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ASF Health Standards Version 11

Standard 28: Laboratory

Required by default in hospitals, ambulatory and primary health clinics · optional in other facility types

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01	1 November 2026	First draft of the laboratory module, drafted from the v10 content (Standard 33) and renumbered. Approved.	Prof. Giorgi Pkhakadze, MD, MPH, PhD

APPROVAL

Approved on 1 November 2026. Approved for use in surveys.

APPROVED BY

Prof. Giorgi Pkhakadze, MD, MPH, PhD
President, Accréditation Sans Frontières **Date:** 1 November 2026

Complete on its own, without internet access. References are listed in section 12. The current version is at france-asf.fr.

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1 Introduction

This document is Standard 28 of ASF Health Standards. It sets out how a medical laboratory keeps its results accurate and reliable: calibrated equipment, verified reagents, validated methods, quality control and external assessment, safe specimen handling, timely and accurate reporting, and traceable amendments.

A standard is a set of numbered criteria. Each criterion says what must be in place (the criterion statement), how it is rated for each setting, what the assessor will check and what evidence the facility must show. The guidance in this document explains what each criterion means in practice, so that a reader who has only this paper can understand and meet it.

Purpose of this document. Standard 28 protects patients whose care depends on a laboratory result, who may be harmed by an inaccurate, late or unreported result, or by a specimen that was mishandled. A laboratory that controls its equipment, methods and reports protects the patient's diagnosis and treatment.

Who should read it. Laboratory managers, nurses and the secretary, clinicians who request tests, and the assessors who verify the service. Each criterion names the positions responsible for it (section 8.2).

The standard is a tool to improve care, not a list of paperwork. Templates and forms named in this document are reference drafts. You may adapt them, replace them with your own, or upload your own documents, provided they meet the same criterion.

2 About ASF and this standard

Accréditation Sans Frontières (ASF) is a non-governmental, non-profit accreditation body. It was legally established in Paris in 2020. ASF develops health standards that are practical, affordable and open to all facilities, including those working with limited resources, in crisis, or in transition.

ASF believes accreditation should be accessible in every sense: geographically, so that facilities in remote areas can take part; financially, so that cost is not a barrier; and in language and format, so that staff can read and use the standard in their own working environment.

Each standard is an independent document. Standard 28 has been written so that it can be read and used on its own. It repeats the definitions, abbreviations and references it needs. A reader who has only this document can understand every criterion in it.

3 How to use this standard

If you are a facility manager or a member of the facilities team, read section 4 to confirm which criteria apply to your facility type, then section 5 to find the rating for your setting. Read each criterion from 28.1 to 28.6, paying attention to the rating, the guidance and the evidence. Prepare the evidence named in each criterion, covering the period stated.

If you are an assessor, use the sample and the checks in each criterion. The pass rule and the immediate-fail rule decide each criterion. A criterion is met only when all its checks are passed and no immediate-fail event is found.

Reading a criterion. Each criterion has: the criterion statement; the three ratings (humanitarian, transition and fragile, standard); the rating rule; the guidance; what good looks like; common mistakes; why it matters; the sample; the checks, with method, evidence and pass condition; the immediate-fail event; the documents with who writes, approves and checks them; the positions responsible; and the references.

Document codes. Each document has a code made of a topic prefix, a type and a number, for example LBT-POL-001 (laboratory, policy, 001). The type is one of FRM (form, a record kept as evidence), REG (register), PLN (plan), POL

(policy), SOP (standard operating procedure) or GDL (guide). The codes identify documents only. The full list is in section 13.

4 Scope

Standard 28 covers calibration, reagent verification, method validation, internal and external quality control, test information, specimen acceptance, transport, STAT and turnaround times, chain of custody, critical values, result authorisation, reports, amendments and suppliers.

The standard applies in three settings. The rating for each criterion is given for each setting, and the facility uses the rating for its own setting: **humanitarian settings** (emergency or crisis, very limited resources), **transition and fragile settings** (a health system in change or under strain), and **standard settings** (full resources).

WHERE STANDARD 28 APPLIES

Standard 28 applies to medical laboratory testing. It is required by default in hospitals, ambulatory clinics and primary health clinics, optional in long-term care, home care, dental and aesthetic clinics, and not applicable to telemedicine and fitness and wellness. A criterion is marked N/A for a facility type that does not provide laboratory testing.

Criterion	Applies to
28.1 Calibration Current and Traceable to a Reference	Hospital, Ambulatory clinic, Primary health clinic, Long-term care, Home care, Dental clinic, Aesthetic and procedure clinic N/A: Telemedicine, Fitness and wellness
28.2 Reagent Lots Verified Before Use	Hospital, Ambulatory clinic, Primary health clinic, Long-term care, Home care, Dental clinic, Aesthetic and procedure clinic N/A: Telemedicine, Fitness and wellness
28.3 Method Validated Before Clinical Use	Hospital, Ambulatory clinic, Primary health clinic, Long-term care, Home care, Dental clinic, Aesthetic and procedure clinic N/A: Telemedicine, Fitness and wellness
28.4 Internal Quality Control Run Before Results Are Released	Hospital, Ambulatory clinic, Primary health clinic, Long-term care, Home care, Dental clinic, Aesthetic and procedure clinic N/A: Telemedicine, Fitness and wellness
28.5 External Quality Assessment Participation	Hospital, Ambulatory clinic, Primary health clinic, Long-term care, Home care, Dental clinic, Aesthetic and procedure clinic N/A: Telemedicine, Fitness and wellness
28.6 Test Indications, Limitations and Patient Preparation Given to Users	Hospital, Ambulatory clinic, Primary health clinic, Long-term care, Home care, Dental clinic, Aesthetic and procedure clinic N/A: Telemedicine, Fitness and wellness
28.7 Specimens Accepted, Logged and Rejected by Defined Criteria	Hospital, Ambulatory clinic, Primary health clinic, Long-term care, Home care, Dental clinic, Aesthetic and procedure clinic N/A: Telemedicine, Fitness and wellness
28.8 Specimen Transport Preserves Integrity	Hospital, Ambulatory clinic, Primary health clinic, Long-term care, Home care, Dental clinic, Aesthetic and procedure clinic N/A: Telemedicine, Fitness and wellness

Criterion	Applies to
28.9 STAT Specimens Prioritised and Turnaround Monitored	Hospital, Ambulatory clinic, Primary health clinic, Long-term care, Home care, Dental clinic, Aesthetic and procedure clinic N/A: Telemedicine, Fitness and wellness
28.10 Chain of Custody for Forensic or Legal Specimens	Hospital, Ambulatory clinic, Primary health clinic, Long-term care, Home care, Dental clinic, Aesthetic and procedure clinic N/A: Telemedicine, Fitness and wellness
28.11 Critical Values Communicated and Receipt Verified	Hospital, Ambulatory clinic, Primary health clinic, Long-term care, Home care, Dental clinic, Aesthetic and procedure clinic N/A: Telemedicine, Fitness and wellness
28.12 Results Authorised Before Release	Hospital, Ambulatory clinic, Primary health clinic, Long-term care, Home care, Dental clinic, Aesthetic and procedure clinic N/A: Telemedicine, Fitness and wellness
28.13 Reports Meet a Defined Minimum and Reach the Correct Recipient	Hospital, Ambulatory clinic, Primary health clinic, Long-term care, Home care, Dental clinic, Aesthetic and procedure clinic N/A: Telemedicine, Fitness and wellness
28.14 Result Amendments Traceable to the Original	Hospital, Ambulatory clinic, Primary health clinic, Long-term care, Home care, Dental clinic, Aesthetic and procedure clinic N/A: Telemedicine, Fitness and wellness
28.15 Suppliers and Reagents Qualified	Hospital, Ambulatory clinic, Primary health clinic, Long-term care, Home care, Dental clinic, Aesthetic and procedure clinic N/A: Telemedicine, Fitness and wellness

5 Ratings and colours

Rating	Colour	Meaning
Must		Required in every setting. Criteria that can directly affect a patient's life are always Must, and no setting lowers them.
Medium		Required, adapted to what a transition setting can realistically do.
Minimum		The lowest acceptable level in a humanitarian setting, where resources are very limited.

In standard settings every criterion is Must.

TRAINING LEVELS

Level	Colour	Meaning
Essential		Must be completed by the people named in the role table.
Recommended		Good practice. Not checked as a requirement.
Optional		May be used for development.

6 Abbreviations

Abbreviation	Meaning
EQA	External quality assessment, a scheme in which a neutral provider sends the same samples to many laboratories
IQC	Internal quality control, control material run in the laboratory to check each analytical run
ISO	International Organization for Standardization
STAT	Urgent test, from the Latin statim (immediately)
WHO	World Health Organization

DOCUMENT CODE PREFIXES

Prefix	Topic
LBT	Laboratory

7 Terms and definitions

Term	Definition
Acceptance criteria	The defined conditions a specimen or reagent must meet before it is used or tested.
Amendment	A recorded change to a result that has already been released, linked to the original result.
Chain of custody	The documented record of every person who handled a specimen, from collection to disposal.
Critical value	A result so far outside the normal range that it needs immediate action by a clinician.
Reportable range	The range of results a method can measure with the accuracy stated in its validation.
Traceability	The property of a result that can be related to a stated reference through an unbroken chain of calibrations.

8 Standard 28 at a glance

Standard 28: Laboratory is a standard of ASF Health Standards for medical laboratories. It is required by default in hospitals, ambulatory clinics and primary health clinics, and each criterion shows the facility types it applies to. It covers equipment, methods, quality control, specimens, reporting and suppliers.

The standard has fifteen criteria. Each is shown below and explained on its own page in section 9.

8.1 CRITERIA AND RATINGS

No.	Criterion	Humanitarian	Transition	Standard
28.1	Calibration Current and Traceable to a Reference	Minimum	Must	Must
28.2	Reagent Lots Verified Before Use	Minimum	Must	Must
28.3	Method Validated Before Clinical Use	Minimum	Must	Must
28.4	Internal Quality Control Run Before Results Are Released	Minimum	Must	Must
28.5	External Quality Assessment Participation	Minimum	Must	Must
28.6	Test Indications, Limitations and Patient Preparation Given to Users	Minimum	Medium	Must
28.7	Specimens Accepted, Logged and Rejected by Defined Criteria	Minimum	Must	Must
28.8	Specimen Transport Preserves Integrity	Minimum	Must	Must
28.9	STAT Specimens Prioritised and Turnaround Monitored	Minimum	Medium	Must
28.10	Chain of Custody for Forensic or Legal Specimens	Minimum	Medium	Must
28.11	Critical Values Communicated and Receipt Verified	Minimum	Must	Must
28.12	Results Authorised Before Release	Minimum	Must	Must
28.13	Reports Meet a Defined Minimum and Reach the Correct Recipient	Must	Must	Must
28.14	Result Amendments Traceable to the Original	Minimum	Medium	Must
28.15	Suppliers and Reagents Qualified	Minimum	Medium	Must

8.2 RESPONSIBILITIES

Each criterion names the positions responsible for it. Each position should have written terms of reference. ISCO-08 codes are shown for each role and are recorded in the staff register.

No.	Criterion	Positions responsible or involved
28.1	Calibration Current and Traceable to a Reference	Manager (ISCO 1342) · Secretary (ISCO 3344)
28.2	Reagent Lots Verified Before Use	Nurse (ISCO 2221) · Manager (ISCO 1342)

No.	Criterion	Positions responsible or involved
28.3	Method Validated Before Clinical Use	Manager (ISCO 1342) · Secretary (ISCO 3344)
28.4	Internal Quality Control Run Before Results Are Released	Manager (ISCO 1342) · Secretary (ISCO 3344)
28.5	External Quality Assessment Participation	Manager (ISCO 1342) · Secretary (ISCO 3344)
28.6	Test Indications, Limitations and Patient Preparation Given to Users	Nurse (ISCO 2221) · Manager (ISCO 1342)
28.7	Specimens Accepted, Logged and Rejected by Defined Criteria	Manager (ISCO 1342) · Secretary (ISCO 3344)
28.8	Specimen Transport Preserves Integrity	Manager (ISCO 1342) · Nurse (ISCO 2221)
28.9	STAT Specimens Prioritised and Turnaround Monitored	Manager (ISCO 1342) · Secretary (ISCO 3344)
28.10	Chain of Custody for Forensic or Legal Specimens	Manager (ISCO 1342) · Nurse (ISCO 2221)
28.11	Critical Values Communicated and Receipt Verified	Manager (ISCO 1342) · Secretary (ISCO 3344)
28.12	Results Authorised Before Release	Manager (ISCO 1342) · Nurse (ISCO 2221)
28.13	Reports Meet a Defined Minimum and Reach the Correct Recipient	Manager (ISCO 1342)
28.14	Result Amendments Traceable to the Original	Manager (ISCO 1342) · Secretary (ISCO 3344)
28.15	Suppliers and Reagents Qualified	Manager (ISCO 1342) · Secretary (ISCO 3344)

Reporting lines. The reporting line and supervision of each role are taken from the ASF terms of reference for that role, published on france-asf.fr. For this standard the manager is the facilities manager. A facility with a different structure records its own reporting lines in its organogram.

Role	Reports to	Supervises
Manager (ISCO 1342)	The chief executive officer or the clinic owner.	Nurses and the secretary in the laboratory.
Nurse (ISCO 2221)	The manager.	No direct reports.
Secretary (ISCO 3344)	The manager.	No direct reports.

8.3 E-LEARNING

The e-learning courses for this standard, who must take each one, who is recommended to take it, and the criteria it supports, are listed in section 11.

8.4 RELATED COURSES IN THE GMJ ACADEMY

These courses cover the same subjects in more depth or for a specific type of facility. They are optional. They are not required by the criteria.

