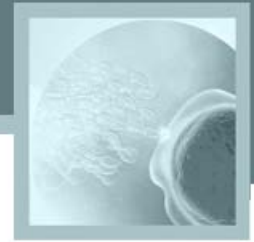


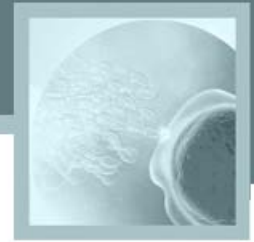


SQA-V *Gold* Technology





- High performance, analytical medical device
- Performs complete quantitative evaluation of semen quality and semen parameters
- Rapid results – *under 2 minutes*
- Self-testing, self-calibrating
- Controls: Latex Beads/Stabilized Sperm
- Video visualization system
- Computer interface
- Electro-optics, computer algorithms, video microscopy



Semen Parameters

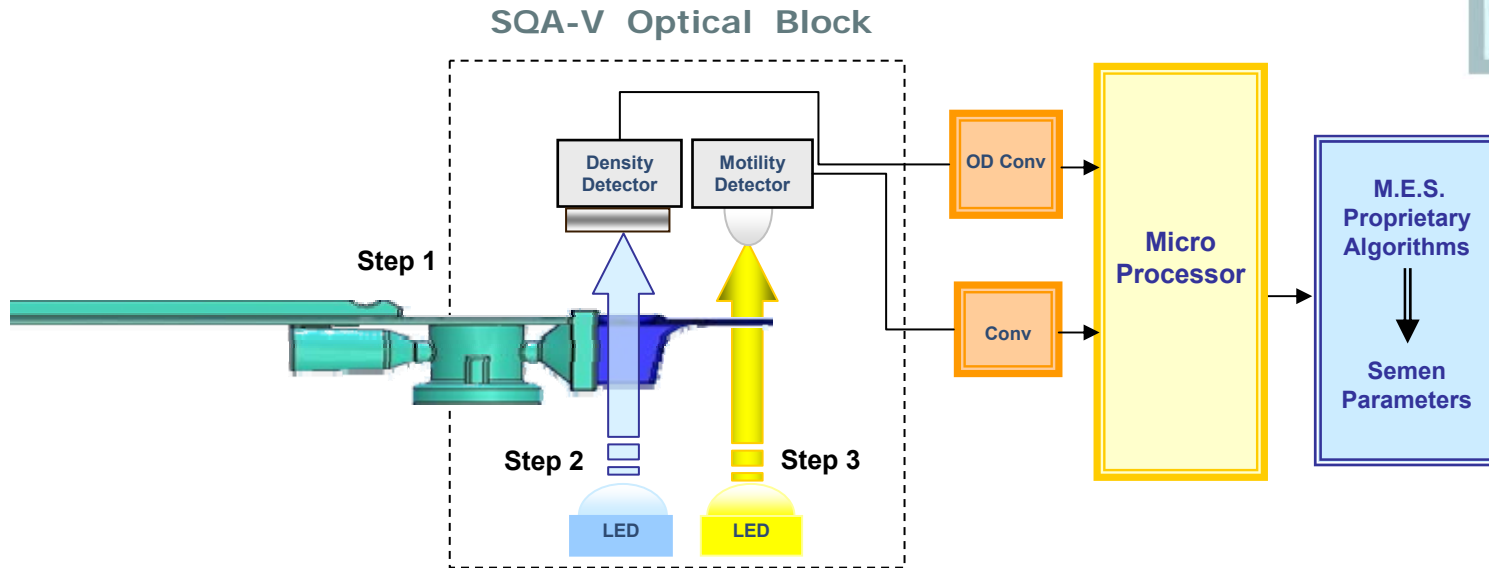
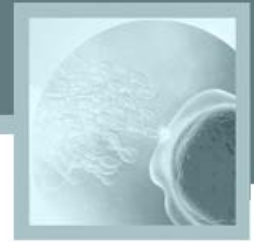
Sperm Concentration	M/ml	Motile Sperm Concentration	M/ml
Motility (<a + b + c>)	%	Progressively Motile Sperm Conc (a)	M/ml
Rapid Progressive Motility (a)	%	Progressively Motile Sperm Conc (b)	M/ml
Slow Progressive Motility (b)	%	Functional Sperm Concentration: Prog. Motile Sperm w/Norm Morphology	M/ml
Non Progressive Motility (c)	%	Total Number Sperm/Ejaculate	M
Immotility (d)	%	Total Progressive Sperm/Ejaculate	M
Morphology: % Normal Forms (MORPH. NORM. FORMS,WHO 3rd / 4th)	%	Total Motile Sperm/Ejaculate	M
Velocity	mic /sec	Total Functional Sperm/Ejaculate	M
Postvasectomy: Motile, Immotile and Total Sperm/Scan	#	Sperm Motility Index	#
		Postvasectomy: Motile, Immotile and Total Sperm/sample volume	M



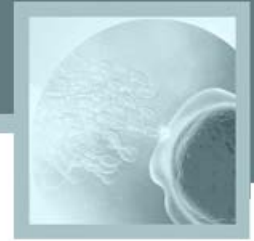
A semen sample is aspirated into the two measurement chambers of the SQA-V testing capillary

- Sperm concentration is measured in the “Tall” chamber of the capillary
- Motility is measured in the “Thin” section.

