



Summary of Waived Testing Requirements*

CAP ACCREDITATION PROGRAMS

Reagents

- Lot-to-lot reagent confirmation of acceptability not required
- Follow manufacturer instructions

Competency

- Training must be completed prior to performing patient testing
- Competency must be assessed annually (semiannual competency not required for new waived testing personnel)
- May select which competency elements to assess

Correlation

- Initial correlation between waived instruments (eg, glucose meters) not required
- Correlation between waived instruments and main laboratory instrument not required
- Multi-instrument comparison not required

Quality Control

- Follow manufacturer instructions
- QC results must be judged acceptable and recorded prior to release of patient results
- If control results exceed tolerance limits, corrective action must be documented
- Internal control results need not be documented for instruments using such controls, if—and only if—an unacceptable instrument control automatically locks the instrument and prevents release of patient results
- Frequency of QC is defined by the manufacturer
- External controls run as required by manufacturer

Calibration and Calibration Verification

- Follow manufacturer instructions
- Calibration verification every six months not necessary unless required by manufacturer

Analytical Measurement Range (AMR)

- Follow manufacturer instructions
- Initial AMR validation and six-month interval verification not necessary unless required by manufacturer

Method Performance Specifications

- Verification not required EXCEPT for reference range
- Follow manufacturer's instructions for instrument setup and use

Other checklist requirements in areas of proficiency testing, instrument maintenance, procedure manuals, specimen handling, results reporting, and safety remain the same for waived and nonwaived testing.

*Inspection Checklist Edition 07/29/13. Waived testing is covered in the following Checklists: All Common, Point-of-Care, Chemistry, Hematology, Immunology, Microbiology, Urinalysis, and Limited Service. List of currently waived analytes can be found at accessdata.fda.gov/scripts/cdrh/cfdocs/cfclia/analyteswaived.cfm.

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