Point of Care Testing Policy (LTR52997)

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Point of Care Testing Policy

PRINCIPLE:
Point of Care Testing (POCT) refers to those analytical patient-testing activities provided within the institution, but performed outside the physical facilities of the clinical laboratories. The central criterion of POCT is that it does not require permanent dedicated space. Examples include kits and instruments that are hand-carried or otherwise transported to the vicinity of the patient for immediate testing at that site or analytic instruments that are temporarily brought to a patient care location.

CLIA classifies tests according to complexity into waived and nonwaived categories. The nonwaived category is further subdivided into tests of moderate and high complexity. Provider-performed microscopy (PPM) is a subset of moderately complex tests. The CAP category of Provider Performed Testing (PPT) and Limited Waived Testing is **not** the same as the US CLIA term “provider performed microscopy” (PPM). Rather, it includes certain “waived” tests under CLIA as well as PPM.

The College of American Pathologists allows testing that is personally performed by a physician or midlevel practitioner credentialed by the institution’s medical staff (e.g. physician assistants, nurse practitioners, certified nurse midwives) in conjunction with the physical examination or treatment of a patient. According to CAP, this testing is limited to thirteen tests including vaginal pool fluid smears for ferning and fecal occult blood (waived test technologies). Patient management is often facilitated by immediate and direct clinician performance of certain laboratory tests at the time of a patient encounter. Although these tests may be simple to perform, standards must be maintained to ensure correct results. Note that some of the CAP standards for Point of Care Testing do **not** apply to testing performed by physicians and mid-level practitioners.

CAP requirements for competency assessment, quality control, reagents and calibration are different for waived tests, as compared to moderately complex tests. CAP requirements for proficiency testing, quality management, procedure manuals, specimen handling, results reporting, instruments and equipment, personnel, and safety are the same for both waived and moderately complex tests.

POLICY:
The POCT program at BVHS follows manufacturer instructions for all test systems without modification. CAP requires that validation records be provided if the test has been modified. Note that changes in the specimen type, collection device, or intended medical use are examples of common modifications. If the laboratory modifies the manufacturer’s instructions for an FDA-cleared/approved test, the modifications to the test must be validated by the laboratory. In addition, the test becomes subject to checklist requirements for high complexity testing, including personnel qualifications, competency assessment, method performance specifications, proficiency testing (nonwaived program enrollment), comparability of instruments/methods, quality control, reagents, instrument maintenance and function checks, and calibration and

analytic measurement range verification. Also, CAP requirements in the “Nonwaived” sections of the Point-of-Care Testing Checklist and All Common Checklist apply.

The chief pathologist at Blanchard Valley Hospital Laboratory serves at the Point of Care Testing program medical director and is responsible for all aspects of testing in the POCT program on the BVHS Findlay campus. The laboratory medical director (pathologist) at Bluffton Hospital serves as the Point of Care Testing program medical director and is responsible for all aspects of testing in the POCT program on the BVHS Bluffton campus. This includes medical, technical and scientific oversight of testing in the POCT program. The instruments and equipment in use have been approved by the laboratory medical director or designee. The laboratory administrative director, manager, coordinator, section coordinator, quality coordinator, point of care testing coordinator, or staff technologist can serve as the designee. They can also be contacted to quickly assist with unusual problems to minimize any adverse impact on patient care. Adequate support may require sending the sample to the Main Laboratory or retesting by a different method/device.

Room and refrigerator temperatures, along with humidity, must be adequately controlled in all seasons for laboratory testing. Laboratories must follow the manufacturer’s instructions for temperature and humidity to ensure the proper functioning of instruments, equipment, and test systems. If humidity or temperature are not maintained within the expected range due to extreme weather conditions, a proper step could be for the laboratory to work with its facilities department to adjust environmental conditions or consider the use of portable equipment to adjust conditions near the instrument. Both thermometers, which measure temperature in certain range, and hygrometers, which measure relative humidity in certain ranges, as documented by the manufacturers, must be fully capable of measuring values within the determined acceptable ranges for point of care testing.

Thermometers should be present on all temperature-controlled instruments and environments and checked daily. Thermometric standard devices must be recalibrated, recertified, or replaced prior to the date of expiration of the guarantee of calibration. An appropriate thermometric standard device of known accuracy (guaranteed by manufacturer to meet NIST Standards) must be available along with the thermometer certificate of accuracy.

Thermometers should be periodically evaluated for damage (eg, separation of columns). Thermometers with obvious damage must be rechecked for continued use.

The laboratory monitors and records temperatures using a calibrated thermometer for temperature-dependent storage devices such as refrigerators, temperature-dependent equipment, and temperature-dependent environments such as ambient reagent storage, conditions for instrument operation and conditions for test performance. Temperature dependent storage devices and temperature-dependent environments where reagents, supplies, and patient/client specimens are stored within a specified temperature range must be checked daily.

Use of a continuous monitoring device or a minimum/maximum thermometer satisfies the requirement for daily temperature recording, including during laboratory closures (eg, evenings, weekends, holidays), as the monitoring data is evaluated on the next business day prior to use. Both the high and low temperatures must be recorded. To ensure correct temperature readings, the minimum/maximum thermometer device must be reset prior to the monitoring period. It is not necessary to record low and high temperatures on days when the laboratory is in operation if daily temperatures are recorded.

Temperature-dependent equipment and temperature-dependent environments used for procedures at a specified temperature range must be checked on each day of use. Temperature-dependent environments refer to areas of the laboratory where specific instruments, equipment, kits, or supplies have manufacturer or laboratory specified ambient temperature ranges for proper operation, storage, or use.

Temperatures may be recorded either manually, or using a recording device or system by: 1) recording the numerical temperature, or 2) placing a mark on a graph that corresponds to a numerical temperature. If temperatures are recorded manually, the identity of the individual recording temperatures must be recorded.(initials of the individual are adequate).

