Medical Electronic Systems Ltd.

Comparison of Automated Technology (SQA-V) and Manual Technology (Microscope) for Routine Semen Analysis

Sperm Concentration	Microscope per WHO		Automated SQA-V	
Sample preparation & counting methodology	Mix the sample. Use a hemacytometer or a Makler counting chamber. Follow counting chamber instructions. **Count** 200 sperm cells twice, verify that the difference between the two counts is within the acceptable statistical rage. If not, the sample must be rerun.		Mix the sample. Fill a capillary and follow the on-screen instructions for **automated testing**.	
Technology Source of errors	Manual count under the microscope. Accuracy and precision are dependent on observer proficiency and experience. **Subjective** nature of manual counting leads to high inter- and intra-operator discrepancies. Test results will vary depending on the type of counting chamber used.		Automated System based on the **objective** electro-optical method (spectrophotometry).	
Sample size tested Sample fraction tested (2-5 ml sample) Number of cells measured	10 µl 0.2% - 0.5% 200 x 2	The overall specimen is **poorly represented** because of the small sample size.	650 µl 13% - 32.5% Millions of cells	The overall specimen is **adequately represented** because of the large sample size**.**
Results Average testing time	Counted **manually** - based on the type of counting chamber used. Results include counting and subjective errors. **15-20 min**.		Fully objective **automated** test results archived in a database. **75 seconds** for all semen parameters.	
Accuracy	The actual **coefficient of variation > 9-20%.** The acceptable coefficient of variation is up to 10% if counting 200 sperm cells (WHO'99 manual). The difference between duplicate counts of 200 sperm cells can reach 14%.		The actual **coefficient of variation < 2%.**	

Sperm Motility	Microscope per WHO		Automated SQA-V	
Sample preparation & counting methodology	Mix the sample. Use a standard slide or a Makler counting chamber. Follow counting instructions of the WHO and differentiate cells according to a velocity grading system. **Count** 200 sperm cells twice, verify that the difference between the two counts is within the acceptable statistical rage. If not, the sample must be rerun.		Mix the sample. Fill a capillary and follow the on-screen instructions for **automated testing**	
Technology Source of errors	Manual count under the microscope. Accuracy and precision are dependent on observer proficiency and experience. **Subjective** nature of manual counting leads to high inter- and intra-operatordiscrepancies. Motility is frequently over-estimated.		Automated System based on the **objective** electro-optical method (signal processing of the light modulations caused by the motile sperm cells).	
Sample size tested Sample fraction tested (2-5 ml sample) Number of cells measured	10 µl 0.2%-0.5% 200 x 2	The overall specimen is **poorly represented** because of the small sample size.	50 µl 1%-2.5% Thousands	The overall specimen is **adequately represented** because of the large sample size**.**
Results Average testing time	**Manual** count and calculation based on the number of cells for each type of velocity grading system: a, b, c, d. **15-20 min**.		Fully objective **automated** test results archived in a database. **75 seconds** for all semen parameters.	
Accuracy	The actual **coefficient of variation > 9-20%.** The acceptable coefficient of variation is 14% - 50% if counting 200 sperm cells (WHO'99 manual). The percentage difference between duplicate counts of 200 sperm cells can reach 10 % (absolute units).		The actual **coefficient of variation < 3%.**	

Sperm Morphology	Microscope per WHO		Automated SQA-V	
Sample preparation & counting methodology	Mix the sample. Follow WHO fixing and staining instructions for Papanicolaou method. Differentiate morphological abnormalities using WHO or Kruger strict criteria. **Count** 200 sperm cells twice, verify that the difference between the two counts is within the acceptable statistical rage. If not, the sample must be rerun.		Mix the sample. Fill a capillary and follow the on-screen instructions for **automated testing**	
Technology Source of errors	Manual assessment and count under the microscope. Accuracy is highly dependent on the proficiency and experience of the technician/MD. High inter- and intra-operator variability due to the **subjective** nature of the test; requiring the ability to accurately assess and differentiate sperm cells with morphological abnormalities.		**Automated test**. Calculated parameter (proprietary algorithm) based on the correlation between progressive motility and normal morphology.	
Sample size tested Number of cells measured	10 µl 200 x 2	The overall specimen is **poorly represented** because of the small sample size.	50 µl Thousands	The overall specimen is **adequately represented** because of the large sample size**.**
Results Average testing time	**Manual** grading system based on the assessment and classification of individual spermatozoa characteristics and abnormalities (head, neck, mid-piece, etc according to WHO). **15-20 min**.		Fully **automated** test results archived in a database. **75 seconds** for all semen parameters.	
Accuracy	The actual **coefficient of variation > 9-40%.** The acceptable coefficient of variation is 14% - 50% if counting 200 cells (WHO'99 manual). The percentage difference between duplicate counts of 200 sperm cells can reach 10 % (absolute units) .		The actual **coefficient of variation < 3%.**	