Course	Subject	Criteria	GMJ Academy course page
Equipment, Reagents & Traceability (LAB-04)	Equipment calibration and traceability	28.1	English · Georgian
Facilities, Environment & Suppliers (LAB-05)	Specimen acceptance and facilities	28.7	English · Georgian
Post-Examination: Reporting & Critical Values (LAB-08)	Critical values and reporting	28.11	English · Georgian

28.1 Calibration Current and Traceable to a Reference

HUMANITARIAN SETTINGS	TRANSITION AND FRAGILE SETTINGS	STANDARD SETTINGS
Minimum	**Must**	**Must**

Applies to: 7 of 9 facility types: Hospital, Ambulatory clinic, Primary health clinic, Long-term care, Home care, Dental clinic, Aesthetic and procedure clinic. **Not applicable to:** Telemedicine, Fitness and wellness. Each setting shows its rating above.

> **Criterion.** Each instrument and measuring device is calibrated or verified at the set interval against a traceable reference, and its calibration status is current before any patient result is released.

Rating rule. Minimum in humanitarian settings. Must in transition and fragile settings. Must in standard settings: every instrument and measuring device is calibrated or verified on schedule, with traceability to a reference.

GUIDANCE

Calibration tells the laboratory that a device reads correctly against a known reference. A device that has drifted gives results that look normal and are wrong, so the laboratory must know, for every instrument and measuring device, when it was last calibrated or verified and when it is next due.

The calibration and maintenance register (LBT-REG-001) lists each device with its interval. The calibration certificate (LBT-FRM-006) should name the reference used, so that the result can be traced back to a recognised standard. Where a device has no traceable reference, the laboratory states how it has been verified instead.

When a calibration expires, the device is taken out of use until it is calibrated again. The out-of-calibration procedure (LBT-SOP-011) says who decides this and how patient results produced in the gap are reviewed. Results from the period are not released without that review.

> **Good practice.** Every device is calibrated or verified on schedule, traceable to a reference, and removed from use the moment its calibration expires.

> **Partial because.** Calibration is recorded, but some devices are overdue or traceability is not shown on the certificates.

WHAT GOOD LOOKS LIKE

- Each device has a calibration date, a due date and a named person responsible in the register.
- The calibration certificate names the reference standard used.
- Out-of-calibration devices are labelled and removed from use the same day.
- Results produced between the last good calibration and the failure are reviewed and recorded.

COMMON MISTAKES

- Calibration is recorded as done, but the certificate does not show traceability.
- A device stays in use after its due date because nobody checked the register.
- Repairs are made, but no calibration is done afterwards.
- Verification is accepted from a supplier without checking the reference used.

> **Why it matters.** An instrument that is out of calibration gives results that look normal and are wrong. Calibration kept current on every instrument that produces a reportable result is the basis of accurate results.

WHAT THE ASSESSOR CHECKS

Sample. Review the calibration and maintenance records for all measuring devices for the last 12 months, and the traceability certificates.

1 **Each device is calibrated or verified at the set interval.**

Method. Check each device on the register against its calibration date and interval.

Evidence to show. Equipment calibration and traceability (LBT-POL-001).

Pass when. Every device is within its calibration interval.

2 **Calibration is traceable to a reference standard.**

Method. Check the certificate for each calibration for the traceable reference cited.

Evidence to show. Calibration and maintenance register (LBT-REG-001).

Pass when. Every calibration certificate names a traceable reference.

3 **A device out of calibration is withdrawn from patient testing.**

Method. Check each failed or overdue calibration for the withdrawal record.

Evidence to show. Calibration and maintenance register (LBT-REG-001).

Pass when. Every failed or overdue device has a withdrawal record.

Pass. The criterion is met when every check above is passed.

Immediate fail. A chemistry analyser used for patient results eight months after its calibration expired. This fails the criterion on its own, whatever else is in place.

EVIDENCE AND DOCUMENTS

Code	Document	Writes	Approves	Checks
LBT-REG-001	Calibration and maintenance register	Manager	Chief executive	Manager
LBT-POL-001	Equipment calibration and traceability	Manager	Chief executive	Chief executive
LBT-FRM-006	Calibration certificate file	Manager	Chief executive	Manager
LBT-SOP-011	Out-of-calibration action	Manager	Chief executive	Chief executive

POSITIONS RESPONSIBLE

Position	Why it applies	Training
Manager (ISCO 1342)	Maintains the Equipment calibration and traceability	Governance & Document Control for Laboratory Accreditation (LAB-01); Equipment, Reagents & Traceability (LAB-04) Must
Secretary (ISCO 3344)	Keeps the Calibration and maintenance register	Governance & Document Control for Laboratory Accreditation (LAB-01); Equipment, Reagents & Traceability (LAB-04) Must

REFERENCES FOR THIS CRITERION

- International Organization for Standardization (2022). ISO 15189:2022 Medical laboratories: Requirements for quality and competence. Geneva: ISO. https://www.iso.org/standard/76677.html
- International Organization for Standardization (2020). ISO 17511:2020 In vitro diagnostic medical devices: Metrological traceability of values assigned to calibrators and control materials. Geneva: ISO. https://www.iso.org/standard/69984.html

28.2 Reagent Lots Verified Before Use

HUMANITARIAN SETTINGS	TRANSITION AND FRAGILE SETTINGS	STANDARD SETTINGS
Minimum	**Must**	**Must**

Applies to: 7 of 9 facility types: Hospital, Ambulatory clinic, Primary health clinic, Long-term care, Home care, Dental clinic, Aesthetic and procedure clinic. **Not applicable to:** Telemedicine, Fitness and wellness. Each setting shows its rating above.

> **Criterion.** Each new reagent lot is checked against the previous lot or the manufacturer's acceptance criteria before it is used for patient testing, and the check is recorded.

Rating rule. Minimum in humanitarian settings. Must in transition and fragile settings. Must in standard settings: each new reagent lot is verified against defined criteria before it is used.

GUIDANCE

A new reagent lot can behave differently from the last one, even from the same manufacturer. Each new lot is therefore checked before it is used on patients, usually by running the new lot alongside the previous lot or against controls with known values.

The verification record (LBT-FRM-001) states the acceptance criteria, the results obtained and the decision. The criteria come from the previous lot or the manufacturer's acceptance limits, and they are written down before the test is run.

A lot that fails verification is quarantined and recorded in the lot register (LBT-REG-010). It is not used on patients until the failure has been investigated and the decision to release it is signed.

> **Good practice.** Every new reagent lot is verified against defined acceptance criteria before use, and rejected lots are quarantined and logged.

> **Partial because.** Lots are checked, but the criteria are not defined or failed lots are not clearly kept out of use.

WHAT GOOD LOOKS LIKE

- Each new lot is compared with the previous lot before it is used on patients.
- The acceptance criteria are written before the test is run.
- A failed lot is labelled and stored separately, with the reason recorded.
- The lot number of every reagent is recorded against each patient result.

COMMON MISTAKES

- A new lot goes straight into use because the old one ran out.
- The lot check is done, but the criteria are changed after the result is known.
- Lot numbers are not recorded, so a problem cannot be traced.
- Control results are run only on the new lot, without a comparison.

> **Why it matters.** A new batch of reagent can behave differently from the last. Checking each new lot against the laboratory's own quality control before use prevents results going wrong unnoticed.

WHAT THE ASSESSOR CHECKS

Sample. Review the reagent lot verification records for 20 new reagent lots in the last 12 months.

1 **Each new lot is checked before it is used on patients.**

Method. Check each lot receipt for the verification entry dated before first use.

Evidence to show. Reagent lot verification record (LBT-FRM-001).

Pass when. Every sampled lot has a verification dated before first use.

2 **The check follows the manufacturer's acceptance criteria.**

Method. Check each verification for the criteria and the result recorded.

Evidence to show. Reagent lot verification record (LBT-FRM-001).

Pass when. Every verification records the criteria and the result.

3 **A lot that fails is not used.**

Method. Check each failed lot for its removal from use.

Evidence to show. Reagent lot verification record (LBT-FRM-001).

Pass when. No failed lot appears in patient testing.

Pass. The criterion is met when every check above is passed.

Immediate fail. A new reagent lot used on patients without any check against the previous lot. This fails the criterion on its own, whatever else is in place.

EVIDENCE AND DOCUMENTS

Code	Document	Writes	Approves	Checks
LBT-FRM-001	Reagent lot verification record	Manager	Chief executive	Manager
LBT-SOP-012	Reagent lot verification procedure	Manager	Chief executive	Chief executive
LBT-POL-005	Reagent and consumable acceptance	Manager	Chief executive	Chief executive
LBT-REG-010	Reagent lot register	Manager	Chief executive	Manager

POSITIONS RESPONSIBLE

Position	Why it applies	Training
Nurse (ISCO 2221)	Completes the Reagent lot verification record	Governance & Document Control for Laboratory Accreditation (LAB-01); Equipment, Reagents & Traceability (LAB-04) Must
Manager (ISCO 1342)	Checks the criterion at each review	Governance & Document Control for Laboratory Accreditation (LAB-01); Equipment, Reagents & Traceability (LAB-04) Must

REFERENCES FOR THIS CRITERION

- International Organization for Standardization (2022). ISO 15189:2022 Medical laboratories: Requirements for quality and competence. Geneva: ISO. https://www.iso.org/standard/76677.html

28.3 Method Validated Before Clinical Use

HUMANITARIAN SETTINGS	TRANSITION AND FRAGILE SETTINGS	STANDARD SETTINGS
Minimum	**Must**	**Must**

Applies to: 7 of 9 facility types: Hospital, Ambulatory clinic, Primary health clinic, Long-term care, Home care, Dental clinic, Aesthetic and procedure clinic. **Not applicable to:** Telemedicine, Fitness and wellness. Each setting shows its rating above.

> **Criterion.** Each test method is validated for its intended clinical use, covering precision, accuracy, reportable range and reference intervals, before it is used on patients.

Rating rule. Minimum in humanitarian settings. Must in transition and fragile settings. Must in standard settings: each method is validated for its clinical use and revalidated after significant change.

GUIDANCE

A test must be shown to work for the purpose it is used for. Validation covers precision, accuracy, the reportable range, the reference interval and the limits of detection and interference, as far as they apply to the test.

The validation report (LBT-FRM-007) gives the acceptance limit for each parameter and the result obtained. The report is signed before the method is used for patient care, and the method is listed in the method validation register (LBT-REG-002).

A method is validated again when it changes significantly, for example a new reagent platform, a new software version or a change in sample type. The change control policy (LBT-POL-006) says which changes need revalidation.

> **Good practice.** Every method is validated for its clinical use, and revalidated after each significant change, before results are reported.

> **Partial because.** Validation is done, but some reports omit a parameter or changes are not followed by revalidation.

WHAT GOOD LOOKS LIKE

- The validation plan is written before the study starts and states the acceptance limits.
- Each parameter has a result, a limit and a decision in the report.
- A method change triggers a documented review of whether revalidation is needed.
- Method validation is repeated with a new lot of critical reagents where the manufacturer advises it.

COMMON MISTAKES

- A method is used because the manufacturer says it is validated, without local data.
- The report gives a result for precision but not for the reportable range.
- The method is changed in the software but not in the validation file.
- Validation data are kept only in the instrument, not in the register.

> **Why it matters.** A method used for patient results must first be shown to work for this laboratory. Validation or verification before clinical use prevents results from an unproven method.

WHAT THE ASSESSOR CHECKS

Sample. Review the method validation records for the last 5 tests introduced or changed in the last 2 years.

1 **Each method is validated for its intended use before patient testing.**

Method. Check each validation report for its date against the first patient result.

Evidence to show. Method validation before clinical use (LBT-SOP-001).

Pass when. Every method was validated before its first patient result.

2 **The validation covers precision, accuracy, reportable range and reference interval.**

Method. Check each report for these four elements.

Evidence to show. Method validation register (LBT-REG-002).

Pass when. Every report covers all four elements.

3 **A method change triggers revalidation.**

Method. Check each change in the register for a revalidation entry.

Evidence to show. Method validation register (LBT-REG-002).

Pass when. Every change has a revalidation entry before use.

Pass. The criterion is met when every check above is passed.

Immediate fail. A new assay put into clinical use on the manufacturer's claims alone, with no local validation. This fails the criterion on its own, whatever else is in place.

EVIDENCE AND DOCUMENTS

Code	Document	Writes	Approves	Checks
LBT-SOP-001	Method validation before clinical use	Manager	Chief executive	Chief executive
LBT-REG-002	Method validation register	Manager	Chief executive	Manager
LBT-FRM-007	Method validation report	Manager	Chief executive	Manager
LBT-POL-006	Method introduction and change control	Manager	Chief executive	Chief executive

POSITIONS RESPONSIBLE

Position	Why it applies	Training
Manager (ISCO 1342)	Maintains the Method validation before clinical use	Governance & Document Control for Laboratory Accreditation (LAB-01); Personnel & Competence in Laboratory Accreditation (LAB-03) Must
Secretary (ISCO 3344)	Keeps the Method validation register	Governance & Document Control for Laboratory Accreditation (LAB-01); Personnel & Competence in Laboratory Accreditation (LAB-03) Must

REFERENCES FOR THIS CRITERION

- International Organization for Standardization (2022). ISO 15189:2022 Medical laboratories: Requirements for quality and competence. Geneva: ISO. https://www.iso.org/standard/76677.html

- World Health Organization. WHO operational handbook on tuberculosis: Module 3: Diagnosis. Geneva: WHO. https://www.who.int/publications/i/item/9789240110991

28.4 Internal Quality Control Run Before Results Are Released

HUMANITARIAN SETTINGS	TRANSITION AND FRAGILE SETTINGS	STANDARD SETTINGS
Minimum	**Must**	**Must**

Applies to: 7 of 9 facility types: Hospital, Ambulatory clinic, Primary health clinic, Long-term care, Home care, Dental clinic, Aesthetic and procedure clinic. **Not applicable to:** Telemedicine, Fitness and wellness. Each setting shows its rating above.

> **Criterion.** Internal quality control material is run at the set interval and with each analytical run, and results are reviewed against defined rules before patient results are released.

