Andrology

Standard	Guidance
The following specialty sustaining standards of practices shall be incorporated into the laboratory's quality management system, where applicable to the scope of services provided.	
Andrology Standard 1 (AN S1) For automated methods for sperm counts and/or motility, electronic controls should be run as instrument checks, as recommended by the manufacturer, at least once during each day of use.	Electronic controls, used in accordance with the manufacturer's recommendations, are acceptable alternatives to matrix controls if: a) A system is in place to monitor the entire analytical system; b) The laboratory first establishes, through documented studies, the stability of the instrument; and, c) Matrix controls, if available, are run at least once per week of use. Acceptable validation documentation could include matrix appropriate control data, which shows method stability over several weeks.
Andrology Standard 2 (AN S2) For manual sperm counts and concentration: a) a minimum of two levels of quality control shall be run each day of use; b) counts shall be performed, in duplicate, using two separate counting chambers, or two separate aliquots; and c) acceptable precision limits for duplicate counts shall be defined.	Quality control for sperm counts should include a normal and at least one abnormal level in the expected range of patient samples. Acceptable controls are two levels of a standardized solution measured each day of use on two different counting chambers. Patient specimens used, as controls should be verified in the same run with the assayed material. Tolerance limits should be established for the value of each control. The results of duplicate counts should be averaged. It is recommended that precision limits be determined based on an approximate 95% confidence interval for differences between the two counts. If the difference exceeds the precision limits, fresh duplicate preparations should be recounted.

Andrology

Standard	Guidance
Andrology Standard 3 (AN S3) When sperm counts, motility and concentration are performed manually: a) testing shall be performed, in duplicate from one dilution, using two separate counting chambers; b) forward progression shall be evaluated and graded as a subset of motility; and, c) acceptable precision limits for duplicate testing shall be defined.	
Andrology Standard 4 (AN S4) When sperm morphology is assessed, stains shall be used to facilitate classification of cell types.	
Andrology Standard 5 (AN S5) Cervical mucus penetration tests shall be performed in duplicate.	
Andrology Standard 6 (AN S6) Indirect anti-sperm antibody test methods shall include a positive and a negative control with each assay.	
Andrology Standard 7 (AN S7) Sperm-egg interaction tests (e.g., hamster-egg penetration assay, hemizona bioassay) shall include a positive control with each assay.	