If an automated (including remote) temperature monitoring system is used instead of manual temperature monitoring, laboratory personnel must have ongoing immediate access to the temperature data so that appropriate corrective action can be taken if a temperature is outside of the acceptable range. System records must demonstrate daily functionality of the automated system in accordance with manufacturer's instructions. This does not require routine daily review of the system records.

Acceptable ranges are to be defined for all temperature-dependent storage devices, equipment and environments (including test-dependent ambient temperature) in accordance with the manufacturer's instructions. All temperature logs or records should be marked with a defined acceptable range, based on the instruments, equipment, test kits, and phlebotomy supplies stored at that particular location. This will be determined by the BVHS Laboratory Point of Care Testing Coordinator or designee.

Hygrometers should be present near all humidity sensitive instruments and environments and checked daily. Hygrometers must be replaced prior to the date of expiration of the guarantee of calibration. Each hygrometer certificate of accuracy from the manufacturer should be retained and available. Hygrometers should be periodically evaluated for damage, replacing batteries as needed.

The laboratory monitors and records relative humidity using a calibrated hygrometer for humidity - dependent conditions for instrument operation and conditions for test performance. Humidity dependent environments where reagents, supplies, and patient/client specimens are stored within a specified relative humidity range must be checked daily.

Use of a continuous monitoring device or a minimum/maximum hygrometer satisfies the requirement for daily relative humidity recording, including during laboratory closures (eg, evenings, weekends, holidays), as the monitoring data is evaluated on the next business day prior to use. Both the high and low relative humidity value must be recorded. To ensure correct relative humidity readings, the minimum/maximum hygrometer device must be reset prior to the monitoring period. It is not necessary to record low and high relative humidity results on days when the laboratory is in operation, if daily relative humidity readings are recorded.

Humidity sensitive instruments and humidity-dependent environments used for procedures at a specified relative humidity range must be checked on each day of use. Humidity-dependent environments refer to areas of the laboratory where specific instruments, equipment, kits, or supplies have manufacturer or laboratory specified relative humidity ranges for proper operation, storage, or use.

Relative humidity values may be recorded either manually, or using a recording device or system by: 1) recording the numerical relative humidity value, or 2) placing a mark on a graph that corresponds to a numerical relative humidity result. If relative humidity values are recorded manually, the identity of the individual recording the relative humidity must be recorded.(initials of the individual are adequate).

If an automated (including remote) humidity monitoring system is used instead of manual humidity monitoring, laboratory personnel must have ongoing immediate access to the relative humidity data so that appropriate corrective action can be taken if a relative humidity value is outside of the acceptable range. System records must demonstrate daily functionality of the automated system in accordance with manufacturer's instructions. This does not require routine daily review of the system records.

Concerning relative humidity, acceptable ranges are to be defined for all humidity-dependent instruments and environments in accordance with the manufacturer's instructions. All relative

humidity logs or records should be marked with a defined acceptable range, based on the instruments, equipment, test kits, and supplies stored at that particular location. This will be determined by the BVHS Laboratory Point of Care Testing Coordinator or designee

Listed are some point of care testing methods with relative humidity monitoring requirements:

CoaguChek for PTINR – relative humidity 10% to 85% (no condensation)
Hemochron Signature Elite for ACT+ and ACT LR – no requirement
HemoCue for hemoglobin – no requirement
I-STAT Wireless for cartridges G, EG7+, and CG8+- relative humidity 10-90% non-condensing
StatStrip for glucose – relative humidity 10-90%

A complete electronic procedure manual is available in the work area and readily available to all personnel in the Laboratory Department of THE CORE (via the BVHS website at www.bvhealthsystem.org). Written procedures for start-up, operation, maintenance, and shutdown of instruments and equipment, as applicable, are available for all point of care testing. To date, none of the point of care testing instruments require a procedure for emergency shutdown. In the event of instrument downtime, specimens can be sent to BVH Laboratory and/or Bluffton Hospital Laboratory, if necessary. To review a procedure, one should go to THE CORE, then Departments, then Clinical, then Laboratory, then Laboratory Point of Care Testing. All the point of care testing procedures are available there. They are also available online by accessing the Laboratory Test Catalog.

The director reviews and approves all new policies and procedures, as well as changes to existing documents, before implementation. Trained operator input can be requested and used to make sure that current practice does indeed match the policy and procedure documents. The POCT procedure manual is reviewed by the current laboratory medical director or designee at least every two years. Note that the laboratory medical director must ensure that the collection of policies and technical protocols is complete, current, and has been thoroughly reviewed by a knowledgeable person. Technical approaches must be scientifically valid and clinically relevant. Note that the paper/electronic signature review must be at the level of each procedure, or as multiple signatures on a listing of named procedures. A single signature on a Title Page or Index of all laboratory procedures is not sufficient documentation that each procedure has been carefully reviewed. It is not required that a signature or initials be present on each page of a procedure.

Under the same CLIA number as BVH Laboratory, point of care testing at BVHS Findlay campus is limited to the following tests/test systems with required CAP proficiency testing or alternative assessment, and equipment/methods and departments/areas:

Glucose (Whole Blood Glucose) by Nova StatStrip (Alternative Assessment) (waived)
-limited to finger stick and/or heel stick and/or arterial testing at bedside, outpatient areas, and health screening events

1. Emergency
2. Nursing
   - 2nd Floor Pavilion, ICU & CCU
   - Ruse Building, BV Ruse OR 09 Recovery
   - 3rd Floor Pavilion, Obstetrics including Labor & Delivery and Special Care Nursery
   - 4th Floor Pavilion, Infusion / Covid-19, Adult Rehabilitation Unit (ARU)
   - 5th Floor Pavilion, Medical / Oncology and Dialysis
   - 6th Floor Pavilion, Neurology / Orthopedics
3. Surgery including Same Day Surgery and PACU-Recovery
4. Ruse Building, BV Ruse OR 09 Surgery
5. Cath Lab
6. Cardiac Rehab
7. CDS2 Endoscopy
8. Pain Management
9. Orchard Hall

