

**Clinical Chemistry, Endocrinology, Urinalysis, Urine Pregnancy, Therapeutic Substance Monitoring**

Tag #	Standard	Guidance
	All laboratories shall comply with the applicable requirements for quality management systems and sustaining standards of practice.	

<b>Blood pH and Gases</b>		
<b>Tag #</b>	<b>Standard</b>	<b>Guidance</b>
	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.	
BP1a  BP1b	<p><b>Blood pH and Gases Standard 1</b></p> <p>For blood gas instruments:</p> <p>a) three levels of control shall be used on each day of testing, and a minimum of one control shall be run each eight hours of testing; and,</p> <p>b) a control or calibrator shall be run with each patient unless the blood gas instrument internally verifies the calibration at a minimum of every 30 minutes.</p>	

<b>Clinical Toxicology</b>		
<b>Tag #</b>	<b>Standard</b>	<b>Guidance</b>
	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.	
CT1	<p><b>Clinical Toxicology Standard 1</b></p> <p>Comprehensive Toxicology laboratories shall maintain, on-site, acceptable methods for the confirmation of presumptive positive drug screens.</p>	The analytical methods used to confirm presumptive positives are based on chemical and physical principles that differ from those used in the screening procedure.
CT2	<p><b>Clinical Toxicology Standard 2</b></p> <p>For substance of abuse testing, reports of unconfirmed drug screen findings shall clearly state that the positive findings are unconfirmed.</p>	
CT3	<p><b>Clinical Toxicology Standard 3</b></p> <p>For substance of abuse testing, reports shall state the assay cutoff levels used to discern positive from negative results.</p>	

<b>Hematology</b>		
Tag #	Standard	Guidance
	<p>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.</p>	
	<b>CELLULAR HEMATOLOGY</b>	
	<b>Hematology Standard 1</b>	Standard has been deleted. Number reserved.
HM2	<p><b>Hematology Standard 2</b></p> <p>For manual cellular hematology procedures, one level of quality control material shall be run during each eight hours of operation. If a laboratory's primary cellular hematology procedures are manual methods, a minimum of two levels of quality control material are required during each eight hours of operation.</p>	<p>For manual white, red (including reticulocytes) and platelet cell counts, one level of assayed material, or one procedural control, during each eight hours of operation is required.</p> <p>Procedural control is defined as duplicate dilutions of either an assayed control or previously assayed patient specimen. These may be assayed by the same individual or by different people and the results compared to previously defined acceptable limits for differences between duplicates.</p> <p>White blood cell and platelet counts may be compared with a value estimated from a blood smear.</p>
HM3a	<p><b>Hematology Standard 3</b></p> <p>When cell counts are performed manually using a hemocytometer:</p> <p>a) testing shall be performed in duplicate (e.g., counting two hemocytometer chambers from one dilution); and,</p>	
HM3b	<p>b) acceptable precision limits for duplicate specimens shall be defined.</p>	
	<b>COAGULATION</b>	

<b>Hematology</b>		
<b>Tag #</b>	<b>Standard</b>	<b>Guidance</b>
<p>HM4a</p> <p>HM4b</p>	<p><b>Hematology Standard 4</b></p> <p>For automated coagulation procedures, a minimum of two levels of quality control material shall be run:</p> <p>a) each eight hours of operation unless a quality control protocol has been validated as stated in Quality Control Sustaining Standard of Practice 2 (QC SS2).</p> <p>b) each time a change in reagent occurs.</p>	<p>The quality control material should include a normal and at least one abnormal level in the expected range of patient samples.</p>
<p>HM5a</p> <p>HM5b</p>	<p><b>Hematology Standard 5</b></p> <p>For manual coagulation tests:</p> <p>a) each individual performing tests must test a minimum of two levels of quality control material:</p> <p style="margin-left: 40px;">i) prior to testing patient results;</p> <p style="margin-left: 40px;">ii) each time a change in reagents occurs; and,</p> <p>b) patient and control specimens shall be tested in duplicate.</p>	

<b>Andrology</b>		
<b>Tag #</b>	<b>Standard</b>	<b>Guidance</b>
	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.	
AN1	<p><b>Andrology Standard 1</b></p> <p>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.</p>	<p>Electronic controls, used in accordance with the manufacturer's recommendations, are acceptable alternatives to matrix controls if:</p> <ul style="list-style-type: none"> <li>a) a system is in place to monitor the entire analytical system;</li> <li>b) the laboratory first establishes, through documented studies, the stability of the instrument; and,</li> <li>c) matrix controls, if available, are run at least once per week of use.</li> </ul> <p>Acceptable validation documentation could include matrix appropriate control data, which shows method stability over several weeks.</p>
AN2	<p><b>Andrology Standard 2</b></p> <p>For manual sperm counts and concentration:</p> <ul style="list-style-type: none"> <li>a) a minimum of two levels of quality control shall be run each day of use;</li> <li>b) counts shall be performed, in duplicate, using two separate counting chambers, or two separate aliquots; and</li> <li>c) acceptable precision limits for duplicate counts shall be defined.</li> </ul>	<p>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.</p> <p>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.</p>

<b>Andrology</b>		
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<p>AN3a</p> <p>AN3b</p> <p>AN3c</p>	<p><b>Andrology Standard 3</b></p> <p>When sperm counts, motility and concentration are performed manually:</p> <p>a) testing shall be performed, in duplicate from one dilution, using two separate counting chambers;</p> <p>b) forward progression shall be evaluated and graded as a subset of motility; and,</p> <p>c) acceptable precision limits for duplicate testing shall be defined.</p>	<p>The results of duplicate testing should be averaged. If less than 10% discrepancy is obtained, the results may be reported. If the difference exceeds 10%, the specimen shall be analyzed a third time and the average of the three test results should be reported.</p>
<p>AN4</p>	<p><b>Andrology Standard 4</b></p> <p>When sperm morphology is assessed, stains shall be used to facilitate classification of cell types.</p>	<p>Stains should be checked at least each day of use for intended reactivity.</p> <p>Slides should be adequately identified by permanent etching or with indelible ink.</p> <p>Unusual slides, or photographic representations thereof, should be kept for future reference and training.</p>
<p>AN5</p>	<p><b>Andrology Standard 5</b></p> <p>Cervical mucus penetration tests shall be performed in duplicate.</p>	
<p>AN6</p>	<p><b>Andrology Standard 6</b></p> <p>Indirect anti-sperm antibody test methods shall include a positive and a negative control with each assay.</p>	
<p>AN7</p>	<p><b>Andrology Standard 7</b></p> <p>Sperm-egg interaction tests (e.g., hamster-egg penetration assay, hemizona bioassay) shall include a positive control with each assay.</p>	