SQA-V Theory of Operation

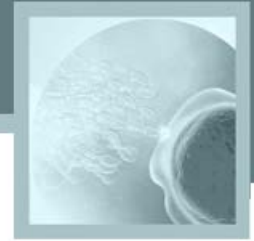


- A testing capillary is inserted into the SQA-V
- Sample concentration is measured by the amount of optical absorption/reflection of light as an IR beam traverses the seminal fluid
- Motility is measured by analyzing modulations in the light source caused by moving sperm cells



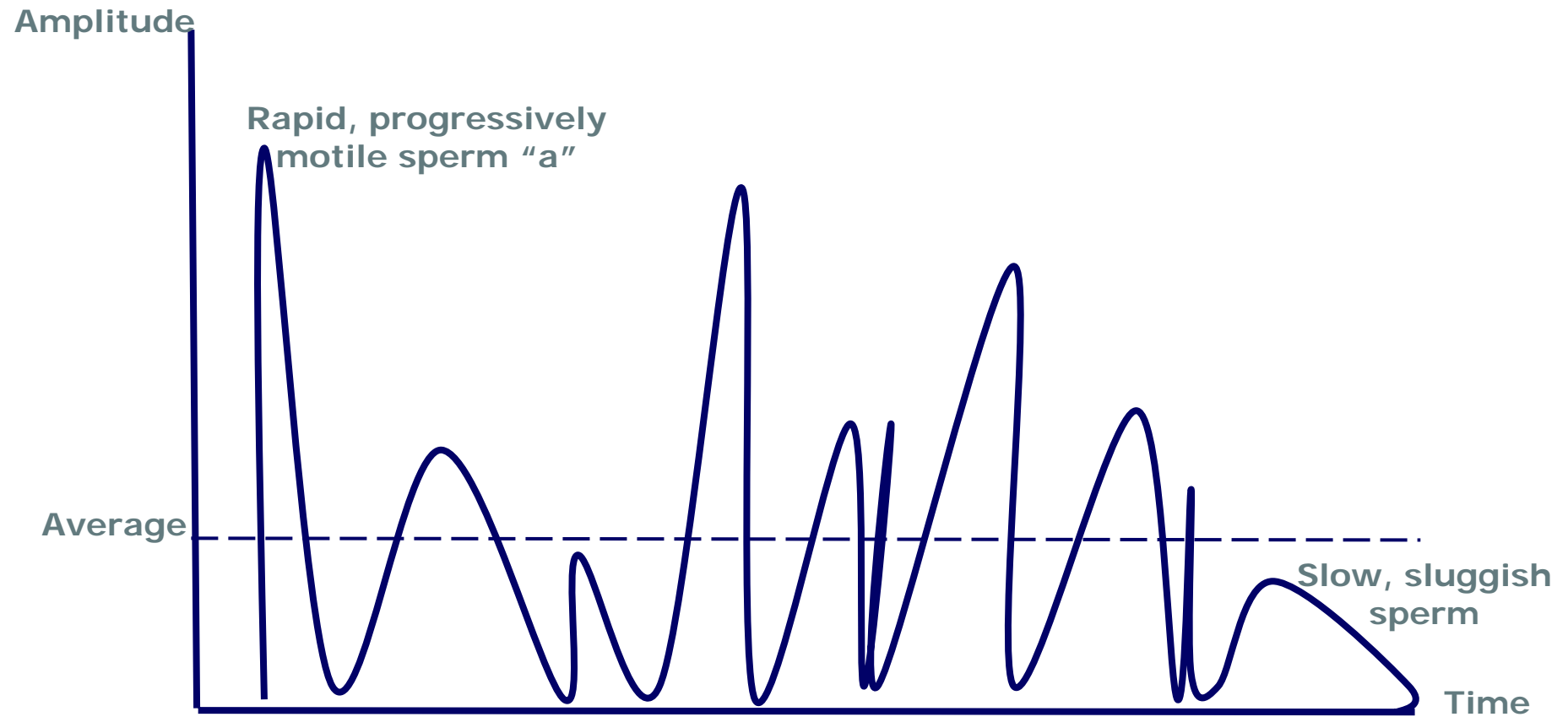
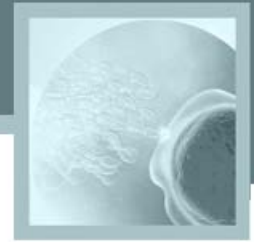
Tens of thousands of cells are measured

