

The inspector may record information from this interview in Part A of the Inspector's Summation Report.

Pre-Summation Conference

Prior to the summation conference, allow 30-60 minutes to meet privately as a group with the inspection team members to discuss and record inspection findings. The goal of the meeting is to ensure that both verbal and written inspection reports are complete and consistent. During the meeting:

- Resolve team members' questions
- Ensure consistency in recording similar findings (eg, deficiency versus recommendation)
- Identify serious deficiencies that may jeopardize patient care and systemic problems where inspectors cited the same or related deficiencies in multiple laboratory sections
- Review the Part A Questions in the Inspector's Summation Report.

If serious deficiencies or systemic issues are identified or any question from Part A is answered "NO," cite the appropriate checklist requirements relating to the issue and the DRA Checklist requirement for the laboratory director responsibility.

Common examples include:

| Issue Observed | Related DRA Requirement |
|---|--------------------------------|
| Lack of laboratory director involvement | DRA.10435 |
| QMS not properly implemented | DRA.10440 |
| Lack of thoroughness of the self-inspection and/or inadequate or untimely correction of deficiencies noted during the self-inspection process | DRA.10445 |
| Inconsistent quality control/lack of corrective action | DRA.10460 |
| Improper handling of proficiency testing materials/lack of follow-up for unacceptable results | DRA.10460 |
| Lack of validation/verification records for new tests or instruments | DRA.10475 |
| Insufficient numbers of personnel or incomplete records for personnel qualifications and/or training | DRA.11300 |
| Unsafe laboratory practices compromise the safety of personnel | DRA.11400 |
| Incomplete records for delegation of duties or duties not effectively carried out by designee(s) (eg, competency assessments not performed as required by designee) or delegation of functions to individuals who lack the necessary qualifications | DRA.11425 |

Summation Conference

Citations in this checklist are optional for discussion at the summation conference to which laboratory staff, hospital administration, and others may be invited. The team leader may instead choose to discuss them with the laboratory director in a private summation meeting.

DEFINITION OF TERMS

Addendum - Information appended to a final report with no changes to the original test result(s); original report is intact and unchanged, the addendum is added as an attachment or supplement to the original report.

Alternative performance assessment - A system for determining the reliability of laboratory examinations for which no commercial proficiency testing products are available, are not appropriate for the method or patient population served by the laboratory, or participation is not required by the accrediting organization.

Amended/amendment - Any change in a previously issued anatomic pathology or cytopathology report intended to correct an inaccuracy, including changes in the diagnosis, narrative text, clinical history, pre- and post-operative diagnoses, patient identification, or other content.

Analytical performance characteristics - For a specific test, the properties of a test identified from data collected during analytical validation or analytical verification studies.

Analytical validation - The process used to confirm with objective evidence that a laboratory-developed or modified FDA-cleared/approved test method or instrument system delivers reliable results for the intended application.

Analytical verification - The process by which a laboratory determines that an unmodified FDA-cleared/approved test performs according to the specifications set forth by the manufacturer when used as directed.

Annual - Every 12 calendar months.

Authority - The power to give orders or make decisions: the power or right to direct someone or control a process.

Biennial - Every 24 calendar months.

Biorepository - An entity that collects, processes, stores, manages, and distributes biospecimens for research purposes. The term laboratory may also be used in the checklist to generically refer to a biorepository participating in the CAP's Biorepository Accreditation Program.

Calculated test result - A reportable patient test result that is not directly measured but rather calculated from one or more directly measured results.

Check - Examination to determine the accuracy, quality or presence of any attribute of a test system.

Clinical performance characteristics - For a specific test, the properties of a test identified from data collected during studies of clinical validation, clinical utility, or clinical usefulness.

Clinical validation - The determination of the ability of a test to diagnose or predict risk of a particular health condition or predisposition, measured by sensitivity, specificity, and predictive values.

Commutable - The property of a reference material that yields the same numeric result as would a patient's specimen containing the same quantity of analyte in the analytic method under discussion (ie, matrix effects are absent).

Confirmation - Substantiation of the correctness of a value or process.

Corrected/correction - A change in a previously issued clinical pathology test report intended to correct an inaccuracy, including changes in test results, patient identification, reference intervals, interpretation, or other content.

Corrective Action - Action taken to eliminate the cause of a detected nonconformity or other undesirable situation.

Correlation - Establishment of a relationship between two or more measured values.

Credentialing - The process of obtaining, verifying, and assessing the qualifications of a practitioner to provide care in a health care organization.

Device - Any reagent, reagent product, kit, instrument, apparatus, equipment or related product, whether used alone or in combination, intended by the manufacturer to be distributed for use in vitro for the examination of human specimens.