Rating rule. Minimum in humanitarian settings. Must in transition and fragile settings. Must in standard settings: internal quality control runs with each analytical run and failures are acted on before release.

GUIDANCE

Internal quality control checks that the method is working on the day it is used. Control material with known values is run at the set interval and with each analytical run, and the results are compared against defined limits before patient results are released.

The rules for accepting or rejecting a run are written in the quality control policy (LBT-POL-007) and applied the same way by every staff member. A failed control stops the run, and the cause is found and corrected before the run is repeated.

Each out-of-control event is recorded on the acceptance and corrective action form (LBT-FRM-008). The record states what was done, what results were held back, and whether any patient was affected.

> **Good practice.** Quality control runs at the set interval with every analytical run, and every failure is investigated and corrected before results are released.

> **Partial because.** Quality control is run, but some failures are released without review or without a recorded action.

WHAT GOOD LOOKS LIKE

- Control material is run at each level specified in the procedure, every day it is used.
- The quality control rules are written down and taught to every analyst.
- A failed control is investigated before the next patient sample is run.
- Quality control trends are reviewed at set intervals, not only when a run fails.

COMMON MISTAKES

- The control is run once a week but the results are reported daily.
- A failed control is repeated until it passes, with no record of the first failure.
- Control limits are changed without a reason recorded.
- Results from a failed run are released because the patient needed them urgently.

> **Why it matters.** Quality control shows whether a test is working on the day. A result released before the control has been run and accepted may be wrong.

WHAT THE ASSESSOR CHECKS

Sample. Review the internal quality control log for 30 analytical runs and the rules applied.

1 **Quality control is run at the set interval and with each run.**

Method. Check each run in the sample for the quality control entry.

Evidence to show. Internal quality control (LBT-SOP-002).

Pass when. Every sampled run has quality control recorded.

2 **Control results are reviewed against defined rules before release.**

Method. Check each run for the rule applied and the review recorded.

Evidence to show. Internal quality control log (LBT-REG-003).

Pass when. Every run records the rule review before release.

3 **An out-of-control run is not released and is corrected.**

Method. Check each out-of-control run for the hold and the corrective action.

Evidence to show. Internal quality control log (LBT-REG-003).

Pass when. Every out-of-control run is held and corrected before results are released.

Pass. The criterion is met when every check above is passed.

Immediate fail. Patient results released from a run where the control was outside its limit. This fails the criterion on its own, whatever else is in place.

EVIDENCE AND DOCUMENTS

Code	Document	Writes	Approves	Checks
LBT-SOP-002	Internal quality control	Manager	Chief executive	Chief executive
LBT-REG-003	Internal quality control log	Manager	Chief executive	Manager
LBT-FRM-008	QC acceptance and corrective action record	Manager	Chief executive	Manager
LBT-POL-007	Quality control policy	Manager	Chief executive	Chief executive

POSITIONS RESPONSIBLE

Position	Why it applies	Training
Manager (ISCO 1342)	Maintains the Internal quality control	Governance & Document Control for Laboratory Accreditation (LAB-01); Personnel & Competence in Laboratory Accreditation (LAB-03) Must
Secretary (ISCO 3344)	Keeps the Internal quality control log	Governance & Document Control for Laboratory Accreditation (LAB-01); Personnel & Competence in Laboratory Accreditation (LAB-03) Must

REFERENCES FOR THIS CRITERION

- International Organization for Standardization (2022). ISO 15189:2022 Medical laboratories: Requirements for quality and competence. Geneva: ISO. https://www.iso.org/standard/76677.html

28.5 External Quality Assessment Participation

HUMANITARIAN SETTINGS	TRANSITION AND FRAGILE SETTINGS	STANDARD SETTINGS
Minimum	**Must**	**Must**

Applies to: 7 of 9 facility types: Hospital, Ambulatory clinic, Primary health clinic, Long-term care, Home care, Dental clinic, Aesthetic and procedure clinic. **Not applicable to:** Telemedicine, Fitness and wellness. Each setting shows its rating above.

> **Criterion.** The laboratory takes part in external quality assessment for each test it performs where a scheme exists, and acts on every unsatisfactory result.

Rating rule. Minimum in humanitarian settings. Must in transition and fragile settings. Must in standard settings: external quality assessment is taken part in for each test where a scheme exists, and failures are investigated.

GUIDANCE

External quality assessment compares the laboratory's results with those of other laboratories using the same test, from a neutral provider. It shows whether results agree with the wider community, which internal control cannot show.

The laboratory enrols for each test where an EQA scheme is available, and records each result in the EQA register (LBT-REG-004). Where no scheme exists, the laboratory uses another method of comparison and records it.

An unsatisfactory result is investigated and the investigation recorded (LBT-FRM-009, LBT-SOP-013). Management reviews the participation policy (LBT-POL-002) at set intervals and records the decision.

> **Good practice.** The laboratory takes part in EQA for every test where a scheme exists, and each unsatisfactory result leads to a documented investigation.

> **Partial because.** EQA is joined for most tests, but some unsatisfactory results are not investigated.

WHAT GOOD LOOKS LIKE

- The laboratory joins an EQA scheme for each test where one exists, and keeps the enrolment record.
- Each EQA result is reviewed by a named person within the time the scheme requires.
- An unsatisfactory result leads to a documented root cause and corrective action.
- EQA results are reported to management with the other quality indicators.

COMMON MISTAKES

- EQA is joined for the easy tests only, and the difficult ones are left out.
- A result is marked satisfactory without comparing the value with the scheme's target.
- An unsatisfactory result is not investigated because the next round was good.
- The scheme provider is changed without a reason recorded.

> **Why it matters.** A laboratory that does not compare its results with others may have a problem it cannot see. External quality assessment shows how its results compare with peers.

WHAT THE ASSESSOR CHECKS

Sample. Review the external quality assessment participation and results for the last 24 months for each test performed.

1 The laboratory takes part in an external scheme for each test where one exists.

Method. Check the participation record against the list of tests performed.

Evidence to show. External quality assessment participation (LBT-POL-002).

Pass when. Every test with a scheme has participation recorded.

2 **Each unsatisfactory result is investigated and acted on.**

Method. Check each unsatisfactory result for the investigation and the corrective action.

Evidence to show. External quality assessment results register (LBT-REG-004).

Pass when. Every unsatisfactory result has an investigation and action.

3 **Results are reviewed at a set interval by the laboratory lead.**

Method. Check the review entries for the set interval.

Evidence to show. External quality assessment results register (LBT-REG-004).

Pass when. Every result is reviewed at the set interval.

Pass. The criterion is met when every check above is passed.

Immediate fail. Three unsatisfactory external results for one test with no investigation. This fails the criterion on its own, whatever else is in place.

EVIDENCE AND DOCUMENTS

Code	Document	Writes	Approves	Checks
LBT-REG-004	External quality assessment results register	Manager	Chief executive	Manager
LBT-POL-002	External quality assessment participation	Manager	Chief executive	Chief executive
LBT-FRM-009	EQA result record	Manager	Chief executive	Manager
LBT-SOP-013	EQA unsatisfactory result investigation	Manager	Chief executive	Chief executive

POSITIONS RESPONSIBLE

Position	Why it applies	Training
Manager (ISCO 1342)	Maintains the External quality assessment participation	Governance & Document Control for Laboratory Accreditation (LAB-01); Facilities, Environment & Suppliers (LAB-05) Must
Secretary (ISCO 3344)	Keeps the External quality assessment results register	Governance & Document Control for Laboratory Accreditation (LAB-01); Facilities, Environment & Suppliers (LAB-05) Must

REFERENCES FOR THIS CRITERION

- International Organization for Standardization (2022). ISO 15189:2022 Medical laboratories: Requirements for quality and competence. Geneva: ISO. https://www.iso.org/standard/76677.html
- World Health Organization. Manual for organizing a national external quality assessment programme for health laboratories and other testing sites. Geneva: WHO. https://www.who.int/publications/i/item/9789241549677

28.6 Test Indications, Limitations and Patient Preparation Given to Users

HUMANITARIAN SETTINGS	TRANSITION AND FRAGILE SETTINGS	STANDARD SETTINGS
Minimum	**Medium**	**Must**

Applies to: 7 of 9 facility types: Hospital, Ambulatory clinic, Primary health clinic, Long-term care, Home care, Dental clinic, Aesthetic and procedure clinic. **Not applicable to:** Telemedicine, Fitness and wellness. Each setting shows its rating above.

> **Criterion.** Clinicians and patients receive information on the indications, limitations and required preparation for each test, in the test catalogue or on the request form.

Rating rule. Minimum in humanitarian settings. Medium in transition and fragile settings. Must in standard settings: clinicians and patients have current, accurate information on each test.

GUIDANCE

Clinicians need to know what a test can tell them, what it cannot, and how the patient should prepare. Patients need the same, in plain language. A test used for the wrong reason, or with a sample taken at the wrong time, gives a result that misleads.

The test information (LBT-SOP-010) and patient preparation sheets (LBT-FRM-002) are kept for every test. The update log (LBT-REG-011) records each change and the date it was communicated to clinicians.

The test information policy (LBT-POL-008) states who approves a change and how it is released. A change that alters the preparation or the sample requirement is communicated before the next request is accepted.

> **Good practice.** Clinicians and patients have current information on the indications, limits and preparation for each test, and changes are communicated.

> **Partial because.** Information exists for most tests, but some sheets are out of date or changes are not communicated.

WHAT GOOD LOOKS LIKE

- A one-page sheet for each test states the indication, the limit of the test and the preparation.
- The sheet is dated and approved before it is issued.
- Clinicians are told by a named route when a sheet changes.
- Patients get the preparation in writing and in their own language.

COMMON MISTAKES

- The test information is on a wall poster that nobody has updated for years.
- A change to fasting or sample time is made without telling the clinicians.
- The limits of a test are not mentioned, so results are over-read.
- Information is copied from a manufacturer leaflet without adapting it to the local method.

> **Why it matters.** A clinician who orders a test without knowing what it can and cannot tell them will misread the result. Clear written information on each test's purpose and limits is part of a safe result.

WHAT THE ASSESSOR CHECKS

Sample. Review the test catalogue and request forms for 15 tests, and 10 request forms completed in the last 3 months.

1 **Each test states its indication and limitations.**

Method. Check each catalogue entry for the indication and limitation text.

Evidence to show. Test request information sheet (LBT-FRM-002).

Pass when. Every catalogue entry states indication and limitation.

2 **Patient preparation is stated for each test that needs it.**

Method. Check each entry that needs preparation for the instructions given.

Evidence to show. Test request information sheet (LBT-FRM-002).

Pass when. Every test that needs preparation states it.

3 **Clinicians receive the information at the point of request.**

Method. Check each completed request form for the information attached or referenced.

Evidence to show. Test information for users (LBT-SOP-010).

Pass when. Every request form carries or refers to the test information.

Pass. The criterion is met when every check above is passed.

Immediate fail. A fasting test requested with no instruction given to the patient. This fails the criterion on its own, whatever else is in place.

EVIDENCE AND DOCUMENTS

Code	Document	Writes	Approves	Checks
LBT-SOP-010	Test information for users	Manager	Chief executive	Chief executive
LBT-FRM-002	Test request information sheet	Manager	Chief executive	Manager
LBT-POL-008	Test information policy	Manager	Chief executive	Chief executive
LBT-REG-011	Test information update log	Manager	Chief executive	Manager

POSITIONS RESPONSIBLE

Position	Why it applies	Training
Nurse (ISCO 2221)	Completes the Test request information sheet	Governance & Document Control for Laboratory Accreditation (LAB-01) Medium
Manager (ISCO 1342)	Maintains the Test information for users	Governance & Document Control for Laboratory Accreditation (LAB-01) Medium

REFERENCES FOR THIS CRITERION

- World Health Organization. WHO operational handbook on tuberculosis: Module 3: Diagnosis. Geneva: WHO. https://www.who.int/publications/i/item/9789240110991

28.7 Specimens Accepted, Logged and Rejected by Defined Criteria

HUMANITARIAN SETTINGS	TRANSITION AND FRAGILE SETTINGS	STANDARD SETTINGS
Minimum	**Must**	**Must**

Applies to: 7 of 9 facility types: Hospital, Ambulatory clinic, Primary health clinic, Long-term care, Home care, Dental clinic, Aesthetic and procedure clinic. **Not applicable to:** Telemedicine, Fitness and wellness. Each setting shows its rating above.

> **Criterion.** Specimens are accepted, logged and rejected against defined acceptance criteria, and every rejection is recorded with its reason and the notice given to the requester.

Rating rule. Minimum in humanitarian settings. Must in transition and fragile settings. Must in standard settings: specimens are accepted or rejected against defined criteria, and every rejection is logged and notified.

GUIDANCE

A specimen that is damaged, mislabelled, unsuitable or past its stability limit gives an unreliable result. The laboratory defines the acceptance criteria for each specimen type and checks each specimen on receipt against them.

Each rejection is recorded in the rejection log (LBT-REG-005) with the reason. The requesting clinician is told, using the rejection notice (LBT-FRM-010), so that a new specimen can be taken where needed.

The acceptance procedure (LBT-SOP-003) and the acceptance policy (LBT-POL-009) apply equally to every specimen. A specimen is not accepted because it is urgent, unless the criteria have been met.

> **Good practice.** Each specimen is checked against defined acceptance criteria, and every rejection is logged with its reason and notified to the clinician.

> **Partial because.** Criteria are defined, but some rejections are not logged or the clinician is not told.

WHAT GOOD LOOKS LIKE

- The acceptance criteria are on the receiving bench, not only in a file.
- Every rejected specimen is recorded before the sample is discarded.
- The clinician receives a notice on the same day as the rejection.
- Rejection rates by ward or clinic are reviewed each quarter.

COMMON MISTAKES

- A damaged specimen is run anyway because the clinician is waiting.
- A rejection is recorded only verbally.
- Acceptance criteria are not defined for some specimen types.
- The rejection reason is 'unsuitable' with nothing more written.

