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| Title: | Provider Performed Testing Program |
| Department/Service Line: | Laboratory |
| Approver(s): | CLIA Director |
| Location/Region/Division: |  |
| Document Number: |  |
| Last Review/Revision Date:  |  | Origination Date:  |  |

# sCOPE

This document applies to providers that perform point of care laboratory tests and other provider performed microscopy procedures within Baylor Scott & White Health.

# DEFINITIONS

*When used in this document with initial capital letter(s), the following word(s)/phrase(s) have the meaning(s) set forth below unless a different meaning is required by context. Additional defined terms may be found in the BSWH P&P Definitions document.*

**Non-Waived** -Tests categorized as either moderately complex (including provider-performed microscopy) or highly complex by the US Food and Drug Administration (FDA), according to a scoring system used by the FDA.

**Proficiency Testing (PT)** - The evaluation of participant performance against pre-established criteria by means of interlaboratory comparisons.

**Provider-Performed Testing (PPT)** – testing that is personally performed by a physician or midlevel practitioner (e.g. physician assistants, nurse practitioners, certified nurse midwives) in conjunction with the physical examination or treatment of a patient.

**Test System** – The process that includes pre-analytical, analytic, and post-analytic steps used to produce a test result or set of results. May be manual, automated, multi-channel or single-use and can include reagents, components, equipment or instruments required to produce results. May encompass multiple identical analyzers or devices.

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| policy |
| Provider performed testing permits providers to render a rapid diagnosis that can, in turn, facilitate the rapid initiation of treatment. Accurate results rely on following standardized practices for the entire testing sequence, preexamination, examination, and postexamination.Manufacturer’s instructions are followed during all steps of the testing process. |

# PROCEDURE

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**Training Requirements**

All providers are required to satisfactorily complete initial training on the performance of specific tests prior to performing patient testing.

All training is documented using a provided checklist to ensure that each critical step in the process is understood and can be performed correctly before testing patient specimens.

As part of the training, all providers read and sign all applicable policies and procedures.

**Competency Assessment**

**Non-Waived Testing**

During the first year of non-waived testing, competency is assessed every six months. After the first year, competency is assessed annually. Retraining and reassessment of provider competency occurs when problems are identified with test performance.

Competency assessment includes all six elements described below for each test system during each assessment period, unless an element is not applicable to the test system. Elements of competency assessment include but are not limited to:

1. Direct observations of routine patient test performance, including, as applicable, patient identification and preparation; and specimen collection, handling, processing and testing
2. Monitoring the recording and reporting of test results, including, as applicable reporting of critical results
3. Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventative maintenance records
4. Direct observation of performance of instrument maintenance and functions, as applicable
5. Assessment of test performance through previously analyzed specimens, internal blind testing samples of external proficiency testing samples; and
6. Evaluation of problem-solving skills

**Individuals Who May Assess Competency for Non Waived Testing**

Competency may be assessed by the CLIA Director or delegated in writing to an individual meeting the technical consultant qualifications for moderate complexity testing which are listed below:

1. MD, DO, or DPM with a current medical license with at least one year of training and/or experience in non-waived testing in the designated specialty/subspecialty are; OR
2. Doctoral or Master’s degree in a chemical, physical, biological or clinical laboratory science with at least one year of training and/or expertise in non-waived testing in the designated specialty/subspecialty area; OR
3. Bachelor’s degree in a chemical, physical, biological or clinical laboratory science or medical technology with at least two years of experience in non-waived testing in the designated specialty/subspecialty area.

**Waived Testing**

After an individual has performed waived testing for one year, competency must be assessed annually. Retraining and reassessment of provider competency occurs when problems are identified with test performance. For waived test systems, only two of the above six elements of competency must be assessed.

**Specimen Collection**

General specimen collection instructions are included in each specific provider performed testing procedure.

**Personal Protective Equipment**

Appropriate personal protective equipment (gloves, gowns, masks, and eye protectors, etc.) is provided in work areas in which blood and body substances are handled and in circumstances during which exposure is likely to occur.

