

Standards for Diagnostic Laboratory Accreditation: Chemistry

Version: March 2024 – v12

ISQuaEEA International Society for Quality in Health Care External Evaluation Association
Accredited Standards 2022-2026
cpsa COLLEGE OF PHYSICIANS & SURGEONS OF ALBERTA

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Developing Committee:	**Medical Facility Accreditation Committee**
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Introduction

Role of College of Physicians & Surgeons of Alberta (CPSA)

The CPSA is mandated by legislation (Health Professions Act) to regulate the practice of medicine in Alberta and is responsible for licensing physicians, administering standards of practice and conduct, and resolving physician-related complaints. It also provides leadership and direction on issues of importance to the health care system such as access to services, quality improvement, patient safety and privacy. Authority to accredit specified medical services and facilities is one aspect of the mandate. The CPSA administers accreditation programs for those services that the CPSA Council determines deserve explicit standards and verification of compliance with those standards, to ensure the safety of those services to the public in the settings proposed.

Accreditation emphasizes continuous quality improvement and promotes optimum performance to ensure quality health services, and subsequently a high standard of patient care in the Province of Alberta. The CPSA's accreditation programs are overseen by a standing committee, the Medical Facility Accreditation Committee (MFAC), with members appointed by the Council from diverse disciplines in clinical and diagnostic medicine. MFAC conducts a secondary review of practice standards, hears arguments on changes to accreditation standards and reviews all facility accreditation statuses.

CPSA Laboratory Accreditation Program Model

Laboratories are assessed initially when opened and subsequently on a four-year rotation. An interim assessment may also be required as a result of significant changes to the scope and/or location of services.

The key features of the CPSA accreditation assessment model are as follows:

- Assessments are conducted:
  - On a 4-year rotation.
  - By geographic area.
  - With entire zone assessments completed within a calendar year.
- All facilities performing diagnostic laboratory testing for patient management are assessed (both public and private).
- Physician Office Laboratories are not registered or accredited by the CPSA.
- Assessments are conducted by assessment teams of practicing professionals:
  - Assessment Coordinators and/or Accreditation Assessment Officers - CPSA consultants and/or staff who ensure assessments are consistent, comprehensive, accurate and lacking assessor bias; serve as a key assessment resource.
  - Assessors with subject matter expertise (selection based on size of geographical area, number of facilities, scope of services and experience of team members).
- Geographic areas receive pre-assessment notification.
- Assessment teams are vetted for approval to ensure no direct conflict of interest.
- The assessment model encompasses both a desk audit of documentation and an on-site assessment.
- Facilities are required to submit a "Pre-assessment Data Verification Form" listing key facility pre-assessment information required for assessment and are also directed to upload required desk audit documentation utilizing a secure SharePoint site.
- The focus of the on-site assessment is on high risk, patient, staff, safety elements and those activities requiring direct observation and/or validation.

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- Final accreditation reports are distributed to zone/group/facility within a specified time from the last day of the assessment via a secure SharePoint site.
- Responses to non-conformances/citations are due within a specified time of final report receipt; evidence of compliance may be requested for certain key findings for confirmation of compliance. Responses to serious safety non conformances/citations may be requested with a shorter turnaround time.
- Facilities and assessment team members receive evaluation and/or feedback surveys after each assessment to assist the CPSA in process improvement and/or enhancement.
- There is no mandatory mid-cycle assessment.
- Facilities are NOT required to submit on-going self-assessment and/or audit documents.
- Spot inspections may occur without prior notice.

Standards Documents Overview

The Standards are the basis for accreditation decisions and are developed by the Medical Facility Accreditation Committee with final approval by the CPSA Council.

The Standards are evidence based and reference accepted best practices, Provincial and Canadian legislation, relevant International Organization for Standardization (ISO) standards, and other recognized provincial, national, and international standards (e.g., College of American Pathologists, CLSI, CSTM, and Canadian Standards Association). Each accreditation standard has an accompanying reference citation(s).

All standards included in the documents are mandatory requirements for accreditation.

The Standards are process-based and incorporate a quality management system approach. The language, terms and organization of the documents are consistent with ISO 15189.

A review of accreditation standards occurs on an ongoing basis, considering and incorporating stakeholder feedback. Comprehensive formal review occurs on an annual basis.

The CPSA Laboratory Accreditation program currently maintains the following standards documents for the assessment of diagnostic laboratory facilities:

- General
- Anatomic Pathology
- Chemistry
- Fertility Assessment – Semen Analysis
- Flow Cytometry
- Hematology
- Microbiology
- Molecular Diagnostics & Genetics
- Transfusion Medicine

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The 'General Standards' document includes ALL standards common to ALL disciplines. To eliminate redundancy, the discipline-specific standards include ONLY those standards specific and relevant to each discipline. For example, general quality control, proficiency testing, calibration, validation, and procedure manual standards are not repeated in each discipline specific standard.