> **Why it matters.** A specimen that is haemolysed, clotted or too small can give a wrong result. Written rejection criteria, applied the same way by everyone, stop it being tested.

WHAT THE ASSESSOR CHECKS

Sample. Review the specimen receipt and rejection log for 30 rejected specimens and 30 accepted specimens in the last 3 months.

1 **Each specimen is checked against the acceptance criteria on receipt.**

Method. Check each receipt entry for the criteria checked.

Evidence to show. Specimen acceptance and rejection (LBT-SOP-003).

Pass when. Every receipt records the criteria checked.

2 **Each rejection records the reason and the notice given to the requester.**

Method. Check each rejection for the reason and the notice date.

Evidence to show. Specimen receipt and rejection log (LBT-REG-005).

Pass when. Every rejection records reason and notice.

3 **Accepted specimens are logged and identified.**

Method. Check each accepted specimen for the log entry and identifiers.

Evidence to show. Specimen receipt and rejection log (LBT-REG-005).

Pass when. Every accepted specimen is logged with its identifiers.

Pass. The criterion is met when every check above is passed.

Immediate fail. A specimen with no patient identifier accepted and tested. This fails the criterion on its own, whatever else is in place.

EVIDENCE AND DOCUMENTS

Code	Document	Writes	Approves	Checks
LBT-SOP-003	Specimen acceptance and rejection	Manager	Chief executive	Chief executive
LBT-REG-005	Specimen receipt and rejection log	Manager	Chief executive	Manager
LBT-FRM-010	Specimen rejection notice	Manager	Chief executive	Manager
LBT-POL-009	Specimen acceptance policy	Manager	Chief executive	Chief executive

POSITIONS RESPONSIBLE

Position	Why it applies	Training
Manager (ISCO 1342)	Maintains the Specimen acceptance and rejection	Governance & Document Control for Laboratory Accreditation (LAB-01); Facilities, Environment & Suppliers (LAB-05) Must
Secretary (ISCO 3344)	Keeps the Specimen receipt and rejection log	Governance & Document Control for Laboratory Accreditation (LAB-01); Facilities, Environment & Suppliers (LAB-05) Must

REFERENCES FOR THIS CRITERION

- International Organization for Standardization (2022). ISO 15189:2022 Medical laboratories: Requirements for quality and competence. Geneva: ISO. https://www.iso.org/standard/76677.html
- World Health Organization (2020). Laboratory biosafety manual, 4th edition. Geneva: WHO. https://www.who.int/publications/i/item/9789240011311

28.8 Specimen Transport Preserves Integrity

HUMANITARIAN SETTINGS	TRANSITION AND FRAGILE SETTINGS	STANDARD SETTINGS
Minimum	**Must**	**Must**

Applies to: 7 of 9 facility types: Hospital, Ambulatory clinic, Primary health clinic, Long-term care, Home care, Dental clinic, Aesthetic and procedure clinic. **Not applicable to:** Telemedicine, Fitness and wellness. Each setting shows its rating above.

> **Criterion.** Specimens are transported in conditions that preserve their integrity, including packaging, temperature, time limits and labelling, and every deviation is recorded.

Rating rule. Minimum in humanitarian settings. Must in transition and fragile settings. Must in standard settings: specimens are transported in conditions that preserve their integrity, with the transit recorded.

GUIDANCE

Specimens change during transport. Temperature, time, light, shaking and packaging all affect them. The laboratory defines the conditions for each specimen type and makes sure the packaging and the courier keep the specimen within them.

The transport policy (LBT-POL-010) sets the packaging standard, including the packaging used for infectious substances under the WHO Laboratory Biosafety Manual. Each shipment is recorded on the transport record (LBT-FRM-003), with the temperature and time in transit kept in the courier log (LBT-REG-012).

A specimen that has been outside its limits in transit is rejected or flagged, and the decision is recorded. The laboratory tells the sender why, so that the cause can be corrected.

> **Good practice.** Specimens are packed, labelled and transported within their stability limits, with the temperature and time recorded for every shipment.

> **Partial because.** Packaging is in place, but temperature or transit time is not recorded for some shipments.

WHAT GOOD LOOKS LIKE

- The packaging meets the WHO Laboratory Biosafety Manual requirements for the specimen class.
- Each shipment has a temperature record that is checked on arrival.
- A courier is qualified before it is used, and the qualification is recorded.
- A specimen outside its limits in transit is flagged on the report.

COMMON MISTAKES

- Specimens are sent in a bag with ice that has melted.
- Temperature loggers are fitted but the data are never read.
- A courier is used without anyone checking how it carries specimens.
- The transit time is not recorded, so stability cannot be judged.

> **Why it matters.** Some specimens change in transit if they are too warm, too cold, or left too long. The transport conditions must keep the specimen as it was taken.

WHAT THE ASSESSOR CHECKS

Sample. Observe specimen transport from collection to the laboratory for 10 deliveries and review the transport records.

1 **Specimens are packed and labelled to preserve integrity.**

Method. Observe the packaging and labelling of sampled deliveries.

Evidence to show. Specimen transport (LBT-SOP-004).

Pass when. Every sampled delivery is packed and labelled correctly.

2 **Temperature and time limits are kept and recorded.**

Method. Check each transport record for temperature and time against the limit.

Evidence to show. Specimen transport record (LBT-FRM-003).

Pass when. Every record is within its temperature and time limit.

3 **Each deviation is recorded and the specimen is assessed.**

Method. Check each deviation for the record and the decision on the specimen.

Evidence to show. Specimen transport record (LBT-FRM-003).

Pass when. Every deviation has a record and a decision.

Pass. The criterion is met when every check above is passed.

Immediate fail. A specimen left in a hot vehicle for three hours and tested without a deviation record. This fails the criterion on its own, whatever else is in place.

EVIDENCE AND DOCUMENTS

Code	Document	Writes	Approves	Checks
LBT-SOP-004	Specimen transport	Manager	Chief executive	Chief executive
LBT-FRM-003	Specimen transport record	Manager	Chief executive	Manager
LBT-POL-010	Specimen transport policy	Manager	Chief executive	Chief executive
LBT-REG-012	Courier and temperature log	Manager	Chief executive	Manager

POSITIONS RESPONSIBLE

Position	Why it applies	Training
Manager (ISCO 1342)	Maintains the Specimen transport	Governance & Document Control for Laboratory Accreditation (LAB-01); Facilities, Environment & Suppliers (LAB-05) Must
Nurse (ISCO 2221)	Completes the Specimen transport record	Governance & Document Control for Laboratory Accreditation (LAB-01); Facilities, Environment & Suppliers (LAB-05) Must

REFERENCES FOR THIS CRITERION

- World Health Organization (2020). Laboratory biosafety manual, 4th edition. Geneva: WHO. https://www.who.int/publications/i/item/9789240011311
- International Organization for Standardization (2022). ISO 15189:2022 Medical laboratories: Requirements for quality and competence. Geneva: ISO. https://www.iso.org/standard/76677.html

28.9 STAT Specimens Prioritised and Turnaround Monitored

HUMANITARIAN SETTINGS	TRANSITION AND FRAGILE SETTINGS	STANDARD SETTINGS
Minimum	**Medium**	**Must**

Applies to: 7 of 9 facility types: Hospital, Ambulatory clinic, Primary health clinic, Long-term care, Home care, Dental clinic, Aesthetic and procedure clinic. **Not applicable to:** Telemedicine, Fitness and wellness. Each setting shows its rating above.

> **Criterion.** STAT specimens are identified and prioritised, and turnaround time for STAT and routine tests is monitored against defined targets.

Rating rule. Minimum in humanitarian settings. Medium in transition and fragile settings. Must in standard settings: STAT specimens are prioritised and turnaround time is monitored against target.

GUIDANCE

Some results are needed within minutes to change a patient's care. The laboratory identifies STAT specimens on receipt, runs them first and tracks how long each test takes from receipt to result.

Turnaround time is recorded in the monitoring log (LBT-REG-006) for STAT and routine tests, against a target set in the priority and turnaround policy (LBT-POL-011). Targets are reviewed when they are repeatedly missed.

A STAT request is recorded on the request form (LBT-FRM-011) with the clinical reason and the requester. A request without a clinical reason is not automatically treated as STAT; the policy says how this is decided.

> **Good practice.** STAT specimens are identified and prioritised on receipt, and turnaround time is monitored for STAT and routine tests against a target.

> **Partial because.** STAT specimens are marked, but turnaround is not monitored against a target for all tests.

WHAT GOOD LOOKS LIKE

- STAT specimens are labelled with a distinct mark and placed at the front of the queue.
- Turnaround is measured from receipt to authorised result for each test.
- The target for each test is written in the priority policy.
- Missed targets are reviewed at the monthly quality meeting.

COMMON MISTAKES

- Every request is marked STAT, so the mark means nothing.
- The clock starts at result entry, so the delay before receipt is hidden.
- A STAT result is released without authorisation to meet the target.
- Targets are set once and never reviewed.

> **Why it matters.** An urgent (STAT) specimen that waits in the queue can delay treatment for a critical patient. A written procedure to flag, handle and track urgent specimens gets them to the front.

WHAT THE ASSESSOR CHECKS

Sample. Review the STAT specimen log and the turnaround time records for the last 3 months.

1 **STAT specimens are identified and prioritised on receipt.**

Method. Check each STAT specimen for its identification and its priority in the workflow.

Evidence to show. STAT specimens and turnaround (LBT-SOP-005).

Pass when. Every STAT specimen is identified and prioritised.

2 **Turnaround is measured against the defined targets.**

Method. Check the turnaround log for each target against the actual time.

Evidence to show. Turnaround time monitoring log (LBT-REG-006).

Pass when. Turnaround is measured for every test against its target.

3 **Targets missed are reviewed and acted on.**

Method. Check each missed target for the review and action.

Evidence to show. Turnaround time monitoring log (LBT-REG-006).

Pass when. Every missed target has a review and action.

Pass. The criterion is met when every check above is passed.

Immediate fail. A STAT potassium result left in the queue for four hours with no alert. This fails the criterion on its own, whatever else is in place.

EVIDENCE AND DOCUMENTS

Code	Document	Writes	Approves	Checks
LBT-SOP-005	STAT specimens and turnaround	Manager	Chief executive	Chief executive
LBT-REG-006	Turnaround time monitoring log	Manager	Chief executive	Manager
LBT-POL-011	Priority and turnaround policy	Manager	Chief executive	Chief executive
LBT-FRM-011	STAT request record	Manager	Chief executive	Manager

POSITIONS RESPONSIBLE

Position	Why it applies	Training
Manager (ISCO 1342)	Maintains the STAT specimens and turnaround	Governance & Document Control for Laboratory Accreditation (LAB-01) Medium
Secretary (ISCO 3344)	Keeps the Turnaround time monitoring log	Governance & Document Control for Laboratory Accreditation (LAB-01) Medium

REFERENCES FOR THIS CRITERION

- International Organization for Standardization (2022). ISO 15189:2022 Medical laboratories: Requirements for quality and competence. Geneva: ISO. https://www.iso.org/standard/76677.html

28.10 Chain of Custody for Forensic or Legal Specimens

HUMANITARIAN SETTINGS	TRANSITION AND FRAGILE SETTINGS	STANDARD SETTINGS
Minimum	**Medium**	**Must**

Applies to: 7 of 9 facility types: Hospital, Ambulatory clinic, Primary health clinic, Long-term care, Home care, Dental clinic, Aesthetic and procedure clinic. **Not applicable to:** Telemedicine, Fitness and wellness. Each setting shows its rating above.

> **Criterion.** Forensic and legal specimens are handled under a documented chain of custody from collection to disposal, and every transfer is signed.

Rating rule. Minimum in humanitarian settings. Medium in transition and fragile settings. Must in standard settings: forensic and legal specimens are handled under an unbroken chain of custody.

GUIDANCE

A forensic or legal specimen may be used as evidence. The laboratory must show who had it, when, and what was done to it, at every step from collection to disposal. A gap in that record can make the result unusable.

The chain of custody procedure (LBT-SOP-006) sets out the steps. The form (LBT-FRM-004) records each transfer with the name, the time and the signature of the person receiving the specimen, and the register (LBT-REG-013) lists each case.

The policy for forensic and legal specimens (LBT-POL-012) states how the specimen is stored and when it is disposed of. The disposal is recorded in the register and signed.

> **Good practice.** Every forensic or legal specimen has an unbroken chain of custody from collection to disposal, with each transfer recorded.

> **Partial because.** Custody forms are used, but some transfers or the disposal of a specimen are not recorded.

WHAT GOOD LOOKS LIKE

- The custody form is started at the point of collection and travels with the specimen.
- Every signature includes a name, a role and the time.
- Storage locations are recorded for each specimen in the chain.
- Disposal is recorded and witnessed.

COMMON MISTAKES

- The custody form is filled in afterwards from memory.
- A specimen is left unattended on a bench between transfers.
- The name of the receiver is missing from a transfer.
- The case is closed without recording how the specimen was disposed of.

> **Why it matters.** A specimen used as legal evidence must show, at each step, who held it and what happened to it. Without that custody record, the evidence can be challenged.

WHAT THE ASSESSOR CHECKS

Sample. Review the chain of custody forms for 10 forensic or legal specimens in the last 12 months.

1 **Each specimen has a chain of custody from collection.**

Method. Check each form for the first entry at collection.

Evidence to show. Chain of custody for forensic and legal specimens (LBT-SOP-006).

Pass when. Every sampled specimen has a form from collection.

2 **Each transfer is signed and dated.**

Method. Check each transfer on the form for a signature and date.

Evidence to show. Chain of custody form (LBT-FRM-004).

Pass when. Every transfer is signed and dated.

3 **The specimen is disposed of only as recorded.**

Method. Check the disposal entry against the form.

Evidence to show. Chain of custody form (LBT-FRM-004).