**Result Reporting**

All testing and results are documented in the EHR and should include the following elements:

* Patient identifier
* Test ordered/performed and physician’s name/identifier
* Date/time of specimen collection
* Test result
* Reference interval or interpretive notes, as appropriate

**Quality Management Program**

The Quality Management Program for Provider Performed Testing exists to ensure that all testing is performed correctly, by appropriately trained staff, and results in high quality laboratory testing that contribute to the overall delivery of excellent healthcare. The program also exists to help meet regulatory requirements and includes the following items.

**Quality Control**

For those tests for which quality control is required (i.e. Urine Dipstick Testing), controls are performed each day of patient testing and are analyzed by those who routinely perform patient testing.

QC failures are identified and appropriate corrective action taken and documented prior to patient testing.

**Storage of Reagents, Kits, and Controls**

All reagents are stored per manufacturer’s specifications and used within the appropriate expiration date.

**Instrument Maintenance and Function Checks**

Accurate and reliable patient tests are achieved only when the equipment used in the testing process is properly operated and maintained. Providers must follow the manufacturer’s instructions in the operator’s manual for operation and maintenance.

***Centrifuges***

Centrifuges are inspected and cleaned each day of patient use. Operating speeds are checked at least annually.

***Microscopes***

Microscopes are inspected, cleaned, and checked each day of patient use. Annual microscope maintenance is performed by Biomed or a contracted third party. Cover the microscope when not in use and leave the 10x objective in position.

**Detecting and Correcting Reporting Errors**

**Proficiency Testing**

Each testing site is enrolled in an approved proficiency testing program for each test performed at that specific location.

***PT Materials***

* Proficiency testing samples must be handled to maintain stability prior to testing including maintaining proper temperature, protecting from light, or other measures based on the manufacturer’s directors.
* Handle all proficiency testing samples as potentially infectious and follow all guidelines for safe handling.

***Performance***

* Proficiency testing samples are integrated into the routine workload and analyzed by providers who routinely perform patient testing.
* Samples are rotated through all providers throughout the year.
* Referral of proficiency samples to other laboratories is prohibited, nor can providers discuss proficiency testing results with other laboratories.

***Submission of Results***

* CLIA Director of designee (delegated in writing) signs the attestation statement.
* Results are submitted to the PT agency.

***Review and Investigation***

* Upon receipt of PT results from PT agency, all results are reviewed and compared to intended results in a timely fashion.
* In the event a PT sample is not evaluated (ungraded) by the agency, the results must be evaluated to include information on why the results were not evaluated and how the laboratory’s results compared to the peer group.
* All PT results (regards of acceptability) are evaluated for bias or trends that may suggest a problem.
* Corrective Action is initiated when indicated.
* The CLIA Director or designee reviews and approves all PT reports, resolutions and corrective actions and documents this review.

***Records***

* All PT records are maintained for 2 years after the date the testing was performed.
* Records include worksheets, instrument tapes, reporting forms, evaluation reports, participant summaries, and documentation of follow up.

# ATTACHMENTS

Training Checklist

Competency Checklist

# RELATED DOCUMENTS

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| <Refer to the User’s Guide for information on how to format Related Documents.> |

Document Name (Document Number)

Document Name (Document Number)

<or>

None.

# REFERENCES

1. CLSI. *Physician and Nonphysician Provider-Performed Microscopy Testing; Approved Guideline – Second Edition.* CLSI document POCT10-A2. Wayne, PA: Clinical and Laboratory Standards Institute; 2011.
2. CAP Point of Care Testing Checklist

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| Revision History |
| <Instructions – Add a new row for each previous revision as needed. Retain all revisions for the life of the document and for two years following retirement of the document once taken out of service. New documents are effective on the Origination Date as noted in the header of the document.> |
| **Version #** | **Date Implemented** | **Brief Revision Statement** |
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