10. Laboratory Outpatient

ACT (Activated Clotting Time) by HemaChron Signature Elite (CAP proficiency testing) (nonwaived)

1. Surgery (ACT+) – limited to testing patients during surgery
2. Cath Lab (ACT-LR) – limited to testing during heart catherization
3. CCU (ACT-LR) – limited to testing for Impella pump stabilization

Sodium, potassium, ionized calcium, pCO2, pO2, pH, Glucose, Hematocrit (Critical Care Blood Gas, i-STAT) by i-STAT (CAP proficiency testing) (nonwaived)

1. Special Care Nursery – limited to testing newborns including cord blood
2. Surgery – limited to testing patients during surgery, usually on arterial or venous blood

Creatinine (Critical Care Blood Gas, i-STAT) by i-STAT (CAP proficiency testing) (waived)

1. Radiology/Imaging – limited to testing prior to specialized imaging

Vaginal pH (Amniotic Fluid Leakage – Nitrazine) by Nitrazine Paper (CAP proficiency testing) (waived)

1. Obstetrics- limited to testing at bedside

PAMG-1 protein marker of the amniotic fluid in vaginal discharge (Rupture of Fetal Membranes Testing) by AmniSure (CAP proficiency testing) (nonwaived)

1. Obstetrics - limited to testing at bedside

Prothrombin Time & INR (Whole Blood Coagulation) by CoaguChek X Plus (CAP proficiency testing) (waived)

1. Pharmacy – limited to testing for medication management-outpatient coumadin clinic
2. Cath Lab - limited to testing during heart catherization

Provider Performed Testing- Vaginal pool fluid smears for ferning (Alternative Assessment) (nonwaived)

1. Obstetrics

Provider Performed Testing- Occult blood, fecal (Alternative Assessment) (waived)

1. Emergency Room

Under the same CLIA number as Bluffton Hospital Laboratory, point of care testing at Bluffton Hospital is limited to the following tests/test systems with required CAP proficiency testing or alternative assessment, and equipment/methods and departments/areas:

Glucose (Whole Blood Glucose) by Nova StatStrip (waived) ((Alternative Assessment)

-limited to finger stick and/or heel stick and/or arterial testing at bedside and outpatient areas

1. ED (Emergency)
2. MED-SURG 1st floor Inpatient
3. MED-SURG 2nd floor (Swing Beds)
4. SURG (Surgery)
5. LAB (Laboratory Outpatient)

Creatinine (Critical Care/Aqueous Blood Gas with Chemistry) by i-STAT (CAP proficiency testing) (waived)

1. Radiology/Imaging – limited to testing prior to specialized imaging

Each department/area director / manager / supervisor / education coordinator or designee is responsible for:

Proficiency testing**:**

Performing testing on proficiency samples that are assigned to the testing personnel responsible for patient testing in a particular department / area. Rotating testing on proficiency samples among multiple identical instruments and rotating testing among trained operators is required. Proficiency samples are to be tested in the same manner as patient samples.

Calibration Verification / AMR (nonwaived testing) :

Performing testing on calibration verification / AMR samples that are assigned to the testing personnel responsible for patient testing in a particular department / area.

Comparability of Methods / Instruments (nonwaived testing)

Performing testing on samples on multiple identical instruments and/or multiple methods that are assigned to the testing personnel responsible for patient testing in a particular department / area.

Instruments and Equipment Maintenance (both waived and nonwaived testing):

1. Maintaining a schedule or system of the regular checking of critical operating characteristics of all instruments in use. Instrument and equipment maintenance and function check records are to be reviewed and assessed at least monthly. This supervisory review must be documented.

   If problems are identified, such as maintenance not performed as scheduled, the reviewer must record corrective action. The review of records related to tests that have an approved individualized quality control plan (IQCP) must include an assessment of whether further evaluation of the risk assessment and quality control plan is needed based on problems identified such as trending for repeat failures.

2. Documenting the monthly evaluation of instrument maintenance and function, including temperatures and relative humidity of rooms/refrigerators/freezers in which reagents or patient specimens are kept. Taking corrective action for out of range temperatures and/or relative humidity is required and the responsibility of the staff working in the area. Monthly supervisory review must be documented.

   If acceptable temperature ranges for temperature-dependent storage devices, equipment and environments were exceeded, there should be evidence of corrective action taken, including an evaluation for adverse effects. Note that if acceptable temperature ranges are exceeded, stored reagents, controls, calibrators, or other materials must be checked to confirm the accuracy or quality of the material before use, with records retained. The check should follow a defined procedure.

   If acceptable relative humidity ranges for humidity-dependent equipment and environments were exceeded, there should be evidence of corrective action taken, including an evaluation for adverse effects. Note that if acceptable relative humidity ranges are exceeded, stored reagents, controls, calibrators, or other materials must be checked to confirm the accuracy or quality of the material before use, with records retained. The check should follow a defined procedure.

Reagents

1. Storing and handling all reagents (chemicals, controls, test strips, testing cartridges, etc.) following the manufacturer's instructions. Reagents must be stored and handled in a manner that will prevent environmentally-induced alterations that could affect reagent

stability and test performance. If the manufacturer defines a required storage temperature range, the temperature of storage areas must be monitored daily. If a staff member identifies a problem with a reagent that was used for patient testing (such as expired vial or reagent subjected to unacceptable storage conditions, etc.) a trained operator or supervisor must evaluate the potential impact on patient test results and retain records of the evaluation and actions taken.

2. Using all reagents (chemicals, controls, test strips, testing cartridges, etc.) within their indicated expiration date. Expiration dates assigned by a manufacturer must be observed. The staff members must assign an expiration date if an expiration date is not provided by the manufacturer. This includes assigning an open expiration date according to the manufacturer's instructions.
3. Using the component(s) of a reagent kit according to the instructions of the manufacturer. If there are multiple components of a reagent kit, only those within the kit lot are to be used, unless otherwise specified by the manufacturer. Mixing kit components from different lots is generally not allowed.