Pass when. Every disposal matches the recorded custody.

Pass. The criterion is met when every check above is passed.

Immediate fail. A legal specimen with a gap in custody between two staff members. This fails the criterion on its own, whatever else is in place.

EVIDENCE AND DOCUMENTS

Code	Document	Writes	Approves	Checks
LBT-SOP-006	Chain of custody for forensic and legal specimens	Manager	Chief executive	Chief executive
LBT-FRM-004	Chain of custody form	Manager	Chief executive	Manager
LBT-POL-012	Forensic and legal specimen policy	Manager	Chief executive	Chief executive
LBT-REG-013	Chain of custody register	Manager	Chief executive	Manager

POSITIONS RESPONSIBLE

Position	Why it applies	Training
Manager (ISCO 1342)	Maintains the Chain of custody	Governance & Document Control for Laboratory Accreditation (LAB-01) Medium
Nurse (ISCO 2221)	Completes the Chain of custody form	Governance & Document Control for Laboratory Accreditation (LAB-01) Medium

REFERENCES FOR THIS CRITERION

- International Organization for Standardization (2022). ISO 15189:2022 Medical laboratories: Requirements for quality and competence. Geneva: ISO. https://www.iso.org/standard/76677.html

28.11 Critical Values Communicated and Receipt Verified

HUMANITARIAN SETTINGS	TRANSITION AND FRAGILE SETTINGS	STANDARD SETTINGS
Minimum	**Must**	**Must**

Applies to: 7 of 9 facility types: Hospital, Ambulatory clinic, Primary health clinic, Long-term care, Home care, Dental clinic, Aesthetic and procedure clinic. **Not applicable to:** Telemedicine, Fitness and wellness. Each setting shows its rating above.

> **Criterion.** Critical values are communicated to a responsible clinician by a defined route within a defined time, and receipt is verified and recorded.

Rating rule. Minimum in humanitarian settings. Must in transition and fragile settings. Must in standard settings: critical values are communicated to a responsible clinician in time, and receipt is recorded.

GUIDANCE

A critical value is a result so far outside the normal range that it needs immediate action. The laboratory defines which results are critical and makes sure a responsible clinician is told within the set time.

The critical value policy (LBT-POL-013) lists the values and the time limit. The communication procedure (LBT-SOP-007) sets the route, including what happens when the responsible clinician cannot be reached. The notification record (LBT-FRM-012) and the log (LBT-REG-007) show each call.

Receipt is acknowledged by the clinician, who gives their name and the time. The route should be written down and tested, as part of the patient safety approach set out in the WHO Global Patient Safety Action Plan 2021–2030.

> **Good practice.** A defined list of critical values is communicated to a responsible clinician within the set time, and each notification is acknowledged and recorded.

> **Partial because.** Critical values are phoned, but the time is not recorded or receipt is not acknowledged.

WHAT GOOD LOOKS LIKE

- The list of critical values is posted at each bench and held in the information system.
- The communication time is recorded for each notification.
- A read-back of the value is required from the clinician.
- The route is tested at least once a year.

COMMON MISTAKES

- Critical values are passed on by a message left at the nurses' station.
- The time of notification is not recorded.
- No one checks whether the clinician received the call.
- The critical list was set years ago and has not been reviewed since.

> **Why it matters.** A critical result, such as a dangerously high potassium, must reach a responsible clinician at once. A result left in a report or on a screen can cost a life.

WHAT THE ASSESSOR CHECKS

Sample. Review the critical value log for 30 critical results in the last 3 months.

1 Each critical value is communicated to a responsible clinician.

Method. Check each log entry for the recipient named.

Evidence to show. Critical value communication (LBT-SOP-007).

Pass when. Every critical value names a responsible recipient.

2 Communication happens within the defined time.

Method. Check each entry for the time from result to communication.

Evidence to show. Critical value communication log (LBT-REG-007).

Pass when. Every communication is within the defined time.

3 Receipt is verified and recorded.

Method. Check each entry for the read-back and receipt confirmation.

Evidence to show. Critical value communication log (LBT-REG-007).

Pass when. Every entry records receipt confirmed.

Pass. The criterion is met when every check above is passed.

Immediate fail. A critical potassium result left on a voicemail and not acted on. This fails the criterion on its own, whatever else is in place.

EVIDENCE AND DOCUMENTS

Code	Document	Writes	Approves	Checks
LBT-SOP-007	Critical value communication	Manager	Chief executive	Chief executive
LBT-REG-007	Critical value communication log	Manager	Chief executive	Manager
LBT-FRM-012	Critical value notification record	Manager	Chief executive	Manager
LBT-POL-013	Critical value policy	Manager	Chief executive	Chief executive

POSITIONS RESPONSIBLE

Position	Why it applies	Training
Manager (ISCO 1342)	Maintains the Critical value communication	Governance & Document Control for Laboratory Accreditation (LAB-01); Post-Examination: Reporting & Critical Values (LAB-08) Must
Secretary (ISCO 3344)	Keeps the Critical value communication log	Governance & Document Control for Laboratory Accreditation (LAB-01); Post-Examination: Reporting & Critical Values (LAB-08) Must

REFERENCES FOR THIS CRITERION

- World Health Organization (2021). Global Patient Safety Action Plan 2021–2030: Towards eliminating avoidable harm in health care. Geneva: WHO. https://www.who.int/publications-detail-redirect/9789240032705
- International Organization for Standardization (2022). ISO 15189:2022 Medical laboratories: Requirements for quality and competence. Geneva: ISO. https://www.iso.org/standard/76677.html

28.12 Results Authorised Before Release

HUMANITARIAN SETTINGS	TRANSITION AND FRAGILE SETTINGS	STANDARD SETTINGS
Minimum	**Must**	**Must**

Applies to: 7 of 9 facility types: Hospital, Ambulatory clinic, Primary health clinic, Long-term care, Home care, Dental clinic, Aesthetic and procedure clinic. **Not applicable to:** Telemedicine, Fitness and wellness. Each setting shows its rating above.

> **Criterion.** Each result is authorised for release by a qualified person before it leaves the laboratory, and the person authorising is recorded.

Rating rule. Minimum in humanitarian settings. Must in transition and fragile settings. Must in standard settings: every result is authorised by a qualified person before release.

GUIDANCE

A result is only released after a qualified person has checked it against the quality control, the patient's history and the expected range. Authorisation is the last check before the result leaves the laboratory.

The authorisation procedure (LBT-SOP-014) and the policy (LBT-POL-003) state who may authorise each type of result. The authorisation record (LBT-FRM-005) and the authorised results register (LBT-REG-014) show who released each result and when.

A result that does not pass the check is held. It is not released until the cause has been found and the result has been checked again.

> **Good practice.** Every result is authorised by a qualified person before release, and the register shows who released it and when.

> **Partial because.** Results are authorised, but the authoriser is not always qualified or the release is not recorded.

WHAT GOOD LOOKS LIKE

- The authoriser is named on the report, with their qualification and role.
- A result that falls outside the expected range is checked against the history before it is released.
- The authorisation is recorded before the report leaves the laboratory.
- A result that cannot be authorised is held and the reason recorded.

COMMON MISTAKES

- Results are released automatically without any human check, and nobody reviews the rules.
- The authoriser is also the person who ran the test, with no second check.
- A result is released by a person who is not qualified for that test.
- The authorisation is given verbally and not recorded.

> **Why it matters.** A result released without being checked by qualified staff can carry an error to the clinician. A review and authorisation before release is the last check.

WHAT THE ASSESSOR CHECKS

Sample. Review the authorisation records for 30 released results and the competence records of the authorising staff.

1 Each result is authorised before release by a qualified person.

Method. Check each result for the authoriser and the time before release.

Evidence to show. Result authorisation and release (LBT-POL-003).

Pass when. Every released result has an authoriser before release.

2 The authoriser is competent for the test.

Method. Check the authoriser against the competence register for the test.

Evidence to show. Result authorisation record (LBT-FRM-005).

Pass when. Every authoriser is competent for the test.

3 The authoriser is recorded with the result.

Method. Check each result record for the name recorded.

Evidence to show. Result authorisation record (LBT-FRM-005).

Pass when. Every released result shows the authoriser.

Pass. The criterion is met when every check above is passed.

Immediate fail. A result released by a trainee with no authorisation. This fails the criterion on its own, whatever else is in place.

EVIDENCE AND DOCUMENTS

Code	Document	Writes	Approves	Checks
LBT-FRM-005	Result authorisation record	Manager	Chief executive	Manager
LBT-POL-003	Result authorisation and release	Manager	Chief executive	Chief executive
LBT-SOP-014	Result authorisation procedure	Manager	Chief executive	Chief executive
LBT-REG-014	Authorised results register	Manager	Chief executive	Manager

POSITIONS RESPONSIBLE

Position	Why it applies	Training
Manager (ISCO 1342)	Maintains the Result authorisation and release	Governance & Document Control for Laboratory Accreditation (LAB-01); Post-Examination: Reporting & Critical Values (LAB-08) Must
Nurse (ISCO 2221)	Completes the Result authorisation record	Governance & Document Control for Laboratory Accreditation (LAB-01); Post-Examination: Reporting & Critical Values (LAB-08) Must

REFERENCES FOR THIS CRITERION

- International Organization for Standardization (2022). ISO 15189:2022 Medical laboratories: Requirements for quality and competence. Geneva: ISO. https://www.iso.org/standard/76677.html

28.13 Reports Meet a Defined Minimum and Reach the Correct Recipient

HUMANITARIAN SETTINGS	TRANSITION AND FRAGILE SETTINGS	STANDARD SETTINGS
Must	**Must**	**Must**

Applies to: 7 of 9 facility types: Hospital, Ambulatory clinic, Primary health clinic, Long-term care, Home care, Dental clinic, Aesthetic and procedure clinic. **Not applicable to:** Telemedicine, Fitness and wellness. Each setting shows its rating above.

> **Criterion.** Each report contains a defined minimum set of information, including identifiers, test name, result, units, reference interval and authoriser, and reaches the correct recipient.

Rating rule. Must in every setting: every report contains the defined minimum information and each release is logged.

GUIDANCE

A report is the only part of the laboratory's work that most clinicians see. It must carry enough information to be read correctly: the patient identifier, the test name, the result, the units, the reference interval and the date and time of collection and reporting.

The report content procedure (LBT-SOP-008) defines the minimum set. The template checklist (LBT-FRM-013) is used whenever a template is changed. The release log (LBT-REG-015) records each release, and the report policy (LBT-POL-014) says how reports are delivered.

A report that is delivered in a different form, such as a fax or a message, carries the same information and is recorded in the same way.

> **Good practice.** Every report carries the defined minimum information, uses a checked template, and each release is logged.

> **Partial because.** Reports are issued, but some omit units, reference ranges or the release time.

WHAT GOOD LOOKS LIKE

- Every report carries the same minimum information, in the same order.
- The reference interval is printed next to each result, with its units.
- The report shows the date and time of collection and of release.
- Corrections are shown on the report, not hidden.

COMMON MISTAKES

- A report has no units, so a number cannot be read correctly.
- The reference interval is from an older method and is not updated.
- The report omits the requesting clinician's name.
- Reports are released in batches without a record.

> **Why it matters.** A report without the patient's identity, the specimen type or the test date cannot be used safely. Every report must carry a defined minimum of information.

WHAT THE ASSESSOR CHECKS

Sample. Review 20 laboratory reports and the delivery records for the last 3 months.

1 **Each report contains the defined minimum information.**

Method. Check each report against the minimum content list.

Evidence to show. Laboratory report content and delivery (LBT-SOP-008).

Pass when. Every report contains all the minimum content.

2 **The report reaches the correct recipient.**

Method. Check each delivery against the requester recorded.

Evidence to show. Laboratory report content and delivery (LBT-SOP-008).

Pass when. Every report reaches the requester named.

3 **Reports carry the authoriser and reference interval.**

Method. Check each report for the authoriser and the reference interval.

Evidence to show. Laboratory report content and delivery (LBT-SOP-008).

Pass when. Every report carries both.

Pass. The criterion is met when every check above is passed.

Immediate fail. A report sent to the wrong ward, with another patient's result on it. This fails the criterion on its own, whatever else is in place.

EVIDENCE AND DOCUMENTS

Code	Document	Writes	Approves	Checks
LBT-SOP-008	Laboratory report content and delivery	Manager	Chief executive	Chief executive
LBT-POL-014	Laboratory report policy	Manager	Chief executive	Chief executive
LBT-FRM-013	Report template checklist	Manager	Chief executive	Manager
LBT-REG-015	Report release log	Manager	Chief executive	Manager

POSITIONS RESPONSIBLE

Position	Why it applies	Training
Manager (ISCO 1342)	Maintains the Laboratory report content and delivery	Governance & Document Control for Laboratory Accreditation (LAB-01); Post-Examination: Reporting & Critical Values (LAB-08) Must
Manager (ISCO 1342)	Checks the criterion at each review	Governance & Document Control for Laboratory Accreditation (LAB-01); Post-Examination: Reporting & Critical Values (LAB-08) Must

REFERENCES FOR THIS CRITERION

- International Organization for Standardization (2022). ISO 15189:2022 Medical laboratories: Requirements for quality and competence. Geneva: ISO. https://www.iso.org/standard/76677.html

28.14 Result Amendments Traceable to the Original

HUMANITARIAN SETTINGS	TRANSITION AND FRAGILE SETTINGS	STANDARD SETTINGS
Minimum	**Medium**	**Must**

Applies to: 7 of 9 facility types: Hospital, Ambulatory clinic, Primary health clinic, Long-term care, Home care, Dental clinic, Aesthetic and procedure clinic. **Not applicable to:** Telemedicine, Fitness and wellness. Each setting shows its rating above.

> **Criterion.** Any change to a released result is recorded as an amendment, traceable to the original result, with the reason, the date and the person who made the change.

Rating rule. Minimum in humanitarian settings. Medium in transition and fragile settings. Must in standard settings: every change to a released result is an amendment traceable to the original.

