

Title:	Provider Performed Testing Program		
Department/Service Line:	Laboratory		
Approver(s):	CLIA Director		
Location/Region/Division:	Baylor Scott & White Health		
Document Number:	BSWH.LAB.PPT.001.P_V3		
Last Review/Revision Date:	See Signatures	Origination Date:	08/2015

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.

Alternative Assessment - A system for determining the reliability of laboratory examinations for which no commercial proficiency testing products are available, are not appropriate for the method or patient population served by the laboratory, or participation is not required by the accrediting organization. For PPT, this may be accomplished through competency assessment.

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.

POLICY

Provider performed testing permits providers to render a rapid evaluation/diagnosis that can, in turn, facilitate the rapid initiation of management/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

Training Requirements

All providers will be directed to Laboratory Management for details on initial training requirements.

Training may be 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 acknowledge all applicable policies and procedures.

Competency Assessment

Competency Assessment may be documented using the provided checklist (BSWH.LAB.PPT.001.A1) to ensure that each critical step in the process is understood and can be performed correctly to continue patient testing.

Competency may be assessed by the CLIA Director or delegated in writing to a qualified individual using the attached form: Delegation of Responsibilities: Competency Assessment (BSWH.LAB.PPT.001.A2).

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

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, at least one 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 incorporated as part of the patient encounter in the EHR (Electronic Health Record).

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, documented, and 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 periodically. Operating speeds are checked at least annually by Biomed.

Microscopes

Microscopes are inspected, checked, and cleaned (if necessary) each day of patient use. Annual microscope maintenance is performed by Biomed or a contracted third party. It is recommended that microscopes be covered when not in use and left in the 10x objective in position.

Proficiency Testing/Alternative Assessment

Each testing site is enrolled in an approved proficiency testing program or participates in alternative assessment as required for each test performed at that specific location.

External PT Program Requirements

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 directions.
- All proficiency testing samples should be handled as potentially infectious and all guidelines for safe handling followed.

PT Performance

- Proficiency testing samples are integrated into the routine workload and analyzed by providers who routinely perform patient testing.
- Samples are rotated among providers through the year.

- Referral of proficiency samples to other laboratories is prohibited, nor should providers discuss proficiency testing results with other laboratories.

Submission of Results

- CLIA Director or 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.

Alternative Assessment Program Requirements

If a laboratory elects to participate in an alternative assessment program in lieu of external proficiency testing, the site will administer unknowns at least semi-annually.

Alternative Assessment Materials

- At least 5 unknowns will be used during each assessment.
- Unknowns are rotated among providers through the year.
- BSWH may use Medical Training Systems (MTS) to administer the Alternative Assessment Program.

Alternative Assessment Performance and Review

- Providers should not discuss alternative assessment results with other providers or laboratories.
- Success is a score of greater than or equal to 80%.
- The CLIA Director or designee reviews and approves all alternative assessment resolutions and corrective actions and documents this review.

Records

- All PT/Alternative Assessment 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.
- BSWH laboratories will, on a reasonable basis, make available the laboratory's annual proficiency testing results upon request.

ATTACHMENTS

Provider Performed Testing Competency Assessment Checklist (BSWH.LAB.PPT.001.A1)

Delegation of Responsibilities: Competency Assessment (BSWH.LAB.PPT.001.A2)

Provider Performed Testing Competency Assessment Checklist Example (BSWH.LAB.PPT.001.A3)

RELATED DOCUMENTS

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

REVISION HISTORY

Version #	Effective Date	Description of Change	Revised By	Removed Date
2	10/18/2016	Directed providers to Laboratory for training details. Added additional details Proficiency Testing Section. Updated Competency Assessment Form.	PPT Working Group	9/20/17
3	9/20/17	Updated waived testing competency assessment requirements. Added Alternative Assessment Section.	Raven Steward	

Attachment Title:	Provider Performed Testing Competency Assessment Checklist		
Attachment Number:	BSWH.LAB.PPT.001.A1_V2	Last Review/Revision Date:	See Signatures

Provider Name: _____
 Period of Evaluation: _____
 Evaluator(s): _____

Choose an item.