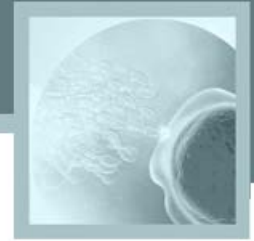
- Light interruptions (modulations) are converted into an electronic signal that displays “peaks and valleys”
- The electronic signal peaks are averaged and translated into motility based on a proprietary algorithm



- Each category of sperm (a, b, c and d) move differently, therefore the light modulations they create are unique and translate into distinct electronic signals.
- Rapidly progressive sperm create light modulations that differ from those produced by slowly progressive sperm.
- Immotile sperm does not create any light disturbances at all!

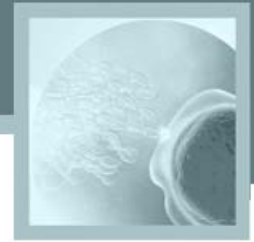
Electronic Signals From Motile Sperm



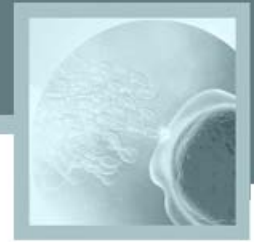


Millions of sperm cells are analyzed

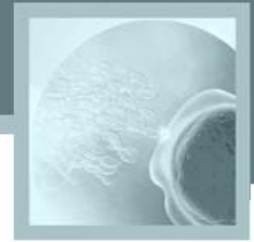
- A light beam traverses the seminal plasma and light is absorbed by sperm cells
- An optical density detector measures the amount of light absorbed by the cells
- This measurement is translated into total cell concentration based on a proprietary algorithm



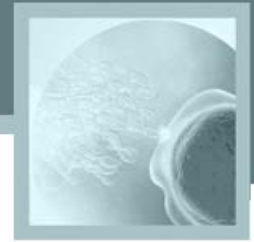
- Based on a correlation between sperm motility and morphology, MES developed a proprietary algorithm that calculates NORMAL morphology based on motility, progressive motility, and velocity
- This parameter has been shown to be very useful as a qualitative screen for normal vs. abnormal morphology



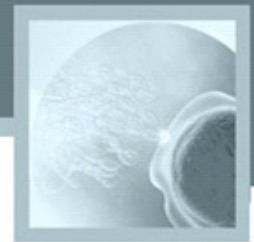
- **Color video display**
- **Magnification of x300 to x500**
- **Allows viewing of both capillary or slide samples**
- **At x300 cell concentration can be measured**
- **Using V-Sperm, the magnification can be increased and the screen can be frozen for easy counting or examination**



- **At start-up**
 - **Stabilization and auto-calibration:** Automatically checks system stability and reference ranges for 30 seconds
 - **System noise:** The level of electronic noise is measured and filtered in order to meet acceptable thresholds
 - **Self test:** Electronic signals are produced simulating motility and concentration to verify calibration settings are consistent with factory settings

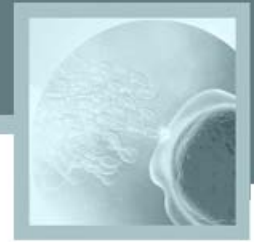


- **Prior to sample testing:**
 - **Auto calibration verification:** Reference values are re-checked. Concentration and motility parameters are measured
 - **System noise:** The level of electronic noise is measured and filtered in order to meet acceptable thresholds
 - **Electronic spikes:** Screens for any measurement points that are out of range electronically



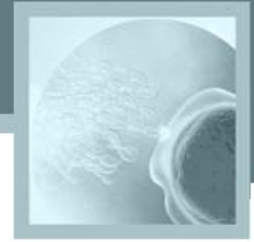
DYNAMIC RANGE OF THE **SQA-V** *Gold*

SAMPLE	SPERM CONC in M/ml	MSC in M/ml	Motility %
FRESH	2-400 or < 2 M/ml	0.2-400 or <0.2 M/ml	0-100%
WASHED	2-200 or < 2 M/ml	0.2-200 or <0.2 M/ml	0-100%
FROZEN	Not reported	0.2-200 or <0.2 M/ml	Not reported
POSTVASECTOMY	Manual Input	0-30 Sperm/Scan	Not reported



SQA-V Precision		
SQA-V	Beads*	CV%
Intra Device Variability	High 47 ± 7.0 M/ml	≤ 0.01
	Low 24 ± 3.4 M/ml	≤ 0.01
Inter Device Variability	High 47 ± 7.0 M/ml	≤ 2.00
	Low 24 ± 3.4 M/ml	≤ 2.00

* Beads: The precision and accuracy of the SQA-V was tested using a known concentration of commercially available latex beads.