   If needed, evidence of compliance includes written policies defining allowable exceptions for mixing kit components from different lots.
4. For nonwaived tests, documenting the verification of reagent performance. Each new lot and/or shipment of reagents is to be checked for confirmation of acceptability. New reagent lots and shipments are checked against previous reagent lots or with suitable reference material before or concurrently with being placed in service. Supervisory review must be documented.

   NOTE: The purpose of this check is to confirm that the use of new analytic reagent lots and shipments (including different shipments of the same lot) do not affect patient results. Matrix interferences between different lots of reagents may impact the calibration status of instruments and consistency of patient results. Improper storage conditions during shipping of reagents may have a negative impact on their ability to perform or exhibit the same levels of reactivity as intended.

   The minimum extent of the reagent check is described below; however, the check must be at least as extensive as described in the manufacturer's instructions.

   Qualitative: For qualitative nonwaived tests, minimum cross-checking includes retesting at least one positive and negative sample with known reactivity against the new reagent lot. A weakly positive sample is recommended in systems where patient results are reported in that fashion. Examples of suitable reference materials for qualitative tests include*:*

   1. Positive and negative patient samples tested on a previous lot;

   2. Previously tested proficiency testing materials;

   3. External QC materials tested on the previous lot (such as antigen testing kit controls)

   4. If none of the above options is available, control material provided by the assay manufacturer with the new test kit.

   Quantitative: For quantitative nonwaived tests, patient specimens are preferred to compare a new lot against the previous lot, when possible. Manufactured materials, such as proficiency testing (PT) or QC materials may be affected by matrix interference between different reagent lots, even if results show no change following a reagent lot change. The use of patient specimens confirms the absence of matrix interference. The following materials may be used:

   1. Patient specimens tested on a previous lot

   2. Reference materials or QC products provided by the method manufacturer with

method specific and reagent lot specific target values (This is the preferred choice at BVHS for POCT tests.)

3. Proficiency testing materials with peer group established means;

4. QC materials with peer group established means based on interlaboratory comparison that is method specific and includes data from at least 10 laboratories;

5. Third party general purpose reference materials if commutable with patient specimens for the method (per package insert or method manufacturer)

6. QC material in use with the current reagent lot to check a new shipment of the same reagent lot, as there should be no change in potential matrix interactions with the use of the same lot number of reagent and QC material.

For hematology analyzers, reservoirs containing testing reagents and cleaning/decontaminating solutions must be checked according to manufacturer's instructions.

Evidence of compliance include a written procedure for the confirmation of acceptability of new lots and shipments, with defined acceptability criteria and records for the introduction of new lots and shipments, including lot number(s) tested and comparison of results to the acceptability criteria.

Training and Competency Assessments:

1. Performing and documenting initial adequate, specific training of testing personnel to ensure competence. Prior to starting testing and prior to reporting patient results for new methods or instruments, each individual must have training and be evaluated for demonstration of the skills required for proper test performance of pre-analytic, analytic, and post-analytic phases of testing, as applicable, and their ability to work under the expected level of oversight during routine patient testing.

   NOTE: Neither CAP nor CLIA regulations require any particular level of education for testing personnel who perform waived point of care tests or who train testing personnel to perform waived or nonwaived point of care tests.

2. Maintaining records of training of all POCT personnel that include documentation that all staff have satisfactorily completed initial training on all instruments/methods and specimen collection techniques applicable to the point of care testing that they perform. Instrument training should include its use and maintenance. The training on the use and maintenance of an instrument should be documented. Note that records must show that training specifically applies to testing performed by each individual. Training certificate of completion record sheets should be sent to the BVHS Laboratory POCT Coordinator and then on to the Net Learning Administrator for a permanent electronic record of training for each POCT test. This process will also inform the Laboratory TELCOR administrators to grant device privileges. In addition, this information will be forwarded to IT staff to grant computer system privileges.

   NOTE: The records must cover all testing performed by each individual. Training records must be maintained a minimum of two years. After the initial two-year period, records of successful ongoing competency assessment may be used to demonstrate compliance with this requirement. Evidence of compliance includes records of training in personnel files (e.g. training certificate of completion). Retraining must occur when problems are identified with personnel performance.

   For personnel training of physicians and mid-level practitioners, records are required showing that physicians and mid-level practitioners have satisfactorily completed training

on the performance of specific tests performed. Medical staff credentialing is **not** an acceptable record of training. Prior to starting patient testing and prior to reporting patient results for new methods or instruments, each individual must have training and be evaluated for demonstration of the skills required for proper test performance of pre-analytic, analytic, and post-analytic phases of testing, as applicable, and their ability to work under the expected level of oversight during routine patient testing. The records must cover all testing performed by each individual.

Training records must be maintained for a minimum of two years. After the initial two-year period, records of successful on going competency assessment may be used in lieu of training records to demonstrate compliance with this requirement. Retraining must occur when problems are identified with performance. Records of completed training are evidence of compliance.

3. Maintaining a current list of Point of Care Testing personnel that delineates the specific tests and methods (waived and nonwaived) that each individual is authorized to perform. The supervisor responsible for testing should also be listed. This list should be sent to the BVHS Laboratory POCT Coordinator annually. Note: There are records in TELCOR that identify POCT personnel that are authorized to perform each waived and non-waived test on the Nova StatStrip Wireless glucose meter and i-STAT Wireless analyzer. The roster is a list of trained operators who were granted device privileges by the BVHS Laboratory Point of Care Testing Coordinator or other Laboratory TELCOR administrators upon receipt of a copy of the training certificate of completion from the qualified trainer / assessor. The list should be updated annually.

4. Documenting the program that ensures that each person performing point of care testing both waived and nonwaived, maintains satisfactory levels of competence. Competency must be evaluated and recorded for all testing personnel for each test system. Evidence of compliance must include a written procedure that defines the method and frequency for assessing competency and a record of competency assessment for new and existing employees reflecting the specific skills assessed, the method of evaluation required and documented at defined frequency, as determined by the BVHS Laboratory POCT Coordinator.

