**CAP ACCREDITATION PROGRAMS**

**Reagents**
- Lot-to-lot reagent confirmation of acceptability not required
- Follow manufacturer's instructions

**Personnel**
- 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
- Qualifications of individual assessing competency to be determined by the laboratory director
- Records of educational qualifications must meet requirements as stated in institution's job description (ie, high school graduate or equivalent, license, etc). Primary source verification of educational qualification is acceptable

**Comparability of Instruments/Methods**
- Initial comparability studies between waived instruments (eg, glucose meters) are not required
- Comparability checks between waived instruments and main laboratory instrument not required
- Ongoing multi-instrument comparability checks not required

**Quality Control**
- Follow manufacturer's instructions
- Frequency of QC is defined by the manufacturer
- External controls run as required by manufacturer
- Internal control results need not be recorded for instruments using such controls if—and only if—an unacceptable instrument control automatically locks the instrument and prevents release of patient results
- QC results must be judged acceptable and recorded prior to release of patient results
- If control results exceed tolerance limits, corrective action must be recorded
- Individualized quality control plans are not required for waived instruments or devices

**Calibration and Analytical Measurement Range (AMR)**
- Follow manufacturer's instructions
- Calibration verification every six months not necessary unless required by manufacturer
- Initial AMR validation and six-month interval verification not necessary unless required by manufacturer

**Method Performance Specifications**
- All manufacturer instructions must be followed
- Approval of test for use by the laboratory director or designee meeting CAP director qualifications (director sign-off on test procedure may be used)
- Verification not required, but it is considered a best practice

**Maintenance and Function Checks**
- Follow manufacturer's instructions
- Frequency of maintenance and function checks defined by the manufacturer

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

*Inspection Checklist August 2018 Edition. 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. Recognition of waived test complexity may vary by state.

800-323-4040 | accred@cap.org