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QAP semen analysis results using the SQA-V GOLD in compliance with ISO15189, independently performed byIVF Australia

Background: IVF Australia conducted a six center Quality Assurance Program (QAP) for semen analysis using the automated SQA-V GOLD sperm analyzer. Both precision and accuracy were assessed for concentration, morphology and motility parameters by running prepared frozen semen samples from the same donor distribution.

Methodology: Frozen human semen samples were centrally prepared for the QAP challenge. To ensure the integrity of the samples post thaw and to standardize the outcomes, the samples were prepared following an established freezing protocol. The frozen sample integrity was maintained during the shipping process and each laboratory followed a standardized thawing and testing procedure.

Samples were run in duplicate in a blinded fashion on the resident SQA-V automated semen analyzer at six labs in various locations in Australia. The cumulative test results for Concentration, Motility categories (PR, NP, IM) and Normal Forms (Morphology) based on WHO 5th ed. Manual (2010) were sent to M.E.S. for statistical analysis. Accuracy was determined by comparing results from each participating lab to the overall mean and % deviation for each semen parameter. Intra-device (intra-lab) and inter-device (inter-lab) precision was evaluated by generating coefficients of variation (CV) from duplicate tests.

Results: The results of the QAP test are presented below:

	SAMPLE A		Mean	Deviation from Overall Mean, %	Intra-device CV, %
Replicate	**#1**	**#2**			
LAB #1					
Conc. (M/ml)	75.8	75.8	75.8	-0.9	0.0
PR (%)	38.0	39.0	38.5	2.3	1.8
NP (%)	8.0	8.0	8.0	-4.3	0.0
IM (%)	54.0	53.0	53.5	-1.1	1.3
Morph. (%)	9.0	10.0	9.5	1.7	7.4
LAB #2					
Conc. (M/ml)	69.9	67.4	68.7	8.6	2.6
PR (%)	38.0	40.0	39.0	1.1	3.6
NP (%)	8.0	7.0	7.5	2.2	9.4
IM (%)	54.0	53.0	53.5	-1.1	1.3
Morph. (%)	8.0	9.0	8.5	12.1	8.3
LAB #3					
Conc. (M/ml)	79.8	76.1	78.0	-3.8	3.4
PR (%)	40.0	40.0	40.0	-1.5	0.0
NP (%)	7.0	7.0	7.0	8.7	0.0
IM (%)	53.0	53.0	53.0	-0.2	0.0
Morph. (%)	10.0	10.0	10.0	-3.4	0.0

	SAMPLE A		Mean	Deviation from Overall Mean, %	Intra-device CV, %
Replicate	#1	#2			
LAB #4					
Conc. (M/ml)	70.9	73.6	72.3	3.8	2.6
PR (%)	41.0	41.0	41.0	-4.0	0.0
NP (%)	9.0	8.0	8.5	-10.9	8.3
IM (%)	50.0	51.0	50.5	4.6	1.4
Morph. (%)	11.0	11.0	11.0	-13.8	0.0
LAB #5					
Conc. (M/ml)	74	78.7	76.4	-1.7	4.4
PR (%)	41.0	41.0	41.0	-4.0	0.0
NP (%)	7.0	7.0	7.0	8.7	0.0
IM (%)	52.0	52.0	52.0	1.7	0.0
Morph. (%)	10.0	11.0	10.5	-8.6	6.7
LAB #6					
Conc. (M/ml)	77.6	81.5	79.6	-5.9	3.5
PR (%)	38.0	36.0	37.0	6.1	3.8
NP (%)	8.0	8.0	8.0	-4.3	0.0
IM (%)	54.0	56.0	55.0	-3.9	2.6
Morph. (%)	9.0	8.0	8.5	12.1	8.3

Overall Statistics			
	Mean	**Intra-device (lab) CV, %**	**Inter-device (lab) CV, %**
Conc. (M/ml)	75.1	2.7	5.3
PR (%)	39.4	1.5	4.0
NP (%)	7.7	3.0	7.9
IM (%)	52.9	1.1	2.9
Morph. (%)	9.7	5.1	10.7
	Average:	**2.7**	**6.2**

Conclusions:

- The SQA-V GOLD demonstrated high precision and no systematic discrepancy between the systems.
- The overall averaged device CVs are: 2.7% (intra-lab) and 6.2% (inter-lab).
- The overall CVs for the semen parameters tested are: ≤ 5.1% (Intra-lab) and ≤ 10.7% (inter-lab).
- The SQA-V GOLD deviates less than ± 6%* from the overall mean values for semen parameters Concentration, PR and IM.
- The SQA-V GOLD deviates less than ± 15%from the overall mean values for semen parameters NP and Morphology which are considered low quantification parameters. According to WHO 5th ed. manual (2010),20% precision is considered acceptable when dealing with lower limit quantification (p. 48).

***Of note:** The NEQAS proficiency challenge allowable % bias cutoffs vs. the peer group are as follows: Concentration: Low level challenge <15M/ml: 50% bias; Midrange challenge: 15-30M/ml: 25%; Upper range challenge >30M/ml: 20%.