Preparing for Your Inspection

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Disclaimer

- Follow any stricter state laws
- If a manufacturer says you have to do something that is not required by CLIA requirements or your accrediting agency requirements, you still have to do it
- Surveyors/inspectors are human – we are not 100% consistent… although we do try…

Review of Test Complexity

Test Complexity

- Waived
- Moderate complexity
- High complexity

Waived Test Examples

- Urine hCG test kits
- Mono test kits (whole blood only)
- Influenza test kits
- RSV test kits
- Strep A test kits
- Fecal occult blood
- Drug test kits
- Glucose monitoring devices
- Piccolo chemistries (some panels, whole blood only)
- i-STAT (some panels, whole blood only)
- Urine dipstick tests (read visually or by analyzer)

Moderate Complexity Examples

- Serum hCG
- Wet & KOH Preps
- Urine Sediment Microscopic
- White Cell Differential (without interpretation of atypical cells)

- Hematology analyzers
- Chemistry analyzers
- Coagulation analyzers
- Blood gas analyzers
- Some microbiology culture procedures
  - Group A Strep Screen
  - Urine Colony Count
  - Urine Growth/No Growth

High Complexity Examples

- CSF cell counts
- White cell differential (with interpretation of atypical cells)
- Semen analysis
- Most manual procedures
- Most blood bank testing
- Most microbiology culture identification & sensitivity
- All non-FDA-approved instrument-reagent pairs

Determining Text Complexity

- The lists of previous slides are general ideas.

  There are exceptions to every rule.

- To determine the complexity of your testing:
  - Contact the manufacturer of your instrument, reagent, test kit, etc.
  - Alternatively, consult the FDA's CLIA test database

    https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/results.cfm

Something to keep in mind…

- Modifying the manufacturer's instructions automatically changes the complexity to "high complexity"
- Considered a modified "FDA-approved test"
  - Modifications include, but not limited to:
    - Specimen handling instructions
    - Specimen or reagent dilution
    - Using a different sample matrix (e.g. plasma versus urine)
    - Type of analysis (qualitative versus quantitative)
    - Using the test for purposes other than the manufacturer's stated intended use

Competency Assessment

Requirements

- Competency assessments must be completed on each staff member biannually for the first year, then annually every year after

- After a new test is introduced, competency assessments must be completed prior to reporting patient test results

Requirements

Must include six methods of evaluation:

- Direct observation of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing
- Monitoring the recording and reporting of test results
- Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records
- Direct observation of performance of instrument maintenance and function checks
- Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples
- Assessment of problem solving skills

- Waived tests do not require the six methods of evaluation

Requirements

Direct observation of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing

Documentation Tips

- Ensure that the documentation is clear the testing was directly observed
- Include the specimen ID for the sample tested

Requirements

Monitoring the recording and reporting of test results

Documentation Tips

- Include specimen ID and test information for the reports viewed
- QA Review – overall assessment of results of QA review
- Bonus – include information for critical values reported, test results reported outside the reportable range

Requirements

Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records

Documentation Tips

- Include exactly what records were reviewed including dates

  Example: daily maintenance 2/1/21, test worksheet 1/18/21

Requirements

Direct observation of performance of instrument maintenance and function checks

Documentation Tips

- Ensure that the documentation is clear the testing was directly observed
- What maintenance or function check tasks were observed

Requirements

Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples

Documentation Tips

- Proficiency testing – include what event the individual performed
- Previously analyzed or internal blind – include the recorded test results or instrument printout

Requirements

Assessment of problem solving skills

Documentation Tips

- Paper or electronic quiz
- Verbal quiz – record the topic and overall assessment of individual's response
- Problem previously troubleshooted and documented – record general description of issue and date the problem was documented
- "Break the instrument"

Requirements

Competency assessments for phlebotomists and/or specimen processors

- Is the individual performing the necessary tasks following laboratory procedure?
- Is the individual following safe work practices?
- Does the individual understand what to do when a problem arises?

Requirements

- Competency assessments for supervisors must also be completed
- The documentation can consist of a checklist listing the individual's responsibilities, or other documentation of performance related to the individual's responsibilities

- Key point – is this individual meeting their responsibilities?

Who Can Perform Competency Assessments

High Complexity Testing

- Laboratory Director
- Technical Supervisor
- General Supervisor

Moderate Complexity Testing

- Laboratory Director
- Technical Consultant

Waived Testing

- Laboratory Director
- Any individual designated by the Laboratory Director

If this task is not completed by the Laboratory Director, the individual(s) responsible must be delegated in writing by the Laboratory Director

Proficiency Testing

What tests require proficiency testing?

- All non-waived regulated analytes must be enrolled in an approved program
- Waived testing does not require proficiency testing

- A list of regulated analytes can be found in Section I of the CLIA guidelines, CLIA brochure #8 (Proficiency Testing)

- Non-waived analytes that are not regulated must still be evaluated. Options include:
  - Enrollment in a proficiency program
  - Alternative performance assessment

Documentation – Testing and Submission

Saved paperwork must include:

- Test booklet or information receiving with samples
- Submission report forms
- Instrument printouts or copy of result logs
- Attestation page/statement

Documentation – Testing and Submission

Attestation page/statement must be signed by each individual performing testing, and the Laboratory Director or appropriate designee

- Appropriate designees include Technical Supervisor (high complexity tests) and Technical Consultant (moderate complexity tests)

Documentation – Testing and Submission

Must test the proficiency samples in the same manner as patient samples

- You cannot repeat the samples unless you would do so with a patient
- Review of morphology, cell identification, etc. is acceptable if it would routinely be reviewed by another individual
- Performance of proficiency testing must be rotated among all staff who perform the testing