GUIDANCE

A result that is later found to be wrong must be corrected, but the original must remain visible. Any change to a released result is recorded as an amendment, so that a clinician can see what was reported first, what was changed and why.

The amendment procedure (LBT-SOP-009) and policy (LBT-POL-015) say who may authorise an amendment. The amendment form (LBT-FRM-014) states the reason and links the amended result to the original. The amendment log (LBT-REG-008) lists every change.

Where the amended result changes the clinical meaning, the clinician is told directly and the notification is recorded.

> **Good practice.** Every change to a released result is an amendment linked to the original and signed off by an authorised person, with the reason recorded.

> **Partial because.** Amendments are recorded, but the reason or the link to the original result is missing for some.

WHAT GOOD LOOKS LIKE

- An amendment shows the original result and the corrected result, with the reason.
- The amendment is signed by an authorised person other than the one who first released the result.
- The amendment is logged in the amendment register.
- The clinician is told when the change alters the clinical meaning.

COMMON MISTAKES

- The original result is overwritten, so the change cannot be seen.
- An amendment is made without a reason written down.
- The amendment is made by the person who first released the result, with no check.
- Amendments are made in the information system without a log.

> **Why it matters.** A result that is changed after release must show what it was and what it became, and why. Without that, the change cannot be trusted or reviewed.

WHAT THE ASSESSOR CHECKS

Sample. Review the result amendment log for all amendments in the last 12 months.

1 Each amendment is recorded as an amendment to the original result.

Method. Check each amendment for the link to the original result.

Evidence to show. Result amendments (LBT-SOP-009).

Pass when. Every amendment is linked to the original.

2 **Each amendment states its reason, date and person.**

Method. Check each amendment entry for the reason, date and person.

Evidence to show. Result amendment log (LBT-REG-008).

Pass when. Every amendment states reason, date and person.

3 **The original result remains visible in the record.**

Method. Check the record for the original value kept.

Evidence to show. Result amendment log (LBT-REG-008).

Pass when. The original value is kept visible in every sampled case.

Pass. The criterion is met when every check above is passed.

Immediate fail. A released result overwritten with no record of the original value. This fails the criterion on its own, whatever else is in place.

EVIDENCE AND DOCUMENTS

Code	Document	Writes	Approves	Checks
LBT-SOP-009	Result amendments	Manager	Chief executive	Chief executive
LBT-REG-008	Result amendment log	Manager	Chief executive	Manager
LBT-FRM-014	Result amendment form	Manager	Chief executive	Manager
LBT-POL-015	Result amendment policy	Manager	Chief executive	Chief executive

POSITIONS RESPONSIBLE

Position	Why it applies	Training
Manager (ISCO 1342)	Maintains the Result amendments	Governance & Document Control for Laboratory Accreditation (LAB-01) Medium
Secretary (ISCO 3344)	Keeps the Result amendment log	Governance & Document Control for Laboratory Accreditation (LAB-01) Medium

REFERENCES FOR THIS CRITERION

- International Organization for Standardization (2022). ISO 15189:2022 Medical laboratories: Requirements for quality and competence. Geneva: ISO. https://www.iso.org/standard/76677.html

28.15 Suppliers and Reagents Qualified

HUMANITARIAN SETTINGS	TRANSITION AND FRAGILE SETTINGS	STANDARD SETTINGS
Minimum	**Medium**	**Must**

Applies to: 7 of 9 facility types: Hospital, Ambulatory clinic, Primary health clinic, Long-term care, Home care, Dental clinic, Aesthetic and procedure clinic. **Not applicable to:** Telemedicine, Fitness and wellness. Each setting shows its rating above.

> **Criterion.** Suppliers of reagents, consumables and equipment services are qualified before use and reviewed at set intervals against defined requirements.

Rating rule. Minimum in humanitarian settings. Medium in transition and fragile settings. Must in standard settings: reagent, consumable and service suppliers are qualified before use and reviewed on schedule.

GUIDANCE

Reagents, consumables and equipment services affect every result. A supplier that delivers a faulty product or an unqualified service can compromise many tests before anyone notices. The laboratory qualifies each supplier before first use and reviews it at a set interval.

The supplier qualification register (LBT-REG-009) lists each supplier, the products or services supplied, the qualification decision and the review date. The qualification form (LBT-FRM-015) records the evidence used, such as certificates or performance data.

The qualification procedure (LBT-SOP-015) and policy (LBT-POL-004) apply to all new suppliers, including those offered at a lower price. A supplier that fails review is removed from the approved list.

> **Good practice.** Every reagent, consumable and service supplier is qualified before first use and reviewed at a set interval.

> **Partial because.** Most suppliers are qualified, but some are used before qualification or not reviewed on time.

WHAT GOOD LOOKS LIKE

- Each supplier is qualified on a defined set of evidence before its first order.
- Supplier performance is reviewed each year, with EQA results and complaints considered.
- A supplier that fails review is removed from the approved list.
- Equipment service engineers are qualified and their work is checked.

COMMON MISTAKES

- A new supplier is used because it is cheaper, without qualification.
- A supplier is never reviewed after the first order.
- A service engineer works on a device without a record of the work done.
- A product is replaced by a different brand without a new qualification.

> **Why it matters.** Reagents, consumables and outside services that are poor quality cause results to be wrong. Buying only from qualified suppliers, and monitoring them, keeps quality up.

WHAT THE ASSESSOR CHECKS

Sample. Review the supplier qualification register and the purchase records for all reagent and service suppliers in use.

1 **Each supplier is qualified before first use.**

Method. Check each supplier on the register for the qualification date before the first purchase.

Evidence to show. Supplier and reagent qualification (LBT-POL-004).

Pass when. Every supplier was qualified before first use.

2 **Qualification is reviewed at the set interval.**

Method. Check each supplier for the review date against the interval.

Evidence to show. Supplier qualification register (LBT-REG-009).

Pass when. Every supplier is reviewed at the set interval.

3 **Unqualified suppliers are not used.**

Method. Check the purchase records against the register.

Evidence to show. Supplier qualification register (LBT-REG-009).

Pass when. No purchase is made from an unqualified supplier.

Pass. The criterion is met when every check above is passed.

Immediate fail. Reagents bought from an unlisted supplier with no quality documents on file. This fails the criterion on its own, whatever else is in place.

EVIDENCE AND DOCUMENTS

Code	Document	Writes	Approves	Checks
LBT-REG-009	Supplier qualification register	Manager	Chief executive	Manager
LBT-POL-004	Supplier and reagent qualification	Manager	Chief executive	Chief executive
LBT-FRM-015	Supplier qualification form	Manager	Chief executive	Manager
LBT-SOP-015	Supplier qualification procedure	Manager	Chief executive	Chief executive

POSITIONS RESPONSIBLE

Position	Why it applies	Training
Manager (ISCO 1342)	Maintains the Supplier and reagent qualification	Governance & Document Control for Laboratory Accreditation (LAB-01) Medium
Secretary (ISCO 3344)	Keeps the Supplier qualification register	Governance & Document Control for Laboratory Accreditation (LAB-01) Medium

REFERENCES FOR THIS CRITERION

- International Organization for Standardization (2022). ISO 15189:2022 Medical laboratories: Requirements for quality and competence. Geneva: ISO. https://www.iso.org/standard/76677.html

10 Questions and answers

Who does Standard 28 apply to?
It applies to medical laboratories. It is required by default in hospitals, ambulatory clinics and primary health clinics, optional in other facility types that provide laboratory testing, and not applicable to telemedicine and fitness and wellness. Section 4 shows the detail.

What do the colours mean for this standard?
Red means Must, required in every setting. Yellow means Medium, required and adapted to what a setting can realistically do. Green means Minimum, the lowest acceptable level.

Must every instrument be calibrated?
Yes. Each instrument and measuring device is calibrated or verified at its set interval against a traceable reference (criterion 28.1).

Must each new reagent lot be checked?
Yes. Each new lot is checked against the previous lot or the acceptance criteria before it is used on patients (criterion 28.2).

Must every method be validated?
Yes. Each method is validated for its clinical use and revalidated after a significant change (criterion 28.3).

Is internal quality control required for every run?
Yes. Control material is run at the set interval and with each analytical run, and failures are acted on before results are released (criterion 28.4).

Must the laboratory join external quality assessment?
Yes, for each test where a scheme exists (criterion 28.5).

Must clinicians receive test information?
Yes. Clinicians and patients receive the indications, limitations and preparation for each test (criterion 28.6).

When is a specimen rejected?
When it does not meet the defined acceptance criteria. Every rejection is recorded with its reason and the clinician is told (criterion 28.7).

Must specimens be transported under controlled conditions?
Yes. Transport preserves integrity, and temperature and time are recorded for each shipment (criterion 28.8).

What is a chain of custody?
The documented record of every person who handled a forensic or legal specimen, from collection to disposal (criterion 28.10).

What must happen to a critical value?
It is communicated to a responsible clinician within the defined time, and receipt is recorded (criterion 28.11).

Who may authorise a result?
A qualified person, before the result is released. The authorisation is recorded (criterion 28.12).

What must a report contain?
The defined minimum information, including identifiers, test name, result, units, reference interval and the date and time (criterion 28.13).

How is a change to a released result handled?
It is recorded as an amendment, linked to the original result, with the reason given (criterion 28.14).

Must suppliers be qualified?
Yes. Suppliers of reagents, consumables and equipment services are qualified before use and reviewed at a set interval (criterion 28.15).

Who is responsible for each criterion?
The criteria assign responsibility to the manager, the nurse and the secretary. Each record should show who wrote and who reviewed it.

Which e-learning courses are required?
All fifteen criteria require the manager to complete Governance & Document Control for Laboratory Accreditation (LAB-01). Each criterion also names its own course. The full list is in section 11.

Are the e-learning courses compulsory?
Only the courses in the e-learning table marked as must take are required, for the roles named. Other courses are recommended.

How is evidence shown to the surveyor?
The records named in each criterion's documents table, covering the period stated in the criterion.

Do I have to use the forms on this page?
No. They are reference drafts. Adapt them, write your own, or upload your own, provided the same criterion is met and the evidence can be shown.

Does this standard set requirements for AI?
No. None of its criteria sets a requirement for artificial intelligence. The criteria cover equipment, methods, specimens and reports directly.

The criterion text is the authority. Do these answers replace it?
No. These answers summarise the criterion. The criterion text is the authority.

The criterion text is the authority. These answers summarise it.

11 E-learning by standard

These are the GMJ Academy courses named in the criteria of this standard. Each course name opens the course page in the academy. Where a course is published in English and in Georgian, both versions are linked. Evidence of training may be a verified micro-credential in the GMJ Academy micro-credential portfolio, or a training certificate kept in the staff file.

Course	Essential for	Recommended for	Criteria	GMJ Academy course page
Governance & Document Control for Laboratory Accreditation (LAB-01) (LAB-01-EN)	Manager	Nurse, Secretary	28.1, 28.2, 28.3, 28.4, 28.5, 28.6, 28.7, 28.8, 28.9, 28.10, 28.11, 28.12, 28.13, 28.14, 28.15	English · Georgian
Equipment, Reagents & Traceability (LAB-04) (LAB-04-EN)	Manager, Nurse	None	28.1, 28.2, 28.15	English · Georgian
Personnel & Competence in Laboratory Accreditation (LAB-03) (LAB-03-EN)	Manager, Nurse	None	28.3, 28.4	English · Georgian
Facilities, Environment & Suppliers (LAB-05) (LAB-05-EN)	Manager, Nurse	None	28.5, 28.7, 28.8	English · Georgian
Post-Examination: Reporting & Critical Values (LAB-08) (LAB-08-EN)	Manager, Nurse	None	28.6, 28.9, 28.10, 28.11, 28.12, 28.13, 28.14	English · Georgian

12 References

CITED FOR CRITERIA

1. International Organization for Standardization (2022). ISO 15189:2022 Medical laboratories: Requirements for quality and competence. Geneva: ISO. https://www.iso.org/standard/76677.html (criterion 28.1, 28.2, 28.3, 28.4, 28.5, 28.7, 28.8, 28.9, 28.10, 28.11, 28.12, 28.13, 28.14, 28.15)
2. International Organization for Standardization (2020). ISO 17511:2020 In vitro diagnostic medical devices: Metrological traceability of values assigned to calibrators and control materials. Geneva: ISO. https://www.iso.org/standard/69984.html (criterion 28.1)
3. World Health Organization. WHO operational handbook on tuberculosis: Module 3: Diagnosis. Geneva: WHO. https://www.who.int/publications/i/item/9789240110991 (criterion 28.3, 28.6)
4. World Health Organization. Manual for organizing a national external quality assessment programme for health laboratories and other testing sites. Geneva: WHO. https://www.who.int/publications/i/item/9789241549677 (criterion 28.5)
5. World Health Organization (2020). Laboratory biosafety manual, 4th edition. Geneva: WHO. https://www.who.int/publications/i/item/9789240011311 (criterion 28.7, 28.8)
6. World Health Organization (2021). Global Patient Safety Action Plan 2021–2030: Towards eliminating avoidable harm in health care. Geneva: WHO. https://www.who.int/publications-detail-redirect/9789240032705 (criterion 28.11)

INTERNATIONAL STANDARDS CITED

1. International Labour Organization (2008). International Standard Classification of Occupations, ISCO-08. Geneva: ILO.

13 Document register

Every document code used in Standard 28, with its type and the criteria that use it. The codes identify the documents; a facility may use its own document if it meets the same criterion.