   Documentation of competency assessment for each point of care test needs to include the performance of section directors / technical supervisors, general supervisors, and technical consultants who perform patient testing and report patient results.

   If testing personnel fail to demonstrate satisfactory performance on the competency assessment, a plan of corrective action to retrain and reassess competency must be followed. NOTE: If it is determined that there are gaps in the individual's knowledge, the employee should be re-educated and allowed to retake the portions of the assessment that fell below the laboratory's guidelines. If, after re-education and training, the employee is unable to satisfactorily pass the assessment, then further action should be taken which may include, supervisory review of work, reassignment of duties, or other actions deemed appropriate by the laboratory director. Records of corrective action that include evidence of retraining and reassessment of competency should be available.

Waived testing competency assessment:
The competency of personnel performing waived testing is to be assessed for each test system at the required frequency. Competency assessment evaluates an individual's ongoing ability to apply knowledge and skills to achieve intended results.

Note that the competency of each person to perform the duties assigned must be assessed following training and before the person performs patient testing and reports patient results. Direct observation of testing, when possible, should be included in the training competency event. After an individual has performed his/her duties for one year, competency must be assessed at least **annually** thereafter. This can be performed

throughout the entire year to minimize impact on workload. Retraining and reassessment of employee competency must occur when problems are identified with an individual's performance.

The competency procedure must outline the practices and procedures used to evaluate competency. Assessment of the elements of competency must be coordinated with routine practices and procedures. Laboratories often use a checklist to record and track elements assessed. Records supporting the assessment must be retained (copies of worksheets, maintenance logs, etc. or information traceable to the original record).

Records of competency assessment may be retained centrally within a healthcare system, but must be available upon request. The laboratory director may determine how competency will be assessed for personnel performing waived testing at multiple test sites (same CAP/CLIA number) or laboratories within the healthcare system (different CAP/CLIA numbers). If there are variations on how a test is performed at different test sites or laboratories, those variations must be included in the competency assessment specific to the site or laboratory.

Nonwaived testing competency assessment:
The competency of personnel performing nonwaived testing is to be assessed for each test system at the required frequency at the laboratory (CAP/CLIA number) where testing is performed . Competency assessment evaluates an individual's ongoing ability to apply knowledge and skills to achieve intended results.

Note that the competency of each person to perform the duties assigned must be assessed following training before the person performs patient testing and reports patient results. Thereafter, during the **first year** of an individual's duties, competency must be assessed at least **semiannually,** preferably after **six months** of initial training and after **twelve months** of initial training. *Note the first competency assessment must be completed within **seven months** from initiation of testing. The second assessment must be completed no longer than twelve months from the starting of testing during the first year an individual tests patient specimens (new employees).* Direct observation of testing must be included in each competency event. After an individual has performed his/her duties for one year, competency must be assessed at least **annually.** The annual assessment of competency can be performed throughout the entire year to minimize impact on workload. Retraining and reassessment of employee competency must occur when problems are identified with an individual's performance.

The competency procedure must outline the practices and procedures used to evaluate competency. Assessment of the elements of competency may be coordinated with routine practices and procedures *if they are assessed by an individual qualified to assess competency.* Laboratories often use a checklist to record and track elements assessed. Records supporting the assessment must be retained (copies of worksheets, maintenance logs, etc. or information traceable to the original record).

Records of competency assessment may be retained centrally within a healthcare system, but must be available upon request. Competency of nonwaived testing personnel must be assessed at the laboratory where testing is performed (CAP/CLIA number) If there are variations on how a test is performed at different test sites or laboratories, those variations must be included in the competency assessment specific to the site or laboratory.

Limited waived testing and PPM by a provider competency assessment:
According to CAP, competency requirements for **waived** tests do not apply to physicians and mid-level practitioners unless required by state or local regulations. For **nonwaived testing (**PPM)**,** CAP requires a documented program to ensure that all physicians and mid-level practitioners performing nonwaived PPM maintain satisfactory levels of competence. For PPM assessment, there should be evidence of competency

assessment specific to the type of laboratory testing performed by each physician and mid-level practitioner, if indicated.

The competency of physicians and mid-level practitioners, performing provider-performed microscopy (PPM) testing, must be assessed by the laboratory director or a qualified designee for each test system. Competency for PPM procedures at BVH must be assessed by the laboratory director or be delegated to an individual meeting the technical consultant qualifications. If PPM is performed under a CLIA Certificate of Provider-Performed Microscopy Procedures, the laboratory director may only delegate competency assessment to another individual qualified as a PPM laboratory director.

The competency of physicians and mid-level practitioners performing provider–performed microscopy (PPM) must be assessed at the required frequency at the laboratory (CAP/CLIA number) where testing is performed.

For more detail, see the "Physicians and Mid-Level Practitioners Policy for Point of Care Testing".

Authorization to perform assessments and qualifications of individuals assessing competency: For both waived and nonwaived testing, only individuals authorized, by job title, experience and education are to perform competency assessments for each point of care test on the test menu. Records of competency assessment must show that assessments were performed by qualified individuals.

Individuals responsible for competency assessments must have the education and experience to evaluate the complexity of the testing being assessed. The laboratory director must delegate, in writing, the performance of competency assessment to qualified personnel. The required qualifications for the competency assessor vary by the complexity of the testing.

Note that a director/manager/supervisor/education coordinator/designee can assess the competency of testing personnel, even if they do not perform the lab tests themselves. As long as those responsible for competency assessments have the education and experience required to evaluate the complexity of the testing being assessed and are delegated to perform that duty, they can perform competency assessments. The competency assessor must be knowledgeable about the test systems assessed. However, the assessor is not required to have a completed competency assessment for those test systems unless the assessor is also defined as testing personnel for that system.

