QwikCheck™
VITALITY

PRODUCT INSERT

INTRODUCTION AND INTENDED USE:

The QwikCheck™ Vitality kit is used to assess the percentage of live spermatozoa in a semen sample by identifying those sperm cells with an intact cell membrane (which do not absorb dye – "dye exclusion method"). The dye exclusion method is based on the principle that damaged plasma membranes, such as those found in non-vital (dead) cells, allow the entry of membrane-impermeant stains. Sperm vitality may be run routinely on all samples, but it is especially important to run on semen samples with less than ~40% progressively motile spermatozoa. Sperm vitality should be assessed as soon as possible after liquefaction of the semen sample and within 1 hour of ejaculation (WHO 5th edition manual, p. 26). The product is intended for in vitro use only.

KIT CONTENTS:

- Five 1.5 ml vials of 0.5% Eosin in 0.9% NaCl / Product Insert

STABILITY AND STORAGE CONDITIONS:

- The product has a one-year closed vial and 3-month open vial shelf life. Note the expiration date on the box and bottle.
- Vials can be stored @ 15-30°C (60-86°F).
- The product is stable and shows no loss of expected performance characteristics after transport/storage over a period of 72 hours at the temperature range of -20^{0}C to +37^{0}C.

INSTRUCTIONS FOR USE:

Procedure

1. Mix the semen sample well.
2. Remove an aliquot of 5 µl of semen and combine with 5 µl of eosin solution on a microscope slide. Mix with a pipette tip by swirling the sample on the slide.
3. Cover with a 22 mm x 22 mm coverslip and let sit for 30 seconds.
4. Insert the slide into the SQA-Vision slide adaptor or (place under a microscope). Insert the loaded adaptor into the SQA-Vision video slot.
5. Activate the Vitality option of the SQA-Vision. Adjust the focus and video settings per the SQA-Vision user guide instructions.
6. Examine the slide at ZOOM OUT (preferably but not required) of the SQA-Vision.
7. Live spermatozoa have white or light pink heads and dead spermatozoa have heads that are stained red or dark pink.
8. 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" and is not a sign of cell death and total membrane disintegration. These cells should be assessed as LIVE.
9. Tally the number of stained (dead) and unstained (vital) cells in each field of view. Enter this number into the SQA-Vision Vitality screen as each field of view is assessed. Press calculate and the Vision will report the # of live vs. dead sperm cells. If using a microscope, calculate as per laboratory protocols for Vitality testing.

Lower reference limit

The lower reference limit for vitality (membrane-intact spermatozoa) is 58% (5th centile, 95% CI 55–63). (Based on WHO 5th edition manual, p.29-30).

PRECAUTIONS AND WARNINGS:

Exercise appropriate laboratory precautions to minimize direct contact with skin or eyes.

REFERENCES:

WHO laboratory manual for the examination and processing of human semen - 5th edition, WHO Press 2010.

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