Code	Document	Type	What it is for	Criteria
LBT-FRM-001	Reagent lot verification record	Form (record)	Reagent lot verification record	28.2
LBT-FRM-002	Test request information sheet	Form (record)	Test request information sheet	28.6
LBT-FRM-003	Specimen transport record	Form (record)	Specimen transport record	28.8
LBT-FRM-004	Chain of custody form	Form (record)	Chain of custody form	28.10
LBT-FRM-005	Result authorisation record	Form (record)	Result authorisation record	28.12
LBT-FRM-006	Calibration certificate file	Form (record)	Calibration certificate file	28.1
LBT-FRM-007	Method validation report	Form (record)	Method validation report	28.3
LBT-FRM-008	QC acceptance and corrective action record	Form (record)	QC acceptance and corrective action record	28.4
LBT-FRM-009	EQA result record	Form (record)	EQA result record	28.5
LBT-FRM-010	Specimen rejection notice	Form (record)	Specimen rejection notice	28.7
LBT-FRM-011	STAT request record	Form (record)	STAT request record	28.9
LBT-FRM-012	Critical value notification record	Form (record)	Critical value notification record	28.11
LBT-FRM-013	Report template checklist	Form (record)	Report template checklist	28.13
LBT-FRM-014	Result amendment form	Form (record)	Result amendment form	28.14
LBT-FRM-015	Supplier qualification form	Form (record)	Supplier qualification form	28.15
LBT-POL-001	Equipment calibration and traceability	Policy	Equipment calibration and traceability	28.1
LBT-POL-002	External quality assessment participation	Policy	External quality assessment participation	28.5
LBT-POL-003	Result authorisation and release	Policy	Result authorisation and release	28.12
LBT-POL-004	Supplier and reagent qualification	Policy	Supplier and reagent qualification	28.15

Code	Document	Type	What it is for	Criteria
LBT-POL-005	Reagent and consumable acceptance	Policy	Reagent and consumable acceptance	28.2
LBT-POL-006	Method introduction and change control	Policy	Method introduction and change control	28.3
LBT-POL-007	Quality control policy	Policy	Quality control policy	28.4
LBT-POL-008	Test information policy	Policy	Test information policy	28.6
LBT-POL-009	Specimen acceptance policy	Policy	Specimen acceptance policy	28.7
LBT-POL-010	Specimen transport policy	Policy	Specimen transport policy	28.8
LBT-POL-011	Priority and turnaround policy	Policy	Priority and turnaround policy	28.9
LBT-POL-012	Forensic and legal specimen policy	Policy	Forensic and legal specimen policy	28.10
LBT-POL-013	Critical value policy	Policy	Critical value policy	28.11
LBT-POL-014	Laboratory report policy	Policy	Laboratory report policy	28.13
LBT-POL-015	Result amendment policy	Policy	Result amendment policy	28.14
LBT-REG-001	Calibration and maintenance register	Register	Calibration and maintenance register	28.1
LBT-REG-002	Method validation register	Register	Method validation register	28.3
LBT-REG-003	Internal quality control log	Register	Internal quality control log	28.4
LBT-REG-004	External quality assessment results register	Register	External quality assessment results register	28.5
LBT-REG-005	Specimen receipt and rejection log	Register	Specimen receipt and rejection log	28.7
LBT-REG-006	Turnaround time monitoring log	Register	Turnaround time monitoring log	28.9
LBT-REG-007	Critical value communication log	Register	Critical value communication log	28.11
LBT-REG-008	Result amendment log	Register	Result amendment log	28.14
LBT-REG-009	Supplier qualification register	Register	Supplier qualification register	28.15
LBT-REG-010	Reagent lot register	Register	Reagent lot register	28.2
LBT-REG-011	Test information update log	Register	Test information update log	28.6
LBT-REG-012	Courier and temperature log	Register	Courier and temperature log	28.8
LBT-REG-013	Chain of custody register	Register	Chain of custody register	28.10
LBT-REG-014	Authorised results register	Register	Authorised results register	28.12
LBT-REG-015	Report release log	Register	Report release log	28.13
LBT-SOP-001	Method validation before clinical use	Procedure (SOP)	Method validation before clinical use	28.3

Code	Document	Type	What it is for	Criteria
LBT-SOP-002	Internal quality control	Procedure (SOP)	Internal quality control	28.4
LBT-SOP-003	Specimen acceptance and rejection	Procedure (SOP)	Specimen acceptance and rejection	28.7
LBT-SOP-004	Specimen transport	Procedure (SOP)	Specimen transport	28.8
LBT-SOP-005	STAT specimens and turnaround	Procedure (SOP)	STAT specimens and turnaround	28.9
LBT-SOP-006	Chain of custody for forensic and legal specimens	Procedure (SOP)	Chain of custody for forensic and legal specimens	28.10
LBT-SOP-007	Critical value communication	Procedure (SOP)	Critical value communication	28.11
LBT-SOP-008	Laboratory report content and delivery	Procedure (SOP)	Laboratory report content and delivery	28.13
LBT-SOP-009	Result amendments	Procedure (SOP)	Result amendments	28.14
LBT-SOP-010	Test information for users	Procedure (SOP)	Test information for users	28.6
LBT-SOP-011	Out-of-calibration action	Procedure (SOP)	Out-of-calibration action	28.1
LBT-SOP-012	Reagent lot verification procedure	Procedure (SOP)	Reagent lot verification procedure	28.2
LBT-SOP-013	EQA unsatisfactory result investigation	Procedure (SOP)	EQA unsatisfactory result investigation	28.5
LBT-SOP-014	Result authorisation procedure	Procedure (SOP)	Result authorisation procedure	28.12
LBT-SOP-015	Supplier qualification procedure	Procedure (SOP)	Supplier qualification procedure	28.15

Annex A. ISO 15189:2022 clause map

Annexes A to D are part of Standard 28. They do not add criteria and do not change any rating. They show how the fifteen criteria relate to ISO 15189:2022, Medical laboratories: Requirements for quality and competence, and to the ISO 15189 Ready documents, and they list the additional criteria from the ISO 15189 module for a decision. ISO 15189:2022 is a copyrighted publication. This standard uses its clause titles only and does not reproduce its text.

Each row names an ISO 15189:2022 clause area, the Standard 28 criteria that cover it, the ISO 15189 Ready documents that support it, and the status.

Clause	Area	Subject	Standard 28 criteria	ISO 15189 Ready documents	Status
Clause 4	General requirements	Impartiality, confidentiality and requirements regarding patients	Not in the 15 core criteria (see Annex C: 29.1, 29.2) Not in the 15 core criteria (see Annex C: 29.3) Partly: 28.6 (test information)	LAB-P-24, LAB-FR-RISK-04, LAB-SOP-HR-04; LAB-P-10; LAB-SOP-PA-01	Gap / partly covered
Clause 5	Structural requirements	Accountable person, authority, risk management (trace)	None (Annex C: 29.4, 29.6) None (Annex C: 29.5)	LAB-P-01, LAB-JD-01, LAB-P-04, LAB-PR-03, LAB-R-10	Gap
Clause 6	Resource requirements: personnel	Qualification, competence, training, staffing (trace)	None (Annex C: 29.8 to 29.12)	LAB-P-08, LAB-P-09, LAB-PR-07, LAB-PR-08, LAB-SOP-HR-01 to HR-03	Gap
Clause 6	Resource requirements: equipment	Calibration, traceability, maintenance, malfunction (trace)	28.1 Calibration and traceability None for maintenance (Annex C: 29.14, 29.17)	LAB-P-18, LAB-P-19, LAB-PR-10, LAB-PR-11, LAB-SOP-A-05, LAB-SOP-EQ-01 to EQ-04	Covered for calibration; maintenance is Annex
Clause 6	Resource requirements: reagents and consumables	Reagent lot verification (trace)	28.2 Reagent lot verification	LAB-SOP-A-09, LAB-SOP-QC-02, LAB-SOP-BIO-06, LAB-SOP-IMM-04	Covered
Clause 6	Resource requirements: externally provided products and services	Suppliers and services (trace)	28.15 Suppliers qualified and reviewed	LAB-P-22, LAB-PR-29, LAB-SOP-CUST-04	Covered

Clause	Area	Subject	Standard 28 criteria	ISO 15189 Ready documents	Status
Clause 6	Resource requirements: facilities, environment, safety, utilities, waste	Accommodation, environment, PPE, waste, utilities (trace)	None (Annex C: 29.18 to 29.23, 29.25)	LAB-P-12, LAB-P-14, LAB-P-21, LAB-P-28, LAB-PR-12, LAB-PR-13, LAB-SOP-SF-01 to SF-07	Gap
Clause 6 / 7.6	Information management	Information systems, access, data security (trace)	None (Annex C: 29.20, 29.26)	LAB-P-11, LAB-P-43, LAB-SOP-31, LAB-SOP-IT-01, LAB-FR-IT-01 to IT-06	Gap
Clause 7.2	Pre-examination processes	Request, patient preparation, specimen acceptance, transport, storage, chain of custody	28.6 Test information 28.7 Specimen acceptance 28.8 Transport 28.9 STAT and turnaround (partly) 28.10 Chain of custody	LAB-P-16, LAB-P-17, LAB-PR-17, LAB-PR-18, LAB-SOP-PA-01 to PA-12, LAB-FR-SM-05 to SM-08	Covered in part; identification and storage are Annex
Clause 7.3	Examination processes: method validation	Method verification and validation before clinical use (trace)	28.3 Method validation	LAB-P-36, LAB-SOP-A-01, LAB-SOP-A-02, LAB-SOP-BIO-08	Covered
Clause 7.3	Examination processes: quality control	Internal quality control, rules, runs (trace)	28.4 Internal quality control	LAB-P-37, LAB-PR-23, LAB-SOP-A-03, LAB-SOP-A-06, LAB-SOP-QC-01	Covered
Clause 7.3	Examination processes: external quality assessment	EQA participation and follow-up (trace)	28.5 External quality assessment	LAB-SOP-A-04, LAB-SOP-23, LAB-SOP-BIO-04, LAB-SOP-COAG-04, LAB-SOP-HEM-06, LAB-SOP-IMM-03	Covered
Clause 7.3	Examination processes: measurement uncertainty	Estimation and reporting of measurement uncertainty (trace)	None in the 15 core criteria	LAB-SOP-40-MU, LAB-FR-MU-01	Gap (trace numbering to check)
Clause 7.4	Post-examination processes: validation, authorisation and release	Result review, authorisation, reporting (trace)	28.12 Result authorisation 28.13 Report content Recipient check: Annex C 29.42	LAB-P-39, LAB-P-42, LAB-SOP-18, LAB-SOP-PO-01, LAB-SOP-PO-02, LAB-PR-22, LAB-PR-32, LAB-MX-01	Covered in part

Clause	Area	Subject	Standard 28 criteria	ISO 15189 Ready documents	Status
Clause 7.4	Post-examination processes: critical values	Critical value communication and receipt (trace)	28.11 Critical values	LAB-P-40, LAB-SOP-19, LAB-SOP-PO-03, LAB-SOP-COAG-06, LAB-SOP-HEM-07	Covered
Clause 7.4	Post-examination processes: amendments	Traceable correction of released results (trace)	28.14 Amendments	LAB-SOP-PO-07, LAB-PR-32, LAB-P-42	Covered
Clause 7.4	Post-examination processes: turnaround, referrals, comments	Turnaround, referred tests, cumulative results, interpretive comments (trace)	28.9 Turnaround (partly) Others: Annex C 29.44 to 29.46	LAB-P-38, LAB-SOP-CUST-03, LAB-SOP-IMM-05	Partly covered
Clause 8	Management system: documents and records	Document control, approval, retention (trace)	None (Annex C: 29.48, 29.49, 29.50)	LAB-P-02, LAB-P-03, LAB-PR-01, LAB-PR-02, LAB-R-01, LAB-R-02, LAB-MX-04, LAB-FR-DOC-01	Gap
Clause 8	Management system: internal audit, nonconformity, corrective and preventive action	Audit, corrective action, prevention (trace: 8.7, 8.8)	None (Annex C: 29.51 to 29.53)	LAB-P-05, LAB-P-06, LAB-PR-04, LAB-PR-05, LAB-SOP-21, LAB-R-07	Gap
Clause 8	Management system: management review	Review, minutes, actions (trace: 8.9)	None (Annex C: 29.54)	LAB-P-07, LAB-PR-06, LAB-FR-MRM-04, LAB-FR-MRM-05, LAB-FR-MRM-06	Gap
Clause 8	Management system: complaints, feedback and improvement	Complaints, user feedback, improvement (trace)	None (Annex C: 29.55 to 29.57)	LAB-P-23, LAB-SOP-CUST-01, LAB-SOP-CUST-02, LAB-FR-CUST-05, LAB-P-25	Gap

Subclause numbers marked (trace) come from the internal source trace and are to be confirmed against the licensed ISO 15189:2022 text.

Annex B. ISO 15189 Ready documents by criterion

Each core criterion lists the ISO 15189 Ready documents that support it. Codes are from the ISO 15189 Ready master index.

Criterion	Topic	ISO 15189 Ready documents (code)
28.1	Calibration and traceability	LAB-P-19, LAB-PR-10, LAB-SOP-A-05, LAB-SOP-EQ-02
28.2	Reagent lot verification	LAB-SOP-A-09, LAB-SOP-QC-02, LAB-SOP-BIO-06, LAB-SOP-IMM-04
28.3	Method validation	LAB-P-36, LAB-SOP-A-01, LAB-SOP-A-02, LAB-SOP-BIO-08
28.4	Internal quality control	LAB-P-37, LAB-PR-23, LAB-SOP-A-03, LAB-SOP-QC-01, LAB-SOP-BIO-03, LAB-SOP-COAG-03, LAB-SOP-HEM-03, LAB-SOP-IMM-02, LAB-SOP-UR-03
28.5	External quality assessment	LAB-SOP-A-04, LAB-SOP-23, LAB-SOP-BIO-04, LAB-SOP-COAG-04, LAB-SOP-HEM-06, LAB-SOP-IMM-03
28.6	Test information for users	LAB-SOP-PA-01, LAB-P-25, LAB-SOP-PO-06
28.7	Specimen acceptance and rejection	LAB-P-17, LAB-PR-17, LAB-PR-18, LAB-SOP-PA-06, LAB-SOP-PA-07, LAB-SOP-UR-04, LAB-SOP-COAG-05
28.8	Specimen transport	LAB-SOP-PA-04, LAB-SOP-PA-05, LAB-P-16
28.9	STAT and turnaround	LAB-P-38, LAB-PR-22
28.10	Chain of custody	LAB-SOP-PA-12, LAB-FR-SM-08
28.11	Critical values	LAB-P-40, LAB-SOP-19, LAB-SOP-PO-03, LAB-SOP-COAG-06, LAB-SOP-HEM-07
28.12	Result authorisation	LAB-P-42, LAB-SOP-18, LAB-PR-32, LAB-MX-01
28.13	Report content	LAB-P-39, LAB-SOP-PO-01, LAB-SOP-PO-02
28.14	Amendments	LAB-SOP-PO-07, LAB-PR-32, LAB-P-42
28.15	Suppliers and external services	LAB-P-22, LAB-PR-29, LAB-SOP-CUST-04

Annex C. Additional criteria from the ISO 15189 module, for decision

These are the 57 criteria from the laboratory module (version 4). Some are already covered by a core criterion. The others are listed here for a decision on whether to adopt them as additional criteria. Adopting them would change the standard and needs approval.