The laboratory director may delegate the BVHS Point of Care Testing Coordinator to authorize individuals, by job title, to perform competency assessment for each point of care test on the test menu. Records of competency assessments must show they were performed by qualified individuals. A list of qualified individuals by name should be made and updated at least every two years for approval by the laboratory director.

- Testing personnel performing high complexity testing (e.g. modified FDA - cleared/approved tests) must be assessed by the section director (technical supervisor) or individual meeting general supervisor requirements if delegated in writing by the section director.

- Testing personnel performing moderate complexity testing must be assessed by a technical consultant or an individual meeting the qualifications of a technical consultant. For moderate complexity testing, the individual assessing competency must have a minimum of a bachelor's degree in a chemical, physical, clinical laboratory science, or medical technology from an accredited institution, with at least two years of laboratory training and/or experience, in nonwaived testing in the designated specialty or subspecialty areas of service for which the individual responsible. This includes moderate complexity testing

performed within the main laboratory, as well as moderate complexity testing performed in blood gas laboratories and point-of-care testing locations.

Currently, the BVHS pathologists and BVHS Laboratory Point of Care Testing Coordinator, and some of other Laboratory associates meet the requirements to assess competency skills of trained operators for nonwaived point of care test systems. Note that some nurses and other health care professionals may meet this requirement too if they have a BS or MS degree. Each individual's degree and work history should be looked at carefully to see if it meets the requirements.

Note; Technical consultant qualifications will be changed effective December 28, 2024. Technical consultant qualifications will require an associate degree in medical laboratory technology, medical laboratory science, or clinical laboratory science and at least 4 years of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service. Individuals who were considered technical consultants for moderately complexity testing if they were qualified and serving, will be grandfathered in as of 12/28/2024 as long as they continue to serve as technical consultants. Note that in the recent CMS CLIA Final Rule, published December 28, 2023, CMS's policy considering nursing degrees as equivalent to biology degrees was reversed.

- Testing personnel performing waived testing must be assessed by an individual meeting the qualifications as determined by the laboratory director. At BVH, Bluffton Hospital, and other BVHS sites, it was determined that the competency assessment should done by somebody who is qualified to be a point of care testing trained operator with an annual competency assessment schedule. The individual, with the exception of the BVHS Laboratory Point of Care Testing Coordinator, Bluffton Hospital Laboratory Coordinator and others who perform training at the educational/supervisory level, should have satisfactorily completed competency assessment requirements after initial training and has performed testing for at least twelve months for that particular point of care test. The individual should be on an annual competency assessment schedule. Preferably, any individual's supervisor or education coordinator would be assigned to document competency assessment.

Competency assessment for waived test systems:
For waived test systems, the laboratory may select which elements, preferably at least two, to assess annually. This task is normally completed by the BVHS Laboratory Point of Care Testing Coordinator. It is not necessary to assess all six elements listed below at each assessment event. The qualifications of individuals assessing competency of waived testing personnel shall be determined by the laboratory director.

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 function checks, as applicable.
5. Assessment of test performance through testing previously analyzed specimens, internal blind testing specimens (eg. de-identified patient specimens), or external proficiency testing specimens; and
6. Evaluation of problem-solving skills.

Competency requirements for waived tests do not apply to physicians and mid-level practitioners unless required by state or local regulations.

Note that JC requirements include assessment of a least two methods for waived testing. The following methods of competency assessment meet JC requirements:

1. Periodic observation of routine work by the supervisor or qualified designee *(Similar to above CAP 1. Direct observations of routine patient test performance, including, as applicable, patient identification and preparation; and specimen collection, handling, processing and testing.)*

2. Monitoring of each user's quality control performance *(Similar to above CAP 3. Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventative maintenance records.)*

3. Performance of a test on a blind specimen (*Similar to above CAP 5. Assessment of test performance through testing previously analyzed specimens, internal blind testing specimens (eg, de-identified patient specimens), or external proficiency testing specimens.)*

4. Use of a written test specific to the test assessed (*Similar to above CAP 6. Evaluation of problem-solving skills)*

Competency assessment for nonwaived test systems:
Competency assessment records must include all six elements described below for each individual on each test system during each assessment period, unless an element is not applicable to the test system. The laboratory must identify the test systems that testing personnel use to generate test results, including both primary and back-up methods used for patient testing. If a single test or analyte is performed using different test systems, a separate assessment is required.

A test system is the process that includes pre-analytic, analytic, and post-analytic steps used to produce a test result or set of results. A test system may be manual, automated, multi-channel or single use and includes instructions, reagents, supplies, equipment, or instruments required to produce test results. A test system may encompass multiple identical analyzers or devices. Different test systems may be used for the same analyte. A test system may include multiple tests performed on the same testing platform (such as an i-STAT analyzer). However, if there are any tests with unique aspects, problems or procedures within the same testing platform (e.g. pretreatment of samples prior to analysis), competency must be assessed as a separate test system to ensure staff are performing those aspects correctly.

The six required elements of competency assessment include but are not limited to:
1. Direct observations of routine 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 function checks
5. Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and
6. Evaluation of problem-solving skills.

The following includes examples of how competency assessment can be coordinated with routine practices and procedures:

- Assessment of the recording of quality control results and instrument maintenance data in element #3 during the monthly supervisory review process of these records.
- Assessment of test performance in element #5 during reviews of proficiency testing or alternative performance assessment records.
- Assessment of problem-solving skills in element #6 from monthly reviews of corrective action logs where problems with quality control or instrument function were investigated.

5. Formal color-blindness testing for personnel who perform laboratory tests or other tasks requiring visual color discrimination. Functional testing limited to discrimination of those colored items pertinent to the job is sufficient. Records of color discrimination testing or functional assessment, if indicated, should be kept as evidence of compliance.

   The following point of care tests require trained operators to exhibit accurate color discrimination:

   a. Vaginal pH (Amniotic Fluid Leakage – Nitrazine) by nitrazine paper
   b. Urine Chemical Analysis by reagent dipstick
   c. BinaxNOW RSV Card
   d. Fecal Occult Blood by Beckman Coulter Hemoccult (blue)
   e. BinaxNOW COVID-19 Ag Card

      Note: Personnel who have difficulties with color discrimination must demonstrate ability to read the test results accurately.

