

# Inspection-Ready Pre-Analytical Checklist

The specimen collection, requisition, transport and record-keeping items a CLIA survey or a CAP, COLA or Joint Commission inspection reaches, with the clause each one answers. For laboratory managers preparing for a survey, and for qualifying the kit, phlebotomy and courier vendors who hold part of the evidence.

Laboratory: \_\_\_\_\_ Prepared by: \_\_\_\_\_ Date: \_\_\_\_\_

## 01 Identification and labeling

- ☐ Written policy requires positive identification of every specimen from collection or receipt through reporting 42 CFR 493.1232
- ☐ Every primary container is labeled with at least two patient-specific identifiers CAP GEN.40491; TJC NPSG.01.01.01
- ☐ Containers are labeled in the presence of the patient, including at home and mobile draws TJC NPSG.01.01.01 EP 2
- ☐ Label stock survives the storage class (freezer, solvents, analyzer racks); barcodes verified at print CLSI AUTO12-A; lab policy
- ☐ Mislabel and unlabeled-specimen events are logged, trended and reviewed Quality indicator

## 02 Requisition

- ☐ Requisition solicits: patient name or unique identifier; name and address of the authorized orderer; tests requested; date and, where appropriate, time of collection; sex and age or date of birth; specimen source where appropriate; information relevant to the test; for Pap smears, LMP and prior abnormal results 42 CFR 493.1241(c)
- ☐ Completeness is checked at accessioning; incomplete requisitions are resolved and the resolution recorded 42 CFR 493.1241; 493.1283
- ☐ Electronic orders carry the same elements across the interface (HL7 or FHIR), tested for every path 42 CFR 493.1241(c)

## 03 Collection manual and supplies

- ☐ A specimen collection manual is available at every location where specimens are collected, including draw sites, mobile phlebotomists and home-collection programs CAP GEN.40050
- ☐ The manual covers patient preparation, container type and amount, timing, preservatives and anticoagulants, handling between collection and receipt, labeling, clinical data, draw order, fill volume and mixing CAP GEN.40100; 42 CFR 493.1242(a)
- ☐ Collection supplies (tubes, swabs, transport media) are within expiration date and stored to the manufacturer's conditions; expired stock is removed CAP GEN.40460; 42 CFR 493.1252(d)
- ☐ Collection kits specify the correct tube, additive and volume per test, with fill lines and inversion counts in the instructions CLSI PRE02; lab policy
- ☐ Collectors' training and competency are documented and current Lab policy; vendor contract

## 04 Transport, packaging and tracking

- ☐ Written transport conditions exist for each specimen type: temperature band, maximum time to the laboratory, orientation and packaging 42 CFR 493.1242(a)

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|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------|
| <input type="checkbox"/> For specimens from remote sites, a tracking system and record show time of dispatch, time of receipt and condition on receipt, covering in-house and contracted couriers | CAP GEN.40530                  |
| <input type="checkbox"/> Temperature in transit is recorded for refrigerated and frozen specimens; excursion handling is written down and followed                                                | 42 CFR 493.1242(a); CLSI PRE04 |
| <input type="checkbox"/> Category B specimens are packed to Packing Instruction 650 (triple packaging, 95 kPa primary or secondary, absorbent, UN3373 mark)                                       | 49 CFR 173.199; IATA PI 650    |
| <input type="checkbox"/> Everyone who prepares or offers hazardous materials shipments has current hazmat training, recurrent at least every three years, with records available                  | 49 CFR 172.704                 |
| <input type="checkbox"/> Lost or unreconciled specimens trigger a documented investigation against dispatch and receipt records                                                                   | CAP GEN.40530; lab policy      |

## 05 Receipt, acceptability and rejection

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|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| <input type="checkbox"/> Date and time of receipt are documented for every specimen                                                                                                                                       | 42 CFR 493.1242(c)    |
| <input type="checkbox"/> Written acceptability and rejection criteria cover unlabeled or mislabeled, hemolyzed, lipemic, clotted, insufficient, wrong tube, out of time or temperature, and expired or damaged containers | 42 CFR 493.1242(a)(7) |
| <input type="checkbox"/> The record system captures the condition and disposition of every specimen that fails the criteria                                                                                               | 42 CFR 493.1283(a)(3) |
| <input type="checkbox"/> The test report states the condition and disposition of any unacceptable specimen                                                                                                                | 42 CFR 493.1291(c)(7) |
| <input type="checkbox"/> Rejection and hemolysis rates are trended by site and collector and fed back; a benchmark (for example 2% hemolysis) is defined                                                                  | Quality indicator     |

## 06 Corrected reports and records

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|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|
| <input type="checkbox"/> When an error in a reported result is detected, the ordering person is notified promptly, a corrected report is issued and the original is retained with it | 42 CFR 493.1291(k) |
| <input type="checkbox"/> Corrected reports are root-caused; those tracing to labeling, requisition or transport errors are counted as pre-analytical failures                        | Quality indicator  |
| <input type="checkbox"/> Requisitions, receipt records and test records are retained for at least two years                                                                          | 42 CFR 493.1105    |

## 07 Vendor evidence (kits, phlebotomy, courier, storage)

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|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|
| <input type="checkbox"/> Each vendor can produce, on request, the records above that it holds on the laboratory's behalf: collection manual distribution, label and requisition formats, dispatch and receipt logs, temperature records, hazmat training records, storage records | CAP GEN.40530; contract |
| <input type="checkbox"/> Vendors handling protected health information operate under a business associate agreement                                                                                                                                                               | 45 CFR 164.502(e)       |
| <input type="checkbox"/> Vendor records have been audited within the last twelve months and the audit is on file                                                                                                                                                                  | Lab policy              |

CLIA certificates are issued to laboratories, not to vendors. Accreditation by CAP, COLA, The Joint Commission or another CMS-approved organization satisfies the CLIA inspection requirement but does not replace the certificate. This checklist is a working aid, not legal advice; confirm each item against the current edition of your accreditor's checklist and the current eCFR text before an inspection.

Sources: 42 CFR Part 493 (eCFR, current as of October 2026); CAP Laboratory General Checklist, December 2025 edition; The Joint Commission, Laboratory National Patient Safety Goals, effective January 2026; 49 CFR 172.704 and 173.199; IATA Packing Instruction 650; CLSI PRE02, PRE04, AUTO12-A; 45 CFR 164.502(e). Prepared by Diagnostic Support Services (DS2), [diagnosticsupportservices.com/resources/guides/clia-vs-cap](https://diagnosticsupportservices.com/resources/guides/clia-vs-cap). DS2 is a kitting, phlebotomy, courier and biostorage provider; it is not a laboratory and does not hold a CLIA certificate.