



FSI Products PPM QUALITY CONTROL
Catalog #AQC113

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INTENDED USE: For In Vitro Diagnostic Use

FSI PPM Quality Control is an assayed suspension designed to evaluate the performance of technologists or analyzers performing testing to determine sperm presence/absence.

PRODUCT DESCRIPTION

FSI PPM Quality Control positive controls contain stabilized human sperm at concentrations commonly observed in clinical practice. Negative controls contain no sperm.

WARNINGS AND PRECAUTIONS

1. Product is for in vitro use only.
2. Product is derived from human semen. Handle and dispose as a potential biohazard. Donor's blood was negative when tested for Human Immunodeficiency Virus (HIV), nonreactive for hepatitis B surface antigen by FDA cleared tests and nonreactive when tested for syphilis by a serologic test for syphilis (STS). Warning: The risk of transmitting infectious agents is present. Donor selection and testing do not eliminate the risk of transmitting infectious agents. Due to the nature of semen collection, bacteria may be present. Wear appropriate laboratory protective safety equipment while handling.
3. Product contains dilute formalin.
4. The Material Safety Data Sheet is available at fertilitysolutions.com/downloads/downloads.html.

STORAGE AND STABILITY

1. Store refrigerated at 2°- 8° C. DO NOT FREEZE.
2. Cap the vial tightly and store upright.
3. Closed vial stability: until the expiration date stated on the label and stored at 2°- 8° C.
4. Open vial stability: 6 weeks after opening when handled properly and stored at 2°- 8° C.

MATERIALS NEEDED

1. FSI PPM QC at room temperature (between 18° and 26° C) and accompanying Levey-Jennings charts.
2. Microscope (recommend phase contrast with 20X objective) tally device OR Computer Assisted Sperm Analyzer (CASA).
3. Vortex mixer, sperm counting chamber(s), micropipettors, tips and diluent for making dilutions if necessary.

PROCEDURE

1. Remove the product from the refrigerator and foam packing. Wait for at least 15 minutes until the product temperature is 18° - 26° C before proceeding. HOWEVER, DO NOT WARM THE PRODUCT, CHAMBER OR STAGE ABOVE ROOM TEMPERATURE OR CLUMPING MAY OCCUR.
2. Pipette any liquid from the cap and add back to the vial before mixing. Do not invert vial during mixing.
3. Vortex on medium speed for 3 to 5 pulses of 3 to 5 seconds each and obtain a vortex. The pellet on the bottom of the vial should be dislodged and the clear liquid will turn turbid during the mixing process. Do not mix product in any other manner. Other mixing methods will not properly re-suspend the sperm.
4. Do not use diluent other than FSI Sperm Immobilizing Diluent (SA101) if making dilutions for chambers such as Hemocytometer. Mix dilutions in manner described above before loading chamber.
5. Use a calibrated micropipettor to precisely remove an amount appropriate for the counting chamber used. Do not use capillary tubes to load chambers. If using a hemocytometer, make dilutions using a calibrated micropipettor to obtain precisely the required amounts of product and diluent. Sterile technique is recommended to avoid contamination.
6. If determining concentration: Perform the count using the laboratory method. Count only complete sperm: those with a head, midpiece and tail. Make the appropriate calculations to determine the concentration (# million sperm per mL) and plot result on corresponding Levey-Jennings Chart included with the product.

EXPECTED VALUES

Expected values were established in the Fertility Solutions clinical reference laboratory, based on analysis of at least 20 replicates. Some of the common reasons that cause results to differ from expected values are listed below. Before repeating the procedure, determine the most likely cause of error.

1. Incomplete vortex mixing or incorrect dilution. Product or dilution not thoroughly mixed and re-suspended.
2. Product temperature not between 18° and 26° C before mixing, product expired, stored incorrectly or contaminated.
3. Counting chamber not loaded correctly or not cleaned adequately. Too few fields analyzed on the chamber.
4. Microscope light source not centered, phase rings not aligned, CASA threshold or calibration settings incorrect.
5. Values incorrectly transcribed on the worksheet.

Call Technical Support at 216-491-0030 ext 200 for product support.

REFERENCES

1. Rothmann SA and Reese AA. The Andrology Trainer: Fourth Edition. Fertility Solutions Inc., Cleveland, 2010.
2. WHO Laboratory Manual for the Examination of Human Semen and Sperm-Cervical Mucus Interaction, Cambridge University Press, 2010.
3. Rothmann SA and Reese AA. "Semen Analysis: The test techs love to hate". Medical Laboratory Observer, April 2007.