6. Records documenting that all personnel performing point-of-care testing are trained and qualified. Personnel performing waived testing, including non-laboratory personnel, must have documented training. Personnel performing (nonwaived) moderate complexity testing, including non-laboratory personnel, must have at a minimum an earned high school diploma or equivalent and have documented training. Personnel performing (nonwaived) high complexity testing, including non-laboratory personnel, must have earned at least an associate degree in a laboratory science or medical laboratory technology from an accredited institution or equivalent education and have documented training and at least three months experience in each specialty which the individual performs high complexity training.

   Note that educational records for both laboratory and non-laboratory (e.g. nurses, respiratory therapists, radiologic technologists, and medical assistants) testing personnel, must be evaluated for qualifications appropriate to the complexity of testing performed, with retention of the records in the personnel file. While certification of technical personnel by a professional organization, such as ASCP or AMT, is highly desirable, records of the certification alone are not considered adequate documentation to demonstrate that educational qualifications have been met. Students gaining experience in the field must work under the direct supervision of a qualified individual.

   Records of qualifications including diploma, transcript, primary source verification report, equivalency evaluation, or current laboratory personnel license (if required) along with certification/registration (if required) and work history in related field should be available as evidence of compliance. This includes nonwaived testing trained operators and/or associates with the delegated tasks of assessing competency for nonwaived testing and/or signing attestation for proficiency testing. Beginning in 2020, BVHS Human Resources staff members will help to satisfy this requirement by securing primary source verification of educational records for all new nursing associates during the pre-employment process. Note that HR staff members do not verify the education on every associate. HR staff members will only verify the education of an associate if requested in

the HR Job Description. If needed by the Laboratory, a request should be made to HR that PSV be completed and put in the associate's file, and forward a copy to the Laboratory.

Records demonstrating educational qualifications for ***nonwaived*** *testing personnel (i.e. diploma or transcript or primary source verification report) must be available in the employee's personnel file and demonstrate compliance with the qualifications based on the complexity of testing personnel.* ***Licenses, registrations, and certifications do not document educational credentials.*** *Copies of diplomas or transcripts, or primary source verification reports document educational qualifications.*

7. For laboratories that perform only waived testing, CLIA does not require policies for assessing personnel competency. Even though CLIA has no specific requirements for personnel performing waived testing, BVHS needs to ensure that patient testing results are correct to assist in making an accurate patient diagnosis. BVHS needs to ensure that testing personnel are following all manufacturers' instructions. Testing personnel who are properly trained and performing the test correctly will aid the physician/provider in making an accurate diagnosis. For laboratories accredited by CAP or JC, the accrediting organization's standards should be reviewed for compliance.

Safety including Infection Control (both waived and nonwaived testing)

All associates, physicians and mid-level practitioners are to follow the BVHS safety policies and procedures when performing point of care testing. The POCT program's goal is to assure the safety of patients and health care personnel commensurate with the scope of its activities, particularly those concerning infection control, hazardous waste, and chemical hygiene.

Standard precautions are used for point of care testing by testing personnel. Gloves must be worn during testing events, hand hygiene performed, and gloves changed between patients, according to Standard Precautions. Hands must be cleaned using an effective antimicrobial method.

Only auto-disabling single-use finger stick devices are used to assisting monitoring of blood glucose and other point of care testing. These devices are designed to be used only once, after which the blade is retracted, capped, or otherwise made unusable. All waste sharps are to be discarded in puncture resistant containers that are easily accessible, located in areas where needles are commonly used, and properly labeled to warn handlers of the potential hazard.

The BVHS Infection Control/Prevention Policy is in effect to prevent transmission of infection. Compliance with the manufacturer's guidelines (when provided) is required. Handheld or portable testing devices must be disinfected after each patient use. Devices and materials designed for single use must not be disinfected and reused.

Proficiency Testing (both waived and nonwaived testing)

For POCT, associates will be required to complete proficiency testing at regular intervals in accordance with the College of American Pathologists Guidelines. Note: The Laboratory staff will not perform proficiency testing in place of other non-laboratory staff who perform POCT patient testing. If proficiency testing is not required, alternative assessment is required. The BVHS Laboratory POCT Coordinator can distribute the CAP proficiency test kits at BVH, enter and approve the results, and serve as the laboratory director's designee for the attestation statement. The Bluffton Laboratory Coordinator or designee can do similar duties at Bluffton Hospital. Samples used for testing are to be stored for at least 90 days after completion of testing. Listed are the current BVH Laboratory POCT CAP proficiency test kits and the corresponding approximate ship dates.

ACT (Activated Clotting Time) by HemoChron Signature Elite (nonwaived) (moderately complex)

1. Surgery (ACT+)
    1. CT3-A (January)
    2. CT3-B (July)

2. Cath Lab (ACT-LR)
    1. CT2-A (January)
    2. CT2-B (July)

Sodium, potassium, ionized calcium, pCO2, pO2, pH, glucose, hematocrit (CG8+) for Surgery and Sodium, potassium, ionized calcium, pCO2, pO2, pH, hematocrit (EG7+) for Special Care Nursery
(Critical Care Blood Gas, i-STAT) by i-STAT (nonwaived) (moderately complex)

AQIS- SEQ #1

1. AQIS-A (March)
2. AQIS-B (June)
3. AQIS-C (October)

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Creatinine (CREA) for Radiology/Imaging and Glucose (G) for Special Care Nursery
(Critical Care Blood Gas, i-STAT) by i-STAT (waived)

AQIS- SEQ #2

1. AQIS-A (March)
2. AQIS-B (June)
3. AQIS-C (October)

Vaginal pH (Amniotic Fluid Leakage – Nitrazine) by Nitrazine Paper (waived)