Module ID	Criterion (module wording)	ISO 15189 clause group	Core criterion	Status
29.1	Impartiality: No Commercial Pressure on Results	4	Annex only	Not in the 15 core criteria
29.2	Conflict of Interest Declared and Reviewed	4	Annex only	Not in the 15 core criteria
29.3	Patient Information Is Kept Confidential	4	Annex only	Not in the 15 core criteria
29.4	Named Accountable Person	5	Annex only	Not in the 15 core criteria
29.5	Risk Register, Reviewed on a Schedule	5	Annex only	Not in the 15 core criteria
29.6	Authority and Responsibilities Are Defined and Documented	5	Annex only	Not in the 15 core criteria
29.7	External Service and Supply Evaluation	6	28.15 (partly)	Covered by core criterion
29.8	Documented Qualification Before Independent Work	6	Annex only	Not in the 15 core criteria
29.9	Competence Reassessed on a Schedule	6	Annex only	Not in the 15 core criteria
29.10	Orientation Before First Independent Shift	6	Annex only	Not in the 15 core criteria
29.11	Training Records Tied to Specific SOPs	6	Annex only	Not in the 15 core criteria
29.12	Adequate Staffing for Safe Operation	6	Annex only	Not in the 15 core criteria
29.13	Calibration Current on Every Reportable Instrument	6	28.1	Covered by core criterion
29.14	Preventive Maintenance on a Fixed Schedule	6	Annex only	Not in the 15 core criteria
29.15	Reagent Lot Verification Before Use	6	28.2	Covered by core criterion

Module ID	Criterion (module wording)	ISO 15189 clause group	Core criterion	Status
29.16	Metrological Traceability to a Recognized Reference	6	28.1	Covered by core criterion
29.17	Equipment Malfunction: Documented Response	6	Annex only	Not in the 15 core criteria
29.18	Personal Protective Equipment, Available and Used	6	Annex only	Not in the 15 core criteria
29.19	Exposure Incident: Documented Response Protocol	6	Annex only	Not in the 15 core criteria
29.20	Information System Access Controlled and Logged	6	Annex only	Not in the 15 core criteria
29.21	Laboratory Accommodation Protects Specimens and Staff	6	Annex only	Not in the 15 core criteria
29.22	Environmental Conditions Are Monitored and Recorded	6	Annex only	Not in the 15 core criteria
29.23	Laboratory Waste Is Segregated and Disposed of Safely	6	Annex only	Not in the 15 core criteria
29.24	Suppliers and External Services Are Qualified and Monitored	6	28.15	Covered by core criterion
29.25	Laboratory Utilities and Failures Are Planned For	6	Annex only	Not in the 15 core criteria
29.26	Laboratory Information Is Managed Securely and Accurately	6 / 7.6	Annex only	Not in the 15 core criteria
29.27	Two-Identifier Patient Verification	7.2	Annex only	Not in the 15 core criteria
29.28	Specimen Labeled at the Point of Collection	7.2	Annex only	Not in the 15 core criteria
29.29	Rejection Criteria, Applied Consistently	7.2	28.7	Covered by core criterion
29.30	Transport Conditions Preserve Specimen Integrity	7.2	28.8	Covered by core criterion
29.31	Chain of Custody for Forensic or Legal Specimens	7.2	28.10	Covered by core criterion
29.32	Specimen Accessioning Logged in Real Time	7.2	Annex only	Not in the 15 core criteria
29.33	Urgent/STAT Specimens Prioritized and Tracked	7.2	28.9	Covered by core criterion

Module ID	Criterion (module wording)	ISO 15189 clause group	Core criterion	Status
29.34	Specimen Retention Before Discard	7.2	Annex only	Not in the 15 core criteria
29.35	Method Validation Before Clinical Use	7.3	28.3	Covered by core criterion
29.36	Internal Quality Control Run Before Patient Results Released	7.3	28.4	Covered by core criterion
29.37	External Quality Assessment Participation	7.3	28.5	Covered by core criterion
29.38	Critical Value Communication, Verified Received	7.4	28.11	Covered by core criterion
29.39	Result Amendment Traceable to Original	7.4	28.14	Covered by core criterion
29.40	Result Authorization Before Release	7.4	28.12	Covered by core criterion
29.41	Report Content Meets a Defined Minimum	7.4	28.13	Covered by core criterion
29.42	Report Delivered to the Correct Recipient	7.4	Annex only	Not in the 15 core criteria
29.43	Turnaround Time Monitored Against a Target	7.4	28.9	Covered by core criterion
29.44	Supplementary and Referred Test Results Tracked to Closure	7.4	Annex only	Not in the 15 core criteria
29.45	Cumulative/Historical Results Available at Review	7.4	Annex only	Not in the 15 core criteria
29.46	Interpretive Comments Added Where Clinically Needed	7.4	Annex only	Not in the 15 core criteria
29.47	Patients Are Informed How to Prepare for Testing	7.2 / 4.3	28.6	Covered by core criterion
29.48	Document Control: One Current Version	8	Annex only	Not in the 15 core criteria
29.49	Document Approval Before Use	8	Annex only	Not in the 15 core criteria
29.50	Retention Schedule Matches Legal Minimum	8	Annex only	Not in the 15 core criteria
29.51	Internal Audit, On a Fixed Schedule	8	Annex only	Not in the 15 core criteria

Module ID	Criterion (module wording)	ISO 15189 clause group	Core criterion	Status
29.52	Corrective Action Closes the Root Cause	8	Annex only	Not in the 15 core criteria
29.53	Preventive Action, Not Only Reactive	8	Annex only	Not in the 15 core criteria
29.54	Management Review, With Minutes and Actions	8	Annex only	Not in the 15 core criteria
29.55	Complaints Logged, Investigated, Closed	8	Annex only	Not in the 15 core criteria
29.56	User Feedback Is Gathered and Acted On	8	Annex only	Not in the 15 core criteria
29.57	Improvement Is Planned, Measured and Reviewed	8	Annex only	Not in the 15 core criteria

Source trace: the trace file groups criteria by clause and gives subclause numbers from published summaries. Those subclause numbers are marked (trace) and must be checked against the licensed ISO 15189:2022 text before publication.

Numbering mismatch: the trace lists criteria 29.50 to 29.59 and assigns criterion 29.49 to measurement uncertainty. The module (v4) has 57 criteria, ending at 29.57, and criterion 29.49 is Document Approval. Measurement uncertainty has no criterion in the module and is listed as a gap in Annex A.

Master index: the 184 ISO 15189 Ready documents are listed by category and code in the master index. Category ranges are not clause-mapped in the index; Annex B maps the core criteria to document codes.

Annex D. ISO 15189 references

The primary reference is the ISO standard itself. The Eurachem leaflet summarises the 2022 changes. Both are listed for the assessor to check against the licensed text.

1. ISO 15189:2022. Medical laboratories: Requirements for quality and competence. Geneva: ISO. https://www.iso.org/standard/76677.html
2. Eurachem (2022). Leaflet: ISO 15189:2022 (changes from the 2012 edition). Eurachem. https://eurachem.org/images/stories/leaflets/15189_2022/Eurachem_Leaflet_15189_2022_EN.pdf

Annex E. Coverage of ISO 15189 across all ASF standards

Annex E shows where each ISO 15189:2022 clause area is covered across all ASF Health Standards, not only in Standard 28. The aim is full coverage of ISO 15189:2022. At the time of this draft, some areas are covered only in part, and some have no criterion yet. Each gap is named with the action that closes it. Full coverage can be claimed only when every row is marked Covered.

Of the 21 ISO 15189:2022 clause areas, 8 are covered by ASF criteria, 9 are partly covered, and 4 have no criterion yet. Accreditation covers 100% of ISO 15189 only when every row below is Covered.

ISO 15189 clause area	Where ASF covers it (live Version 11 criteria)	Status	Action to reach full coverage
Impartiality and freedom from commercial pressure (4.1)	No criterion in any standard	Not yet covered	Add a criterion to Standard 2 (governance): clinical decisions are free from commercial and financial pressure, and conflicts of interest are declared and reviewed.
Confidentiality of patient information (4.2)	Standard 2, 2.4 Patient Data Is Kept Secure; 2.5 Records Are Kept Exactly as Long as Required	Partly	Add a laboratory confidentiality criterion (Annex C 29.3) to Standard 28, or extend 2.4 to cover test results.
Requirements regarding patients (4.3)	Standard 28, 28.6 Test Indications, Limitations and Patient Preparation; Standard 2, 2.10 Patients and Families Have a Voice	Covered	None beyond the Annex C criteria on patient identification (29.27, 29.28).
Accountable person and authority (5.4)	Standard 2, 2.1 The Board Is Accountable	Partly	Add a named laboratory accountable person criterion (Annex C 29.4 and 29.6) to Standard 28.
Risk management (5.6)	Standard 3, 3.6 Facility Risks Are Tracked in One Integrated Register (facility level)	Partly	Confirm that 3.6 includes laboratory risks, or add a laboratory risk register (Annex C 29.5).
Personnel: qualification, competence, training, staffing (6)	Standard 1, 1.1 Staffing Matches Patient Need; Standard 6, 6.1 Ongoing Competency Is Regularly Evaluated, 6.2 Ongoing Education, 6.10 Staff Can Raise Concerns	Covered	Laboratory-specific training records (Annex C 29.8 to 29.11) are optional; the core criteria cover the requirement.
Equipment, calibration and traceability (6)	Standard 28, 28.1 Calibration Current and Traceable to a Reference; Standard 3, 3.4 Medical Equipment Is Maintained on Schedule	Covered	None.
Reagents and consumables (6)	Standard 28, 28.2 Reagent Lots Verified Before Use	Covered	None.
External services and suppliers (6)	Standard 28, 28.15 Suppliers and Reagents Qualified	Covered	None.

ISO 15189 clause area	Where ASF covers it (live Version 11 criteria)	Status	Action to reach full coverage
Facilities, environment, safety and waste (6)	Standard 3, 3.1 to 3.17 (premises, water, cleanliness, equipment); no core criterion for laboratory waste or biosafety	Partly	Add a laboratory biosafety and waste criterion (Annex C 29.22, 29.23) to Standard 28 or to Standard 3.
Information systems and data (6, 7.6)	Standard 2, 2.4 Patient Data Is Kept Secure; Standard 5, 5.1 Digital Care Systems Follow an Assessment and Management Process, 5.3 Technical Expertise	Partly	Add laboratory information system access, audit trail and backup criterion (Annex C 29.20, 29.26).
Pre-examination processes (7.2)	Standard 28, 28.6 to 28.10 (information, acceptance, transport, STAT, chain of custody)	Covered	Identification and labelling (Annex C 29.27, 29.28) are optional additions.
Examination: method validation, quality control, EQA (7.3)	Standard 28, 28.3 Method Validated Before Clinical Use; 28.4 Internal Quality Control; 28.5 External Quality Assessment	Covered	None.
Measurement uncertainty (7.3)	No criterion in any standard	Not yet covered	Add a measurement uncertainty criterion to Standard 28.
Post-examination processes: authorisation, critical values, reports, amendments (7.4)	Standard 28, 28.11 Critical Values; 28.12 Result Authorisation; 28.13 Report Content; 28.14 Amendments	Covered	Recipient check (Annex C 29.42) is optional.
Document control and records (8.2, 8.3)	No explicit document control criterion; Standard 2, 2.3 Policy Gets Followed	Not yet covered	Add a document control criterion (one current version, approval before use) to Standard 2.
Internal audit (8.8)	No criterion in any standard; Standard 63, 63.5 audits handover only	Not yet covered	Add an internal audit criterion to Standard 2.
Nonconformity, corrective and preventive action (8.7)	Standard 2, 2.6 Serious Incidents Get Properly Investigated (incidents only)	Partly	Add a corrective and preventive action criterion (Annex C 29.52, 29.53) to Standard 2.
Management review (8.9)	Standard 2, 2.2 Written Strategic Plan; Standard 18, 18.6 Site-Level Quality Data Is Reviewed by Central Governance	Partly	Add a management review criterion with minutes and actions (Annex C 29.54) to Standard 2.
Complaints and user feedback (8.6 or equivalent)	Standard 2, 2.8 Patient Experience Is Measured Continuously; Standard 6, 6.6 Workforce Feedback Is Gathered and Acted On	Partly	Add a complaints process criterion (Annex C 29.55, 29.56) to Standard 2.
Improvement (8.5)	Standard 2, 2.7 Safety Culture Is Measured	Partly	Add an improvement planning criterion (Annex C 29.57) to Standard 2.

Criterion numbers are checked against the live Version 11 overview. Module 29 IDs are checked against the laboratory module (version 4). Subclause numbers are to be confirmed against the licensed ISO 15189:2022 text.