Digital image analysis - The computer-assisted software detection or quantification of specific features in an image following enhancement and processing of that image, including analysis of immunohistochemistry samples, DNA analysis, morphometric analysis, and in situ hybridization.

Distributive testing - Laboratory testing performed on the same specimen, or aliquot of it, that requires sharing between two or more laboratories (with different CLIA/CAP numbers) to provide a final, reportable result for the originally-ordered test. The laboratories involved may perform separate steps of "wet" testing, or may perform calculations, data analysis/informatics processing, or interpretive processes; all such models fall under the term distributive testing.

Equipment - Single apparatus or set of devices or apparatuses needed to perform a specific task.

Examination - In the context of checklist requirements, examination refers to the process of inspection of tissues and samples prior to analysis. An examination is not an analytical test.

External quality control - A stable material designed to simulate a patient specimen for monitoring the performance of a test procedure or system to ensure reliable results. Common examples include positive and negative liquid materials or swabs provided with test kits; assayed and unassayed liquid controls provided by an instrument manufacturer, third party supplier or prepared by the laboratory; and control slides purchased or prepared by the laboratory to demonstrate appropriate reactivity or staining characteristics. In contrast to internal quality control processes, external quality control materials are not built into the performance of the clinical assay. External quality control materials are not to be confused with external quality assessment (EQA) program materials (external proficiency testing).

FDA - 1) For laboratories subject to US regulations, FDA refers to the US Food and Drug Administration, which is the regulatory body under Health and Human Services (HHS) with authority to regulate *in vitro* diagnostic products such as kits, reagents, instruments, and test systems; 2) For laboratories not subject to US regulations, FDA refers to the national, state or provincial, or local authority having jurisdiction over *in vitro* diagnostic test systems.

Function Check - Confirmation that an instrument or item of equipment operates according to manufacturer's specifications prior to initial use, at prescribed intervals, or after minor adjustment (eg, base line calibration, balancing/zero adjustment, thermometer calibration, reagent delivery).

High complexity - Rating given by the FDA to commercially marketed *in vitro* diagnostic tests based on their risks to public health. Tests in this category are seen to have the highest risks to public health.

Instrument - An analytical unit that uses samples to perform chemical or physical assays (eg, chemistry analyzer, hematology analyzer).

Instrument platform - Any of a series of similar or identical analytical methods intended by their manufacturer to give identical patient results across all models.

Internal quality control - Processes integrated into the testing instrument and/or test system designed to monitor the performance of a test to ensure reliable results. Internal quality control may include electronic, built-in, or procedural control systems. On instruments/test systems with internal QC processes, performing the internal QC is typically a physical requirement of performance of the assay on clinical specimens.

Laboratory - Term used to refer to a clinical laboratory, biorepository, forensic drug testing laboratory, or reproductive laboratory participating in the CAP accreditation programs.

Laboratory Director - The individual who is responsible for the overall operation and administration of the laboratory, including provision of timely, reliable and clinically relevant test results and compliance with applicable regulations and accreditation requirements. This individual is listed on the laboratory's CAP and CLIA certificate (as applicable).

Maintenance - Activities that prolong the life of an instrument or minimize breakdowns or mechanical malfunctions. Examples include cleaning, lubrication, electronic checks, or changing parts, fluids, or tubing, etc.

Moderate complexity - Rating given by the FDA to commercially marketed *in vitro* diagnostic tests based on their risks to public health.

Modification of manufacturer's instructions - Any change to the manufacturer's supplied ingredients or modifications to the assay as set forth in the manufacturer's labeling and instructions. It may include a change to specimen type, instrumentation or procedure that could affect its performance specifications for sensitivity, specificity, accuracy, or precision or any change to the stated purpose of the test, its approved test population, or any claims related to interpretation of the results.

For laboratories subject to US regulations, this includes modifications to FDA-cleared/approved tests. For laboratories not subject to US regulations, it also includes modifications to tests approved by an internationally recognized regulatory authority (eg, CE marking).

Non-conforming event - An occurrence that: 1) deviates from the laboratory's policies or procedures; 2) does not comply with applicable regulatory or accreditation requirements; or 3) has the potential to affect (or has affected) patients, donors, the general public, or personnel safety.

Nonwaived - Tests categorized as either moderate complexity (including provider-performed microscopy) or high complexity according to a scoring system used by the FDA.

Pathologist - A physician who has successfully completed an approved graduate medical education program in pathology.

In the US, a physician is defined as a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine who is licensed by the state to practice medicine, osteopathy, or podiatry within the state in which the laboratory is located. In jurisdictions not subject to US regulations, a physician is defined as an individual who has a primary medical school degree (eg, MBBS, MBChB, MD, DO) in keeping with the standards of that particular jurisdiction.

