Post Vasectomy Analysis on the SQA-V Gold and SQA-Vision: AUA Guidelines Date: March 16, 2021

OVERVIEW:

This bulletin is issued to clarify the SQA-V Gold vs. SQA-Vision Post Vas analysis methodology and standards based on American Urological Association (AUA) recommendations.

American Urological Association (AUA) Guideline (pertaining to Post Vas semen analysis - PVSA):

- Men or their partners should use other contraceptive methods until vasectomy success is confirmed by PVSA (Post Vasectomy Semen Analysis).
- To evaluate sperm motility, a fresh, uncentrifuged semen sample should be examined within two hours after ejaculation.
- Patients may stop using other methods of contraception when examination of one well-mixed, uncentrifuged, fresh post-vasectomy semen specimen shows azoospermia or only rare non-motile sperm (RNMS or ≤ 100,000 non-motile sperm/mL).
- Eight to sixteen weeks after vasectomy is the appropriate time range for the first PVSA. The choice of time to do the first PVSA should be left to the judgment of the surgeon.
- Vasectomy should be considered a failure if any motile sperm are seen on PVSA at six months after vasectomy, in which case repeat vasectomy should be considered.
- If > 100,000 non-motile sperm/mL persist beyond six months after vasectomy, then trends of serial PVSAs
 and clinical judgment should be used to decide whether the vasectomy is a failure and whether repeat
 vasectomy should be considered

SQA-V Gold Post Vas Analysis:

An automated scan for detection of motile spermatozoa is conducted during a 5-minute test. The number of motile sperm per scan represents the total amount of motile spermatozoa detected during the entire testing cycle. As an extremely low concentration of motile spermatozoa may be present in a Post Vas ejaculate, the automated semen assessment is followed by manual scanning of the entire SQA-V capillary depth (300 microns) and recording detected motile and immotile spermatozoa. The SQA-V algorithm converts # Sperm per Scan into # Sperm/Ejaculate Volume in millions, taking into account the SQA-V capillary depth and ejaculate Volume. If results in M/mL are required, the # Sperm/Ejaculate Volume should be divided by the ejaculate volume offline from the semen analysis report. In a standard capillary scan (15 fields of 20-microns each), the lower reportable range is 60,000 sperm/mL (0.06 M/mL) for motile or immotile sperm, which meets AUA recommendations. Standard results are reported as "Motile, Immotile and Total Sperm per Scan" and "Motile, Immotile and Total Sperm per ejaculate volume" following the previous reporting standards in place at the time of SQA-V Gold development.

SQA-Vision Post Vas Analysis:

"Sperm per Scan" is not used as a reporting method on the SQA-Vision. The SQA-Vision reports a quantitative number of Motile and Immotile sperm in both M/mL and $Sperm\ per\ ejaculate\ Volume\ with an infinitely low reportable range depending on the number of fields of view analyzed.$

The SQA-Vision performs an automated scan to assess *Motile Sperm*. In addition, the manufacturer's recommendation is to perform a manual count using the SQA-Vision Post Vas Counter at 'Zoom Out'. A minimum of 50 fields of view should be assessed "lock to lock" using an MES Fixed Coverslip Slide and utilizing the two wells of the slide if required. Each sperm seen at "Zoom Out" on the SQA-Vision's field of view represents 1 M/mL, resulting in a sensitivity of 20,000 sperm/ml (0.02 M/mL) if only one slide well is scanned. The system supports the assessment of multiple slide wells resulting in even higher sensitivity. Motile, Immotile and Total Sperm parameters are reported in M/mL, Sperm per Ejaculate Volume, or interpreted as "Sperm Present" and "Motile Sperm Present" based on the laboratories' standard operating procedure. The SQA-Vision follows current AUA guidelines and recommendations with much greater sensitivity than the SQA-V Gold.