Documentation – Testing and Submission

Tests performed on more than one instrument or method must be tested using the primary instrument or method, or rotated among primary methods with different PT shipments

- Exception: multiple instruments or methods can be tested if the proficiency program has specific reporting for a secondary instrument or method (e.g. waived glucose testing)
- Instrument comparisons should be performed on secondary instruments/methods

Documentation – Result Paperwork

Results must show documentation of review by the Laboratory Director or an appropriate designee, as well as all testing personnel

- Appropriate designees include Technical Supervisor (high complexity tests) and Technical Consultant (moderate complexity tests)

Documentation – Result Paperwork

All results that were not graded must be self-evaluated by the laboratory. This includes:

- Non-participation in an event (i.e. results submitted after the deadline, samples not tested)
- Results submitted incorrectly (i.e. with the incorrect instrument or method information)
- Program assigns an artificial score of 100% with a comment that results were not evaluated due to lack of a peer group or lack of consensus within a peer group

Documentation – PT Failures

- Must have documentation showing evaluation of proficiency testing failures
- Ideally, the documentation should include:
  - Process of investigation
  - Conclusion of the cause of the failure
  - Corrective action to prevent a repeat failure
- An investigation consisting of only the repeat testing documentation is NOT acceptable.

Alternative Performance Assessment

- Must be performed twice per year
- Ensure a procedure includes:
  - How the alternative assessment will be performed
  - How the assessment will be documented
  - Criteria to evaluate acceptability

Performance Verification

Waived Tests

- Follow the manufacturer's instructions for introduction of the instrument and/or test method
- Must be documentation showing the Laboratory Director has approved the instrument and/or test method for use prior to initiating patient testing
- NOTE: Make sure to follow the manufacturer's package insert exactly. To modify anything changes the complexity of the testing from waived to high complexity.

Unmodified, FDA-approved or -cleared

Demonstrate that the performance specifications are comparable to those established by the manufacturer for:

1. Accuracy
2. Precision
3. Reportable Range

    * Not all specifications are applicable to each test (e.g. qualitative testing does not have a reportable range)

Unmodified, FDA-approved or -cleared

- Verify the manufacturer's reference interval(s) is appropriate for your patient population

- Must be documentation showing the Laboratory Director has approved the instrument and/or test method for use prior to initiating patient testing

Modified and Lab Developed (LDT)

In addition to specifications covered on the previous slide, the following must also be established:

1. Analytical sensitivity
   - Lower detection limit
2. Analytical specificity to include interfering substances
   - Ability to correctly identify or quantify an entity in the presence of interfering or cross-reactive substances that might be expected to be present
3. Any other performance characteristics required for test performance (e.g. carryover, specimen stability)

Documentation

1. Validation plan
   - What samples will be tested and when
   - How will the results be analyzed
   - How to determine if the results are acceptable

2. Raw data, instrument printouts

3. Data analysis, summary report

Quality Control

Quality Control Considerations

- Internal control results must be recorded
- Stains must be checked for intended reactivity each day of use, and results documented
  - Exceptions: gram stain, fluorescent stains, immunohistochemical stains, parasitology stains
- Ensure each QC result is documented, not the full panel

Glu = Neg
Bil = Neg
Ket = Neg
SG = 1.020

UA Neg QC = Pass

UA Neg QC = Neg

Quality Control Considerations

- Must use controls with the appropriate matrix
  - Pregnancy tests - Urine vs serum
  - Chemistry (Crea, Glu, Uric, etc) - Serum/plasma vs urine
  - Chemistry (Glu, LDH, etc) - Serum/plasma vs CSF
  - Chemistry (Bilirubin) - Adult vs neonatal
  - Automated cell counts - Whole blood vs CSF/body fluids

Quality Control Review

- Control results must be recorded in a format that facilitates easy review by all laboratory personnel

- Controls results must be reviewed at least monthly by the Laboratory Director or an appropriate designee
    - Is the test providing accurate results?
    - Are the personnel following laboratory procedure?

Quality Control Review

Quality control for quantitative tests should be reviewed more frequently to detect problems that may require corrective action

- QC data must be available in such a manner (i.e. Levey-Jennings charts or statistical data) that staff running the tests can detect problems or trends
- Recommend reviewing weekly for routinely performed tests

Verification for New Lots of Quality Control

Assayed Controls

- Any assayed control material must have the manufacturer's provided statistical parameters verified
- Test the new lot of control concurrently with the lot of control currently in use
- The documentation available from each new lot should include:
  - Manufacturer's package insert with suggested ranges
  - The test results performed on new control lot
  - The control range that will be used (verified) for new control lot

Unassayed Controls

- Any unassayed control material must have statistical parameters calculated
- Test the new lot of control concurrently with the lot of control currently in use
  - CLSI guidelines* recommend 20 individual days for the establishment of statistical parameters
- The documentation available from each new lot should include:
  - The test results performed on new control lot
  - The calculated mean and standard deviation of test results
  - The control range that will be used (established) for new control lot

*Statistical Quality Control for Quantitative Measurement Procedures: Principles and Definitions; Approved Guideline – Third Edition"

Setup for Inspection Success

Be Knowledgeable

- Know what the manufacturer requirements for all test systems are
- Read all of the regulatory requirements that you must follow
- Put all regulatory requirements into a document, along with:
  - How is the lab meeting the requirement
  - What documents demonstrate compliance
  - Where can those documents be located

Electronically Stored Documentation

- Carefully plan out documentation organization
- Consider how documentation review will be retained
- Think ahead to how inspectors will review electronic documentation


SUCCESS!