Performance verification - The set of processes that demonstrate an instrument or an item of equipment operates according to expectations prior to initial use and after repair or reconditioning (eg, replacement of critical components).

Personnel - The collective group of employees and contractors employed by the laboratory organization. Contractors may include those individuals contracted by the laboratory, such as pathologists, clinical or medical laboratory scientists, medical technologists, and non-laboratory individuals, such as respiratory therapists or nurses who perform patient testing. It would not include those individuals contracted outside the authority of the laboratory, such as medical waste disposal contractors, instrument service representatives, or cleaning contractors.

Policy - Written statement of overall guidelines, strategy, approach, intentions and directions endorsed by laboratory leadership that direct or restrict a facility's plans, actions, and decisions.

Predictive marker - Biomarker used independent of histologic findings to identify individuals who are more likely to experience a favorable or unfavorable effect from a specific (targeted) therapy, compared to individuals with the same diagnosis lacking the biomarker.

Preventive action - Action taken to eliminate the cause of a potential nonconformity or any other undesirable potential situation.

Primary source verification report - A document, usually prepared by a third party agent or company that confirms that a job applicant's degree, certificate, or diploma is authentic, licenses were granted, and reported work history (company names, locations, dates and positions held) is accurate. The confirmation is obtained through direct contact with an institution, former employer, or their authorized agents.

Primary specimen - The body fluid, tissue, or sample submitted for examination, study or analysis. It may be within a collection tube, cup, syringe, swab, slide, data file, or other form as received by the laboratory.

Procedure - Set of specific instructions that describe the stepwise actions taken to complete a process, operation, activity, or task.

Process - 1) A set of related tasks or activities that accomplishes a work goal; 2) A set of interrelated or interacting activities that transforms inputs into outputs.

Proficiency testing - Evaluation of participant (laboratory or individual) performance against pre-established criteria by means of interlaboratory comparisons. In some countries, the PT programs for clinical laboratories are called "external quality assessment" programs.

Qualified pathologist - A pathologist who has training in the specific functions to be performed (eg, an anatomic pathologist for anatomic pathology functions, a clinical pathologist for clinical pathology functions, or an anatomic pathologist or dermatopathologist for skin biopsies).

Quality management system (QMS) - A QMS is a set of policies, processes, procedures, and resources designed to ensure high quality in an organization's services.

Reagent - Any substance in a test system other than a solvent or support material that is required for the target analyte to be detected and its value measured in a sample.

Reference interval - The range of test values expected for a designated population of individuals.

Report errors - A report element (see GEN.41096) that is either incorrect or incomplete.

Responsibility - A duty or task that an individual is required or expected to do.

Root cause analysis (RCA) - A systematic process for identifying the causal factor(s) that underlie errors or potential errors in care.

Scope of Service - The scope of service is the description of the tests/services that the laboratory provides to its customers/clients (eg, tests offered, hours of operation, turnaround times).

Secondary specimen - Any derivative of the primary specimen used in subsequent phases of testing. It may be an aliquot, dilution tube, slide, block, culture plate, reaction unit, data extract file, image, or other form during the processing or testing of a specimen. (The aliquots or images created by automated devices and tracked by internal electronic means are not secondary specimens.)

Section Director - The individual who is responsible for the technical and/or scientific oversight of a specialty or section of the laboratory.

Semiannual - Every 6 calendar months.

Sentinel event - An unexpected occurrence that reaches a patient and results in death, permanent harm, or severe temporary harm, unrelated to the natural cause of the patient's illness or underlying condition.

Subject to US Regulations - Laboratories located within the United States and laboratories located outside of the US that have obtained or applied for a CLIA certificate to perform laboratory testing on specimens collected in the US and its territories for the assessment of the health of human beings.

Telepathology - The practice of pathology and cytology in which digitized or analog video, still image(s), or other data files are examined and an interpretation is rendered that is included in a formal diagnostic report in the patient record. It also includes the review of images by a cytotechnologist when a judgment of adequacy is recorded in the patient record.

Test - A qualitative, quantitative, or semiquantitative procedure for detecting the presence of, or measuring of an analyte.

Testing personnel - Individuals responsible for performing laboratory assays and reporting laboratory results.

Test system - The process that includes pre-analytic, analytic, and post-analytic steps used to produce a test result or set of results. A test system may be manual, automated, multi-channel or single-use and can include reagents, components, equipment and/or instruments required to produce results. A test system may encompass multiple identical analyzers or devices. Different test systems may be used for the same analyte.

Visitor - An individual entering the laboratory who is not considered personnel.

Waived - A category of tests defined as "simple laboratory examinations and procedures which have an insignificant risk of an erroneous result." Laboratories performing waived tests are subject to minimal regulatory requirements.