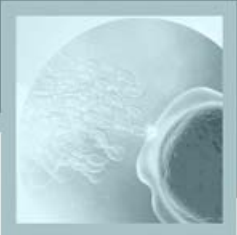
Specificity Claims:

- Concentration: 85%
- Motility: 80%
- Morph Norm Forms (WHO 3rd): 65%
- Morph Norm Forms (WHO 4th strict): 60%

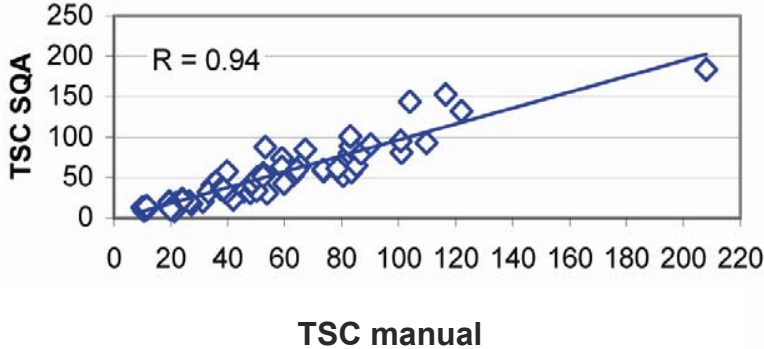
Sensitivity Claims:

- Concentration: 90%
- Motility: 85%
- Morph Norm Forms (WHO 3rd): 85%
- Morph Normal Forms (WHO 4th strict): 65%

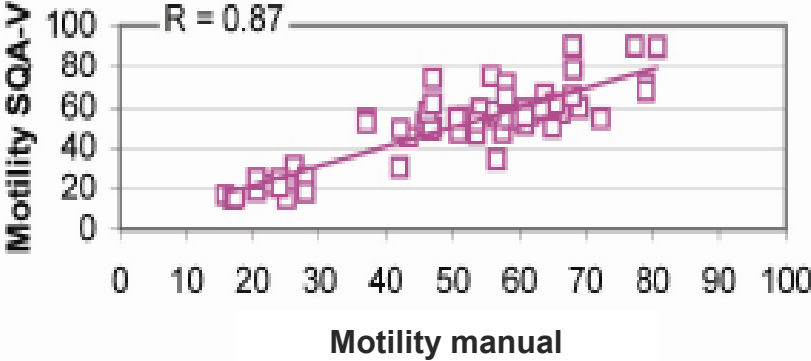
Product Performance Data: Correlation to Manual Method



Concentration: 0.94



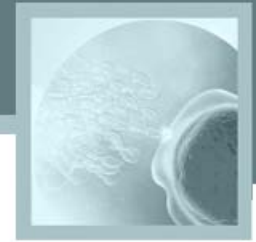
Motility: 0.87



Morphology:

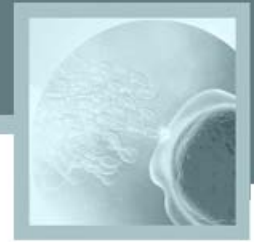
SQA-V ROC ANALYSIS WHO 3rd Morphology (52 SAMPLES)		SQA-V ROC ANALYSIS WHO 4th (Kruger) Morphology (39 SAMPLES)	
True Positive: 45	False Positive: 1	True Positive: 20	False Positive: 3
True Negative: 3	False Negative: 3	True Negative: 7	False Negative: 9
% Sensitivity: 94%		% Sensitivity: 69%	
% Specificity: 75%		% Specificity: 70%	





Precision – Compared to Microscope

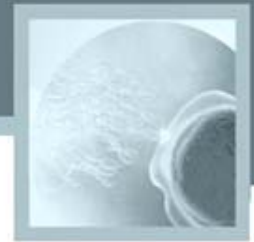
Parameter	Range	Method	
		SQA-V CV%	Microscope CV%
Sperm Concentration M/ml	Entire Range	3.1	6.1
	5-40	5.2	5.9
	41-80	2.1	5.5
	>80	2.5	3.2
Motility %	Entire Range	5.1	7.2
	10-50	7.6	10.3
	51-55	1.5	3.4
	>55	6.0	4.1



Post-vasectomy Testing

Method Comparison 218 Samples with Motile Cells	# Samples Motile Sperm Detected	% Samples Motile Sperm Detected
SQA-V Automated System and Visualization System	207	95%
SQA-V Visualization System only	193	89%
Microscope only	161	74%

THE SQA-V TECHNOLOGY



- High performance, analytical medical device
- Performs complete quantitative evaluation of semen quality and semen parameters
- Rapid results – *under 2 minutes*
- Electro-optics, computer algorithms, video microscopy
- Self-testing, self-calibrating
- Video visualization system

