

SQA-VISION Postvasectomy Validation Protocol

Purpose:

To compare the accuracy of the SQA-Vision Post-vasectomy (PV) test to manual microscopic analysis based on sensitivity and specificity, following WHO 5th and AUA guidelines.

Basic Overview:

Sample preparation

- 20 PV semen samples collected following WHO guidelines and tested within 1 hour of collection at room temperature.
- Test sample WBC and pH using QwikCheck Test Strips.
- Treat each highly viscous or not completely liquefied semen sample with QwikCheck Liquefaction kit.

Testing

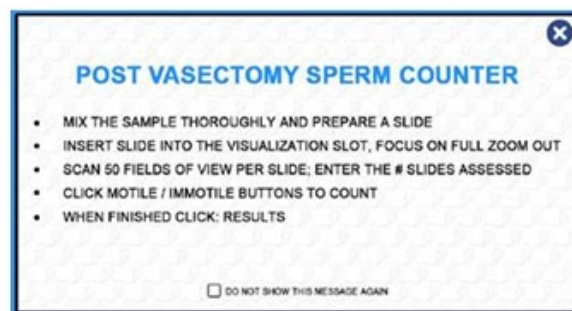
- Begin by testing the PV samples 'as is' without centrifugation or any manipulation.
- If no sperm cells are found, centrifuge the sample at 3000g for 15 minutes.
- Decant most of the supernatant and re-suspend the sperm pellet in approximately 50 µl seminal plasma.
- Test the samples, in parallel (within 2 minutes of each other) on the SQA-Vision Post-Vas mode and under the microscope, counting 50 fields of view.
- Record results of all Immotile and Motile Sperm (M/ml) detected by each method in the PV template provided.

SQA-Vision Default Settings:

- Conc. standard: 2
- Testing criteria: WHO 5th
- POST VAS FOV-CLICK: Leave this box unchecked to freely assess 50 fields of view per slide without clicking 'next' for each new field of view.
- Default test type: PV
- QwikCheck beads: according to the kit labeling

Sample Examination on the SQA-Vision:

- Activate the SQA-Vision PV mode and enter sample/patient information.
- The POST-VAS Counter with sample preparation instructions will open automatically with the following instructions (no need to check NEXT FIELD when changing to a new field of view):



- Mix sample thoroughly and load into a Vision fixed coverslip slide.
- Insert the slide into the slide adaptor and then into the SQA-Vision visualization slot.
- Turn the FOV knob completely counterclockwise.

- Bring image into focus at **Zoom Out**.
- Scan the entire slide path (50 fields of view) by turning the FOV knob clockwise in small increments, stopper-to-stopper.
- Count the Motile and Immotile Sperm observed by clicking the appropriate buttons.
- Click RESULTS to obtain a report.
- Enter this information into the PV Template provided.

Sample Examination Under the Microscope:

- Using a 20-micron depth fixed coverslip slide (can be Vision fixed coverslip slide) count 50 fields of view.
- NOTE: The slide should be calibrated for a specific microscope (microscope fields of view are varying) and specific magnification.
- NOTE: The calibration coefficient established should convert the raw counts into concentration of motile and immotile sperm in M/ml.
- Count 50 fields of view and record number of Motile and Immotile Sperm observed.
- Convert the raw data into M/ml of motile/immotile sperm cells.
- Enter results into the PV Template provided.

Materials Required:

- SQA-Vision
- Phase contrast microscope
- Vision fixed coverslip slides
- 20-micron depth fixed coverslips slides for microscope
- 20 PV semen samples
- Lab pipettes + tips, Calculators, Counters, Data collection template
- Collection containers, Gloves, Kimwipes
- QwikCheck WBC/pH Test Strips and Liquefaction kit.

Documentation:

- PV Template (Excel)