

A Comparison of the SQA-Vp to other Technologies Used in the Laboratory and Production

Item	SQA-Vp	Microscope	
		Laboratory	Production
Overview			
CONCENTRATION	<p>SPECTROPHOTOMETRY: Total number of sperm cells are detected by spectrophotometry at near infrared wavelength and expressed in millions/ml.</p> <p>Millions of cells measured</p>	<p>MANUAL COUNTING: Total number of sperm cells are determined by manual count using a counting chamber and expressed in millions/ml.</p> <p>Hundreds of cells counted</p>	<p>PHOTOMETER: Total number of sperm cells are detected by photometry at visible wavelength and expressed in millions/ml.</p> <p>Millions of cells are measured</p>
MOTILITY	<p>AUTOMATED SIGNAL PROCESSING: Ratio of ALL motile cells (MSC) to total sperm cells (TSC) irrespective of velocity. Reported as a percentage (MSC/TSC x 100).</p> <p>Thousands of cells analyzed</p>	<p>MANUAL COUNTING: Ratio of ALL motile to total sperm cells irrespective of velocity. Reported as a percentage (%).</p> <p>Hundreds of cells measured</p>	<p>MANUAL ESTIMATION: Progressive motility, not % motility is assessed. Please refer to the section below: Progressive Motility and Motility Grading.</p>
PROGRESSIVE MOTILITY and MOTILITY GRADING	<p>AUTOMATED MOTILITY GRADING: 0-5</p> <p>0 = Immotile cells (velocity zero mic/sec) 1 = Non-progressive cells (velocity >0; <10 mic/sec) 2 = Slowly progressive cells (velocity >10; <20 mic/sec) 3 = Moderately progressive (velocity >20; <50 mic/sec) 4 = Good progressive cells (velocity >50; <80 mic/sec) 5 = Excellent progressive (velocity >80 mic/sec)</p>	<p>MANUAL PROGRESSIVE MOTILITY: Progressive motility is assessed by manual cell counting and is expressed as a score or in percentages.</p>	<p>MANUAL ESTIMATION of PROGRESSIVE MOTILITY: Ratio of estimated motile cells to total sperm cells is modified by the technician's impression of velocity resulting in an estimation of % progressive motility.</p>

ITEM	SQA-Vp	MICROSCOPE (LAB)	MICROSCOPE (PRODUCTION)
MORPHOLOGY	<p>AUTOMATED + QwikClick™ Droplet Counter: Ratio of morphologically normal to total sperm cells. Computed automatically and augmented by the QwikClick droplet counts where relevant. The results are expressed in percentage terms.</p> <p>ALGORITHM BASIS: SQA-Vp automated normal morphology is correlated to motility + velocity.</p> <p>The algorithm converts motility and velocity sperm signals into an integrated parameter that highly correlates to WHO based normal morphology.</p> <p>MORPHOLOGY COUNTING: Cell defects that do not impact motility and velocity may therefore be “counted” as morphologically normal by the SQA-Vp.</p> <p>These cells are listed below: Droplets: Highly progressive Sperm cells with droplets.</p> <p>Broken Tails: These cells can move very fast and in circles. When they move in LARGE circles, they can move outside the detection field (aperture) of the SQA-Vp.</p> <p>To include these cells into final morphology result reported by SQA-Vp:</p> <ul style="list-style-type: none"> • Use the QwikClick counter to include sperm cells with droplets AND broken tails. 	<p>MANUAL: Ratio of morphologically normal to total sperm cells based on the technician’s subjective assessment of normal spermatozoa. The results are expressed in percentage terms.</p>	<p>MANUAL: Ratio of morphologically normal to total sperm cells estimated by a subjective impression. The results are expressed in percentage terms.</p>
Sperm sample acceptance criteria	Motility Motility Grading (progressiveness) Morphology	Motility Motility Grading (progressiveness) Morphology	Progressive motility Morphology
Statistical representation	High due to large number of electronic measurements (8000) and large sample size (0.5 ml). CV<2.5%	Lower due to subjective visual estimation and small sample size (0.01 micro-liter in the microscope’s field of view). CV 10%	Not measured in the production lab - Unable to gather relevant statistics due to subjective visual estimation and small sample size (0.01 micro-liter in the microscope’s field of view).

Dosing Calculation	<p>FULLY AUTOMATED: Defaults can be set to automatically calculate doses based on pre-set criteria (no manual data entry).</p>	<p>PARTIAL AUTOMATION: Requires some manual entry.</p>	<p>PARTIAL AUTOMATION: Requires some manual entry.</p>
Traceability	FULL	PARTIAL	PARTIAL
PRODUCTION THROUGH-PUT SOLUTIONS	<p>CAPACITY of the SQA-Vp + P-Sperm:</p> <ol style="list-style-type: none"> 1. 40 samples/hour average – without morphology testing 2. 25 samples/hour testing 100% samples with QwikClick morphology counter. 3. 35-40 samples/hour on MONDAY / HEAVY testing days by eliminating morphology on all but poor morphology boars (automatically selected by software for testing) 4. Use two SQA-Vp's <p>PLEASE NOTE: Pre-extend samples for testing accuracy (motility and morphology).</p>	<p>Not useful in industrial production due to slow throughput.</p>	<p>Fast throughput using subjective results. Potential issues with overall accuracy (testing and processing).</p>