



PRODUCT INSERT

INTRODUCTION AND INTENDED USE:

The QwikCheck™ Dilution kit is used to dilute semen prior to automated or manual semen testing, when indicated. It is also used for sample preparation. The dilution media is Earle's balanced salt solution which contains ingredients known to support sperm motility and viability. It is recommended by WHO for semen sample preparation (WHO 2010, 5th edition manual, page 163). The product is intended for in vitro use only.

KIT CONTENTS:

- 50 ml of sterile Earle's Balanced Salt solution / Product Insert

STABILITY AND STORAGE CONDITIONS:

- The product has a one year shelf life. Note the expiration date on the box and bottle
- Store unopened bottle @ 15-30°C (60-86°F). Refrigerate @ 2-8°C(36-46°F) after opening.
- Bring to 22-26°C (72-79°F) prior to use to prevent cold shock.
- Do not use if the solution contains precipitate or is cloudy.
- 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°C to +37°C (-4°F to +99°F).

INSTRUCTIONS FOR USE:

AUTOMATED SQA-V:

1. Measure the volume of the neat semen sample.
2. If the volume is less than 0.5ml, dilute 1:2 (1+1).
3. Open the dilution kit bottle and pipette the amount of solution equal to the sample volume measured in step 1.
4. Add the solution to the neat semen and thoroughly mix with gentle a circular motion without introducing air bubbles.
5. Fill the SQA-V testing capillary immediately per the directions in the SQA-V user manual.

MANUAL:

1. Follow the laboratory protocols for diluting semen samples for testing.

CLINICAL PERFORMANCE OF SEMEN SAMPLES DILUTED WITH EARLE'S BUFFER (DILUTION KIT CONTENTS):

Parameter:	Correlation Coefficients: Comparison Neat vs. Diluted	Conclusions
Concentration	R = 0.99	Test results demonstrated high correlations for Concentration, Motility, Progressive Motility and Morphology between neat semen samples and those same samples diluted with Earle's buffer (QwikCheck Dilution kit) when run on the SQA-V.
Motility	R = 0.84	
Progressive Motility	R = 0.96	
Morphology	R = 0.96	

PRECAUTIONS AND WARNINGS:

Exercise appropriate precautions to minimize direct contact with skin or eyes and prevent inhalation.

REFERENCES:

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