Instructions: For each applicable element, record success by entering the date of observation (or Survey Date, etc.) and Evaluator's initials. Failures should be documented by writing "UNSUCCESSFUL" in the appropriate box and documenting details in the Comments section. Use NA for any element that is not applicable to a test system.

Non-Waived Tests require all six elements of competency listed below to be assessed during each assessment period, unless an element is not applicable to the test system. For Waived Tests the laboratory may choose which two elements of competency to assess from those listed below.

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 or external proficiency testing samples; and
6. Evaluation of problem-solving skills

Element of Competency		Choose an item.	Choose an item.	Choose an item.					
		Non-Waived	Non-Waived	Non-Waived	Non-Waived	Non-Waived	Waived	Waived	Waived
1. Direct Observation (Patient)	Patient Identification and Preparation								
	Specimen Collection								
	Specimen Handling								
	Processing and Testing								
2. Monitoring	Recording and Reporting of Test Results						NA for Waived Testing	NA for Waived Testing	NA for Waived Testing
3. Review (may be NA for PPT)	Quality Control								
	Proficiency Testing Data								
4. Direct Observation (Equipment)	Microscope use and Maintenance								
	Centrifuge use and Maintenance (if applicable)								
5. Assessment of Test Performance	Proficiency Testing OR								
	Blind Samples (through MTS)								
6. Evaluation of Problem Solving	MTS Quiz								
Comments									

I have had an opportunity to review and ask questions about policies and procedures related to testing above. I feel proficient about performing testing documented above.

Following successful completion of this competency assessment, the provider is deemed competent to perform patient testing unsupervised.

Provider Signature

Date

Evaluator Signature

Date

Evaluator Signature

Date

Attachment Title:	Provider Performed Testing Competency Assessment Checklist - Example		
Attachment Number:	BSWH.LAB.PPT.001.A3_V1	Last Review/Revision Date:	See Signatures

Provider Name: Dr. Mike Example (OBGYN)
 Period of Evaluation: 1/1/16 – 12/31/16
 Evaluator(s): Bertha Boss, Lab Supervisor

Annual Competency Assessment

Instructions: For each applicable element, record success by entering the date of observation (or Survey Date, etc.) and Evaluator's initials. Failures should be documented by writing "UNSUCCESSFUL" in the appropriate box and documenting details in the Comments section. Use NA for any element that is not applicable to a test system.

Non-Waived Tests require all six elements of competency listed below to be assessed during each assessment period, unless an element is not applicable to the test system. For Waived Tests the laboratory may choose which two elements of competency to assess from those listed below.

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 or external proficiency testing samples; and
6. Evaluation of problem-solving skills

Element of Competency		Fern Test	Vaginal Wet Prep	Choose an item.	Choose an item.	Choose an item.	Amniotic pH	Choose an item.	Choose an item.
		Non-Waived	Non-Waived	Non-Waived	Non-Waived	Non-Waived	Waived	Waived	Waived
1. Direct Observation (Patient)	Patient Identification and Preparation								
	Specimen Collection	10/1/16 BB	10/1/16 BB				9/23/16 BB		
	Specimen Handling								
	Processing and Testing								
2. Monitoring	Recording and Reporting of Test Results	10/1/16 BB	10/1/16 BB						
3. Review (may be NA for PPT)	Quality Control	NA	NA						
	Proficiency Testing Data	CMMP-A 2016 100%	CMMP-A 2016 100%						
4. Direct Observation (Equipment)	Microscope use and Maintenance	10/1/16 BB	10/1/16 BB				NA for Waived Testing	NA for Waived Testing	NA for Waived Testing
	Centrifuge use and Maintenance (if applicable)								
5. Assessment of Test Performance	Proficiency Testing OR	CMMP-A 2016 100%	CMMP-A 2016 100%						
	Blind Samples (through MTS)								
6. Evaluation of Problem Solving	MTS Quiz	11/25/16 100%	11/25/16 100%				11/25/16 100%		
Comments									

I have had an opportunity to review and ask questions about policies and procedures related to testing above. I feel proficient about performing testing documented above.

Following successful completion of this competency assessment, the provider is deemed competent to perform patient testing unsupervised.

Mike Example, MD 11/30/16
 Provider Signature Date

Bertha Boss 11/20/16
 Evaluator Signature Date Evaluator Signature Date