of QwikCheck™ Vitality solution to each sample and mix with a pipette tip in a swirling motion.
10. Cover the slides with a 22 mm x 22 mm coverslip and wait for the samples to stop drifting.
11. Assess Vitality of each sample by counting 200 cells. Live spermatozoa have white or light pink heads and dead spermatozoa have heads that are stained red or dark pink.
12. NOTE: 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 and total membrane disintegration. These cells should be assessed as alive.
13. Calculate the percent of vital cells from the total sperm counted.
14. Repeat steps 8 through 13 with a second operator to confirm stain reaction and inter-operator variability.

**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

**PASS:** The vitality values of both operators fall inside the Allowable Target Range.

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