Prior to each assessment, standards documents, tailored to the scope of testing of a facility, and are made available to:

- Facilities for self-assessment and/or to prepare for an on-site accreditation assessment.
- Assessors for on-site assessments.

Document Format:

- Standard number.
- Patient or staff safety risk category (where applicable).
  Each standard has been reviewed to determine if it represents a direct and/or immediate patient or staff safety risk.
  - Those with either a patient safety (PS) or staff safety (SS) designation indicates that any non-compliance may have direct and/or immediate impact on safety.
  - PS/SS standards are 'shaded' for ease of detection.
  - Assessors must ensure that ALL standards with either a PS or SS designation are directly assessed at the time of the on-site assessment.

Safety Risk Category		
PS	**Patient Safety**	non-compliance may have direct and/or immediate impact on patient safety
SS	**Staff Safety**	non-compliance may have direct and/or immediate impact on staff safety

- Description of standard requirement.
- Specific reference(s) (e.g. CLSI, ISO, AABB, College of American Pathologists).
- Interpretation guidance where relevant regarding the application of requirements.
- Assessment of compliance questions (AOC) that provide specific guidance and practical direction for evaluation of compliance with the standard.
  - Although the AOC questions address the key evidence required to meet the intent of each standard, they are not meant to be all encompassing.
  - In addition to the AOC questions, there may be other evidence that demonstrates compliance with the standard. Individual assessors apply their own expertise in determining compliance with each standard.
  - Where AOCs state, "all of the following", compliance with all elements is expected to achieve compliance with the standard.
  - Compliance with the standard may be assessed by review of documents and records, observation, interviews or a combination of these techniques.
  - Upon assessment of the objective evidence, failure to meet the intent and/or requirement of the standard will result in an assessment of non-compliance.

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- "In Progress" citations require submission of future evidence of compliance based on direction from the assessor.
- "Exceeds Requirement" citations are for those situations where a facility exceeds the intent of the standard and employs commendable practice. The intent of capturing these occurences is to promote and focus on quality initiatives.
- Receipt of "FULL" accreditation status is contingent upon satisfactory resolution of all non-compliances (N and P).

Compliance Assessment Category:	
C	meets intent and requirements of standard
P	in progress (working towards meeting intent and requirements of standard; assessor notes evidence of progress towards full compliance)
E	exceeds requirements of standard
N	does not meet intent and/or requirements of standard
N/A	not applicable to scope of service or testing

- Compliance Assessment Category checkboxes.
- Observation field for recording of objective evidence (field is expandable in electronic document).

References

A detailed reference list is provided at the end of this document. Specific reference citations details can be accessed by clicking on individual link(s) included beside each standard. The references support the content and intent of each standard. It should be noted that all components of the cited references may not always be relevant and/or applicable. Compliance is expected with the CPSA standards.

Terms and Definitions

See Diagnostic Laboratory General Standards document for all terms and definitions.

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#	Standard	Reference	Assessment of Compliance
The following standards are discipline-specific and are to be used in conjunction with the CPSA General Standards			
Note: Blood Gas examination standards are covered in the General – Point-of Care Testing Standards document (G.11)			
C.2.0 THERAPEUTIC DRUG MONITORING / TOXICOLOGY			
C.2.1 Therapeutic Drug Monitoring / Toxicology - Equipment, Reagents and Supplies			
C.2.1.1	The laboratory documents and maintains secure access to restricted commercial drugs that are in solid (pure powder) formulations.	GOC[1] Guidance: Low concentration (i.e. 1mg/mL) drugs would be exempt; restricted drugs refer to those included in the federal 'Controlled Drugs and Substances Act' (CDSA)	Is there documentation of the control of restricted drugs used for calibration or controls? Is access to these restricted drugs limited to authorized personnel? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:
C.2.2 Therapeutic Drug Monitoring / Toxicology - Pre-examination Policies, Processes and Procedures			
C.2.2.1	The laboratory provides information to clinical personnel specifying the optimal time of TDM specimen collection relative to pharmacokinetic parameters, where appropriate.	CAP[1] - CHM.28900 CLSI[5] QMS01– 4.1.1	Are there defined criteria provided to clinical personnel on the optimal time of TDM specimen collection relative to drug dosing? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:

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#	Standard	Reference	Assessment of Compliance
C.2.2.2	The examination request form includes all information relevant to therapeutic drug monitoring requests.	CAP[1] - CHM.29000 CLSI[5] QMS01 – 4.1.1	Does the examination request form include all of the following, where applicable: • dosage regimen? • route of administration? • length of time on dosage regimen? • other medications? • time of last medication dose?
			C ☐ P ☐ E ☐ N ☐ N/A ☐
			Observation:
C.2.4 Therapeutic Drug Monitoring / Toxicology - Post-examination Policies, Processes and Procedures			
C.2.4.1	Where applicable, TDM results are reported in relation to patient dosing and/or timing information.	CAP[1] - CHM.29000	Is there a procedure defining criteria for the reporting of TDM results in relation to patient dosing and/or timing information? Is there a mechanism whereby the clinician can easily and accurately link TDM results from the laboratory to the dosage and time of drug administration?
			C ☐ P ☐ E ☐ N ☐ N/A ☐
			Observation:

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#	Standard	Reference	Assessment of Compliance
C.2.4 Therapeutic Drug Monitoring / Toxicology - Post-examination Policies, Processes and Procedures continued			
C.2.4.2	There are protocols for the reporting of toxicology results.	CAP[1] - CHM.15250, .29025 CLSI[7] C52-A3 – 5, 6.3	In addition to the requirements found in the General Standard (G.9.2.5), are the following included in toxicology reports where appropriate: • substances or classes of substances analyzed as part of the toxicology test? • report status for positive results (i.e., unconfirmed, confirmed or pending confirmation)? • for immunoassays, the assay cut-off concentration for each drug or drug class? (cut-off concentrations may alternatively be in a separate chart available to clinicians) • if the report includes unconfirmed screening results, a statement that such results are to be used only for medical (i.e., treatment) purposes? • for the reporting of immunosuppressive drugs: appropriate therapeutic ranges based on the examination method used and the analytic method and method platform? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:

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#	Standard	Reference	Assessment of Compliance
C.3.0 SWEAT EXAMINATIONS			
C.3.1 Sweat Examinations - Equipment, Reagent and Supplies			
C.3.1.1 **PS**	The laboratory implements and ensures the effectiveness of procedures for the disinfection of equipment and facilities used for sweat collection.	CAP[1] - CHM.29150 CLSI[1] C34 – 2.3.2.5-12	Is there evidence of the following: • the disinfection of equipment and facilities used for sweat collection? • a review of disinfection procedures at defined intervals to ensure effectiveness? Do disinfection procedures differ according to whether the patient contact involved intact or non-intact skin? Are disinfectants containing chloride that may contaminate sweat specimens prevented from use? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:
C.3.1.2	The sweat collection device is appropriate for the iontophoresis system.	CAP[1] - CHM.29850 CLSI[1] C34-A3 – 8.6.2	Is the sweat collection device designed for use with the appropriate iontophoresis system so that the stimulation and collection area are equivalent and the appropriate minimum acceptable sweat volume or weight can be achieved? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:

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#	Standard	Reference	Assessment of Compliance
C.3.0 SWEAT EXAMINATIONS			
C.3.1 Sweat Examinations - Equipment, Reagent and Supplies			
C.3.1.3	If the laboratory prepares the pilocarpine solution for iontophoresis, the source of the pilocarpine is USP grade or equivalent.	CAP[1] - CHM.29400 CLSI[1] C34-A3 – 7.1.2	Is the source of pilocarpine used for the preparation of pilocarpine solution USP grade or equivalent? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:
C.3.1.4 **PS**	The protocol specifies the conditions of iontophoresis.	CAP[1] - CHM.29600 CLSI[1] C34-A3 – 6.1.1	Is the iontophoretic current source battery-powered, to avoid the possibility of patient exposure to line voltage? For manually controlled devices, is iontophoresis performed for no more than 5 minutes at a current less than 4 mA, to prevent burns? Is there evidence that the iontophoresis unit has had documented, regular maintenance procedure by qualified personnel at the frequency defined in the QMS? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:

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#	Standard	Reference	Assessment of Compliance
C.3.2 Sweat Examination - Pre-examination Policies, Processes and Procedures			
C.3.2.1	The sweat test is offered only to patients at an appropriate age.	CAP[1] - CHM.29100 CLSI[1] C34-A3 – 8.2	Does the sweat test procedure define the parameters for patient age? Is this procedure adhered to?
			C ☐ P ☐ E ☐ N ☐ N/A ☐
			Observation:
C.3.2.2	The laboratory employs accepted best practice procedures for sweat collection and analysis, including steps to minimize specimen evaporation or contamination.	CAP[1] - CHM.29200 CLSI[1] C34-A3 - 8	Is there evidence that the laboratory sweat collection and analysis procedures are in accordance with manufacturers' instructions and minimize evaporation and contamination when using any of the following: • gauze or filter paper collection pads? • macro duct coils? • nano duct system?
			C ☐ P ☐ E ☐ N ☐ N/A ☐
			Observation:

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#	Standard	Reference	Assessment of Compliance
C.3.2 Sweat Examination - Pre-examination Policies, Processes and Procedures continued			
C.3.2.3	The sweat collection protocol is in accordance with accepted practice and manufacturers' specifications.	CAP[1] - CHM.29300, .29500, .29700, .29800, .29900, .30000, .30100, .30250, .30300 CAP[3] - COM.06100 CLSI[1] C34-A3 – 4.3, 4.4, 8.3, 8.7, 11.2	Do sweat collection protocols specify all of the following, where applicable: • that sweat stimulation and collection is from the patient's lower arm or upper leg, using a site that is free from diffuse inflammation or rash? • that the electrodes used for stimulation are placed such that iontophoretic current never crosses the patient's trunk? • that the area of iontophoretic stimulation is equivalent to the area of sweat collection? • that the sweat collection time does not exceed 30 minutes? • the established minimum acceptable sweat volume or weight based on the area of stimulation, area of collection and standardized time for collection? • specifies that multiple insufficient sweat specimens are rejected and not pooled for analysis? • appropriate sweat specimen labeling procedures? • the recognition of, and appropriate treatment for, patient skin reactions (allergic or burns) to pilocarpine and/or other reagents used in iontophoresis? • manufacturers' storage conditions in the event of a significant delay between collection and analysis? • that iontophoresis is withheld from patients receiving oxygen by an open delivery system? Is there evidence of: • patient collection time records? • rejection of specimens with less than the required volume or weight? • insufficient sweat specimens are not pooled for analysis? C ☐ P ☐ E ☐ N ☐ N/A ☐

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			Observation:

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#	Standard	Reference	Assessment of Compliance
C.3.3 Sweat Examination - Examination Policies, Processes and Procedures			
C.3.3.2	The physiologically appropriate analytical measurement range (AMR) is validated and implemented.	CAP[1] - CHM.30550, .30575 CLSI[1] C34-A3 – 9.7.3	Is the lower limit of the sweat chloride AMR less than or equal to 10 mmol/L without any dilution, concentration or other pre-treatment that is not part of the usual assay process? If the test performed is a confirmatory test (i.e., quantitative analysis of sweat chloride), is the upper limit of AMR for sweat chloride results less than or equal to 160 mmol/L? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:
C.3.4 Sweat Examinations - Quality Assurance of Examination Procedures			
C.3.4.1	The laboratory analyzes controls in the same manner as sweat chloride patient specimens.	CAP[1] - CHM.30600 CLSI[1] C34-A3 – 12.1	If sweat is collected from patients on gauze or filter paper, are controls placed directly onto the same collection material, eluted, and treated in the same manner as a patient specimen? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:

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#	Standard	Reference	Assessment of Compliance
C.3.4 Sweat Examinations - Quality Assurance of Examination Procedures continued			
C.3.4.2	The incidence of insufficient sweat specimens is routinely monitored.	CAP[1] - CHM.30150 CLSI[1] C34-A3 – 8.7.1	Is there evidence of all of the following: • the rate of insufficient sweat specimens is routinely monitored? • the rate of insufficient sweat specimens meets the criteria defined in the QMS? • corrective action occurs if rate exceeds the defined criteria? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:
C.3.5 Sweat Examinations - Post-examination Policies, Processes and Procedures			
C.3.5.1	Patient reports include the specific analytes measured in the sweat analysis and the appropriate reference intervals and/or decision levels.	CAP[1] - CHM.30700 CLSI[1] C34-A3 – 9.5, 13	Is there evidence that patient reports include the following: • the analytes measured in the sweat test? AND • the appropriate reference intervals and/or decision levels? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:
C.3.5.2	Patient reports include the limits of clinical interpretation if the examination is performed using a screening test methodology.	CAP[1] - CHM.30800 CLSI[1] C34-A3 - 10	If the test performed is a screening test (e.g., sweat conductivity) is there evidence that patient reports indicate the limits of clinical interpretation? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:

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#	Standard	Reference	Assessment of Compliance
C.7.0 GAS CHROMATOGRAPHY / HIGH PERFORMANCE LIQUID CHROMATOGRAPHY (GC/HPLC)			
C.7.1 GC/HPLC - Equipment, Reagents and Supplies			
C.7.1.1	The quality and performance of columns, gases, reagents and solvents used for GC and/or HPLC are appropriate and verified for optimal performance.	CAP[1] - CHM.16850, .17100 CLSI[8] C62 – 4.4.1, 6.3	Is there evidence of column verification before use? Are the following of the appropriate grade and quality: • reagents? • solvents? • gases? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:
C.7.1.3 **SS**	Gas lines (particularly those containing explosive gases) are checked regularly for leaks.	CAP[1] - CHM.17050 CLSI[9] GP17-A3 – 8.3	Is there evidence that gas lines (particularly those containing explosive gases) are checked regularly for leaks, including every time tubing or a connection has been manipulated? Is there documentation of corrective action if a leak has been detected? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:

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#	Standard	Reference	Assessment of Compliance
C.7.2 GC/HPLC - Examination Policies, Processes and Procedures			
C.7.2.1	The laboratory evaluates potential carryover from a preceding elevated (high concentration) specimen to the following specimen in each analytical batch analysis and reassesses specimens as required.	CAP[1] - CHM.16800 CLSI[3] EP10-A3 - 4.2	Does the laboratory have criteria for evaluation of potential carryover from a preceding elevated specimen to the following specimen s in each analytical batch? Is there evidence of reassessment of specimens with potential carryover?
			C ☐ P ☐ E ☐ N ☐ N/A ☐
			Observation:

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#	Standard	Reference	Assessment of Compliance
C.7.3 GC/HPLC - Quality Assurance of Examination Procedures			
C.7.3.1	Calibration or calibration verification appropriate to the examination system used, are run in accordance with established and validated protocols.	CAP[1] - CHM.16550 CLSI[8] C62 – 6.6, 8, 9.2	For qualitative assays, is an appropriate calibrator run at a level near the assay's limit of detection (LOD) or at critical decision point(s) (i.e. toxic level)? For quantitative assays, is a multipoint calibration implemented if the measurement has a non-linear response? For measurement systems that have a linear response validated by periodic multipoint calibration verification and AMR validation protocols, is a calibration procedure that uses a single calibrator at an appropriate concentration utilized? Are analyses based on a single point calibration controlled by appropriate quality control samples? If laboratories use historical calibrations: • are controls run to verify the calibration? • does the laboratory have documented validation of the stability of the calibration? Is there evidence of calibration and/or calibration verification records? If a hydrolysis step is required in the assay, does the laboratory include a control (when available) with each batch to evaluate the effectiveness of hydrolysis?
			C ☐ P ☐ E ☐ N ☐ N/A ☐
			Observation:

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#	Standard	Reference	Assessment of Compliance
C.7.3 GC/HPLC - Quality Assurance of Examination Procedures continued			
C.7.3.2	The performance of the column and detector is monitored on each day of use.	CAP[1] - CHM.16950 CLSI[8] C62 – 8, 9	Are unextracted standards, extracted calibrators or controls, analyzed each day to monitor critical aspects of GC performance? Is there evidence that all of the following key parameters are evaluated and monitored at a defined frequency: • retention time? • relative retention time? • separation of closely eluting compounds of interest? • plates? • chromatography quality? • detector response? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:
C.7.3.3	Appropriate controls are extracted and run through the entire procedure.	CAP[1] - CHM.16650 CLSI[8] C62 – 8, 9	Does the written procedure define QC requirements for each examination system that evaluates as much of the complete testing process as is technically feasible? Are there QC records documenting controls on each day of patient testing? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:

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#	Standard	Reference	Assessment of Compliance
C.7.3 GC/HPLC - Quality Assurance of Examination Procedures continued			
C.7.3.4	Appropriate chromatographic characteristics and column performance are recorded, reviewed and approved before results are released.	CAP[1] - CHM.16750, .16770 CLSI[8] C62 – 8, 9	Is there evidence that all of the following are recorded and reviewed prior to results being released: • specimen run order? • chromatographic characteristics? • column performance? Does the run list include: • blanks? • standards? • controls? • patients? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:

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#	Standard	Reference	Assessment of Compliance
C.8.0 MASS SPECTROMETRY			
C.8.1 Mass Spectrometry (MS) - Equipment, Reagents and Supplies			
C.8.1.1	Mass spectrometers are tuned periodically according to manufacturer's recommendations to ensure the instrument meets acceptable tolerance limits.	CAP[1] - CHM.18600, .21410 CLSI[6] C50-A – 4.1.4.1, 4.6.4.1 CLSI[8] C62 - 8.7.1	Is there evidence that the tuned data meets the acceptable tolerance limits? Is tuning performed or verified after major maintenance, environmental change, instrument failure, or when instrument vacuum is compromised? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:
C.8.1.2	Mass spectrometer system performance is verified in compliance with practice recommendations.	CAP[1] - CHM.18610, .18620 CLSI[8] C62 - 9.2	Is there evidence of system performance monitoring that includes all of the following as required: • system suitability specimens? • retention time? • calibrator(s) and internal standards(s)? • calibration slope? • ion ratio(s)? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:

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#	Standard	Reference	Assessment of Compliance
C.8.1 Mass Spectrometry (MS) - Equipment, Reagents and Supplies continued			
C.8.1.3	Mass Spectrometer data analysis tools are validated and monitored for performance.	CAP[1] - CHM.18640 Guidance: Data analysis tools include software or code-based rules, algorithms, machine learning used for automated data analysis.	Is there evidence that data analysis tools used for compound identification and quantification are validated when first installed and re-validated after any modifications, as applicable? Is performance of data analysis tools monitored and verified periodically? (e.g. when changes to software can impact performance). Are custom data analysis tools version controlled? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:
C.8.2 Mass Spectrometry - Examination Policies, Processes and Procedures			
C.8.2.1	Mass spectrometric identifications for single stage mass spectrophotometry (i.e., Gas Chromatography/Mass Spectrometry – GC/MS, Liquid Chromatography/Mass Spectrometry - LC/MS) are performed in compliance with practice recommendations.	CAP[1] - CHM.18700 CLSI[2] C43-A2 – 8.2 CLSI[8] C62	Are there acceptable criteria for compound identification by GC/MS, LC/MS? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:

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#	Standard	Reference	Assessment of Compliance
C.8.2 Mass Spectrometry - Examination Policies, Processes and Procedures continued			
C.8.2.2	Mass spectrometric identifications for tandem mass spectrophotometry (MS/MS) are performed in compliance with practice recommendations.	CAP[1] – CHM.18700 CLSI[2] C43-A2 – 8.2.5 CLSI[6] C50-A	Does the laboratory have tolerance limits that accurately reflect the limitations of the method employed and are supported by references from the literature or experimental data? If the laboratory uses tandem mass spectrometric methods for quantitative purposes only without ion ratios, are there ancillary information and assay characteristics that validate this process (e.g., known administration of a drug to a patient, retention times, potential interferences by endogenous compounds or other drugs and/or metabolites, etc.)? In MS/MS using multiple reaction monitoring, is: • at least one transition monitored for the internal standard? AND • another transition monitored for the analyte? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:

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#	Standard	Reference	Assessment of Compliance
C.8.2 Mass Spectrometry - Examination Policies, Processes and Procedures continued			
C.8.2.3	For LC/MS and MS/MS, the assay includes an evaluation of matrix effects for possible ion-suppression or enhancement.	CAP[1] – CHM.18825, .18850 CLSI[2] C43-A2 – 7.3.2 CLSI[8] C62	Is there documentation of assessment of matrix effects in LC/MS and MS/MS testing? For LC/MS, does the laboratory assay include evaluation to recognize when ion suppression or enhancement occurs? Is there evidence showing monitoring of the signal intensity of the internal standard OR records for alternative methods used? Is there evidence of monitoring of the total ion current intensity, during analysis of extracted matrix blank as part of LC/MS and MS/MS examination development? Is there evidence of an acceptable range of signal intensity of the ion transition(s) selected to monitor each internal standard during the LC/MS and MS/MS analysis of patient specimens?
			C ☐ P ☐ E ☐ N ☐ N/A ☐
			Observation:

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#	Standard	Reference	Assessment of Compliance
C.9.0 INDUCTIVELY COUPLED PLASMA - MASS SPECTROMETRY (ICP/MS)			
C.9.1 Inductively Coupled Plasma - Mass Spectrometry (ICP/MS) - Equipment, Reagents and Supplies			
C.9.1.2	Assay performance is verified each day of use by an appropriate tuning solution or autotune.	CAP[1] - CHM.20400 CLSI[2] C43-A2 – 7.2	Is there evidence of instrument tuning on each day of use? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:
C.9.1.3	Documented procedures for ICP/MS equipment include criteria for the detection of drift in performance.	CAP[1] - CHM.21000 CLSI[6] C50-A – 4.1.4	Do procedures for ICP/MS equipment include criteria for performance and procedures to detect drift in performance? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:
C.9.1.4	Appropriate criteria are defined for selection of both the isotope(s) and the associated internal standard(s) related to each quantified element.	CAP[1] - CHM.21100 CLSI[6] C50-A – 4.1.5, 4.3.6.5	Does the laboratory criteria for the selection of isotopes and internal standards consider interferences (isobaric and polyatomic species) and relative abundances? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:

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#	Standard	Reference	Assessment of Compliance
C.9.2 Inductively Coupled Plasma - Mass Spectrometry (ICP/MS) - Examination Policies, Processes and Procedures			
C.9.2.1	The procedure for ICP/MS ensures optimal peak width and minimization of common interferences.	CAP[1] - CHM.20500, .20600 CLSI[6] C50-A – 4.1.5, 4.3, 4.6.4	Do procedures ensure the optimization of the peak width? Is there evidence that common interferences, such as oxides and doubly charged species, are minimized where appropriate? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:
C.9.2.2	The reaction and/or collision gases are optimized if a reaction and/or collision cell is utilized.	CAP[1] - CHM.20800	Are there records of optimization of reaction and/or collision gases that allow for maximization of sensitivity and minimization of background counts? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:
C.9.2.3	There are processes and/or procedures for the detection and minimization of contamination of ICP/MS results.	CAP[1] - CHM.21200 CLSI[6] C50-A – 4.1.1.7	Is there evidence that potential sources of contamination have been evaluated? Do the procedures detail methods to limit and detect contamination? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:

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#	Standard	Reference	Assessment of Compliance
C.9.3 Inductively Coupled Plasma - Mass Spectrometry (ICP/MS) - Quality Assurance of Examination Procedures			
C.9.3.2	Controls, calibrators and blanks are matrix-matched to the specimen type where necessary.	CAP[1] - CHM.21400 CLSI[6] C50-A – 4.2	Is there a policy defining when the use of matrix-matched controls, calibrators, blanks is required or is unnecessary? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:
C.12.0 URINALYSIS			
C.12.1 Urinalysis General			
C.12.1.1 Urinalysis General - Pre-examination Policies, Processes and Procedures			
C.12.1.1.1	Instructions are available for the proper collection of voided urine specimens.	CAP[2] - URN.22000 CLSI[4] GP16-A3 – 5.3.2	Are instructions available to patients and staff that include all of the following: • midstream and 24 hour urine specimen collection and handling? • specific direction for males, females, infant boys and infant girls? • direction on the preservation of 24 hour specimens? Are the instructions available in each area where urines are collected? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:

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#	Standard	Reference	Assessment of Compliance
C.12.1.1 Urinalysis General - Pre-examination Policies, Processes and Procedures continued			
C.12.1.1.2	There are documented criteria for acceptance or rejection of urine specimens.	CAP[3] – COM.06300 CLSI[4] GP16-A3 – 5.8.3 CLSI[5] QMS01 – 4.1.4 ISO[1] 15189 – 7.2.6	Are specific specimen requirements identified and available? Are there specimen rejection criteria for all of the following: • inappropriate specimen types? • incorrect labeling? • insufficient specimen? • unidentified specimens? • specimens that are not examined within two hours or appropriately preserved? For sub-optimal specimens: • are there instructions for special handling? • is there documentation of disposition? If specimen collection errors are a recurring problem, is there evidence of the laboratory's investigation and corrective action? Is the disposition of all unacceptable specimens documented in the patient report and/or quality management records?
			C ☐ P ☐ E ☐ N ☐ N/A ☐
			Observation:

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#	Standard	Reference	Assessment of Compliance
C.12.1.1 Urinalysis General - Pre-examination Policies, Processes and Procedures continued			
C.12.1.1.3	Urinalysis is performed within two hours of collection or provision is made for appropriate preservation of specimens.	CAP[2] - URN.22300, .22400 CLSI[4] GP16-A3 – 5.6.6, 5.7.2, 6.1.5	Does the urinalysis policy and/or procedure specify all of the following: • urinalysis is performed within two hours of collection where possible? • where not possible, there is suitable preservation of specimens beyond two hours? • media for urine culture is inoculated within 2 hours of collection? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:
C.12.2 Macroscopic Urinalysis			
C.12.2.1 Macroscopic Urinalysis - Equipment, Reagents and Supplies			
C.12.2.1.1	Refractometers are checked at defined intervals with standard solutions of known refractive concentration index and specific gravity.	CAP[2] - URN.26100 CLSI[4] GP16-A3 – 7.3	Is there evidence that refractometers are checked at defined intervals with standard solutions of known refractive concentration index and specific gravity? **C** ☐ **P** ☐ **E** ☐ **N** ☐ **N/A** ☐ Observation:

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#	Standard	Reference	Assessment of Compliance
C.12.2.2 Macroscopic Urinalysis - Examination Policies, Processes and Procedures			
C.12.2.2.1	Macroscopic and/or chemical urinalysis is comprehensive and clinically relevant.	CAP[2] – URN CLSI[4] GP16-A3 – 8	Does routine dipstick urinalysis (whether read manually or by electronic reader) include all of the following, as clinically relevant: • pH? • specific gravity (or ionic concentration)? • glucose? • protein (albumin)? • Blood and/or hemoglobin? • ketone bodies (e.g., acetoacetic acid and/or acetone)? • nitrite? • leukocyte esterase? • urobilinogen? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:

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#	Standard	Reference	Assessment of Compliance
C.12.3 Microscopic Urinalysis			
C.12.3.1 Microscopic Urinalysis – Examination Policies, Processes and Procedures			
C.12.3.1.1	Reference materials are available to assist in the microscopic identification of sediment constituents.	CAP[2] – URN.30750 CLSI[4] GP16-A3 – 9.1	Are appropriate reference materials (atlases, charts or photomicrographs) readily available? Do reference materials reflect current best practice? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:
C.12.3.1.2	There are policies and/or protocols defining when microscopic examination of urine sediment will be performed.	CAP[2] – URN.30700 CLSI[4] GP16-A3 – 9	Are there policies and/or protocols defining the criteria for performance of manual microscopic examinations? Does the criteria include microscopic examination when: • requested by a physician? • indicated by local laboratory clinical protocol (e.g., immunosuppressed, renal, diabetic, or pregnant patient)? • abnormal physicochemical result is obtained (e.g., positive for protein, hemoglobin, leukocyte esterase and/or nitrites)? Do patient reports include microscopic results, if performed based on the defined criteria? When microscopic analysis is not performed, do reports indicate the reason for the abbreviated examination? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:

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#	Standard	Reference	Assessment of Compliance
C.12.3.1 Microscopic Urinalysis – Examination Policies, Processes and Procedures continued			
C.12.3.1.3	Microscopic urinalysis is performed on all specimens using a standardized consistent procedure.	CAP[2] - URN.30700 CLSI[4] GP16-A3 – 9.2.1	Does the procedure for microscopic urinalysis specify which sediment entities are examined? Does the laboratory employ criteria for the consistent identification of all of the following: • blood cells? • epithelial cells? • casts? • microorganisms? • clinically significant crystals? • miscellaneous (e.g., contaminants, mucus threads, sperm)? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:

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#	Standard	Reference	Assessment of Compliance
C.12.3.2 Microscopic Urinalysis – Quality Assurance of Examination Procedures			
C.12.3.2.1	Morphologic observations are routinely assessed to ensure there is consistency among personnel performing urine sediment microscopy.	CAP[2] – URN.30800 CLSI[4] GP16-A3 – 9.3, 11.5	Is there a process and procedure to assess consistency among personnel performing urine sediment microscopy at defined intervals? Is there evidence of assessment of consistency of morphologic observations using processes such as: • circulation of preserved urine sediments with defined abnormalities involving leukocytes, erythrocytes, casts, bacteria, yeast, etc.? • multi-headed microscopy? • use of urine sediment photomicrographs with referee and consensus identifications (e.g., former CAP surveys clinical microscopy photomicrographs)? • digital images? • participation in an external assessment program? Is there records of performance and any corrective action taken for personnel demonstrating significant discrepancies from group consensus? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:
C.12.3.3 Microscopic Urinalysis – Post-examination Policies, Processes and Procedures			
C.12.3.3.1	The results of the microscopic analysis are correlated with macroscopic analysis and discrepant results are investigated.	CAP[2] - URN.30425 CLSI[4] GP16-A3 – 9.2	Is there a procedure for the correlation of microscopic and macroscopic analysis? Is there evidence that discrepant results are investigated? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:

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#	Standard	Reference	Assessment of Compliance
C.12.4 Urinalysis - Automated and Semi-Automated Systems			
C.12.4.1 Urinalysis - Automated and Semi-Automated Systems - Examination Policies, Processes and Procedures			
C.12.4.1.1	There are criteria for identifying urine specimens that may give erroneous results by the dipstick reader and require evaluation by alternate means.	CAP[2] - URN.31250 CLSI[4] GP16-A3 – 10.1	Are there defined criteria for identifying urine specimens that may give erroneous results by the dipstick reader? Are these specimens tested and/or confirmed by alternate means such as visual examination or other confirmatory method?
			C ☐ P ☐ E ☐ N ☐ N/A ☐
			Observation:
C.12.4.1.2	There are criteria for identifying urine specimens that may give clinically relevant erroneous results on morphology systems.	CAP[2] - URN.31400 CLSI[4] GP16-A3 – 10.1.2	Are there defined criteria for identifying specimens that may give clinically relevant erroneous results on the morphology system? Is manual microscopy performed when required?
			C ☐ P ☐ E ☐ N ☐ N/A ☐
			Observation:

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