1. AFL-A (May)
2. AFL-B (September)

PAMG-1 protein marker of the amniotic fluid in vaginal discharge (Rupture of Fetal Membranes Testing) by AmniSure (nonwaived)

1. ROM1-A (May)
2. ROM1-B (September)

INR in Pharmacy's Center for Medication Management and Cath Lab (Whole Blood Coagulation) by CoaguChek X Plus (waived)

1. WP9-A (February)
2. WP9-B (June)
3. WP9-C (September)

<u>Proficiency Testing – Changing Requirements in 2017 for BVH and Bluffton Hospital Labs</u>

Beginning in 2017, proficiency testing (PT) for waived whole blood glucose on glucose meters was longer required for laboratories accredited by the College of American Pathologists (CAP). Instead, laboratories are required to perform alternative performance assessment. These must be performed at least semi-annually. The BVHS Findlay and Bluffton Laboratories are responsible for performing alternative performance assessment such as CAP Quality Cross Check – Whole Blood Glucose (WBGQ). Because WBGQ is not PT, it is not subject to CMS restrictions regarding PT and results are not sent to any US regulatory body. Therefore, one can test multiple glucose meters all at one time. If there are more than 30 meters at a site, one can rotate meters between events or purchase multiple WBGQ kits. WBGQ offers a turn-key solution for semiannual comparability testing, if needed. All participating facilities receive customized reports that not only provide peer group data, but also intralaboratory data.

In summary:

Glucose (Whole Blood Glucose) by Nova StatStrip (Alternative Assessment) (waived)

<u>Blanchard Valley Hospital</u>

1. WBGQ- A (April)

2. WBGQ-B (September)

Bluffton Hospital

1. WBGQ- A (April)
2. WBGQ-B (September)

Also, the following BVHS PPT tests are required to be assessed at least semi-annually:

Provider Performed Testing- Vaginal pool fluid smears for ferning (Alternative Assessment) (nonwaived) (moderately complex)

1. Obstetrics (Blanchard Valley Hospital)

Provider Performed Testing- Occult blood, fecal (Alternative Assessment) (waived)

1.. Emergency Room (Blanchard Valley Hospital)

If the laboratory routinely uses more than one primary method/instrument for reporting the same analyte, proficiency testing can be rotated among the primary methods/instruments. This is similar to personnel rotation for proficiency testing.

According to CMS, "A central laboratory with more than one instrument or methodology for the same test may alternate methods or instruments from one testing event to the next as long as both are routinely used to test patient specimens." All samples for one analyte within a shipment must be tested on the same instrument.

If CAP PT is not reported for a secondary instrument, biannual correlation studies must be performed if more than one instrument is routinely used for patient testing. This requirement can be met by using routine clinical specimens analyzed on all instruments employed in the laboratory.

Safe Specimen Collection and Handling/Processing (both waived and nonwaived testing)

All POCT specimens should be collected and handled according to BVHS Laboratory procedures and policies for patient identification, patient preparation, specimen collection and labeling, specimen accessioning, and specimen preservation (if applicable) before testing. Note that the proximity of the patient to POCT test systems does not preclude the need for proper identification systems to prevent reporting of one patient's result to another's record.

Concerning molecular based microbiology waived tests, there needs to be written policies and procedures for the safe handling and processing of specimens, including those suspected to contain highly infectious pathogens. These policies may be part of an institution's plan, but the plan must specifically address point-of care. The safe handling and processing of specimens may include the need for tight sealing of containers, avoiding spills of hazardous materials, requirements for wearing gloves, the need for respirator protection, and availability and use of vaccinations.

For samples suspected of containing highly infectious pathogens, laboratories must review national, federal, state and local guidelines for the handling of samples from patients suspected to have high risk pathogens, such as Francisella tularensis, avian influenza, Ebola, MERS coronavirus, SARS coronavirus, SARS-CoV-2 coronavirus, or any infectious agent that has a high potential to cause a disease to individuals and the community.

Results Reporting (both waived and nonwaived testing)

POC test results are to be entered into the permanent patient record, preferably in the computer/electronic medical record. If test results are hand-written in the medical record, the results are legible. To ensure patient safety and prevent medical error, health care workers should not make management decisions based on POC test results unless those results are

entered into patient records. Point of care test results may be uploaded into the electronic medical record after decision making.

Records must indicate, by initials or signature, the name of the trained operator who performed each test. It is not necessary to have this information in the chartable patient report, but an audit trail must be kept.

When applicable, all patient results are reported with accompanying reference (normal) intervals or interpretive ranges. Age- and/or sex-specific reference ranges (normal values) or interpretive ranges must be reported with patient test results, as applicable.

Reference intervals (normal ranges) must be established or verified for the population tested. If a formal reference interval study is not possible or practical, then the POCT site should carefully evaluate the use of published data for its own reference ranges, and retain documentation of this evaluation.

Clinical use of results should be consistent with BVHS policies and the manufacturer's recommendations.

Critical Result Notification and Read-Back

Immediate notification of physician (or other clinical personnel responsible for the patient's care) is required when results of designated tests exceed established "critical" values that are important for prompt patient management decisions. Records of notification are to be retained.

NOTE: Alert or critical results are those results that may require prompt clinical attention to avert significant patient morbidity or mortality. The laboratory director, in consultation with the clinicians served, must define the critical values and critical results that pertain to its patient population. The laboratory may establish different critical results for specific patient subpopulations (for example, dialysis clinic patients). Critical results should be defined by the laboratory director, in consultation with the clinicians served.

An appropriate notification includes a direct dialog with the responsible individual or an electronic communication (eg, secure email or fax) with confirmation of receipt by the responsible individual. Allowing clinicians to "opt out" of receiving critical results is strongly discouraged.

Records must be retained showing prompt notification of the appropriate clinical individual after obtaining results in the critical range. These records must include the following:
- Date of communication;
- Time of communication;
- Responsible individual communicating result;
- Person notified using identifiers traceable to that person (a first name alone is inadequate)
- Test results.

Any problem encountered in accomplishing this task should be investigated to prevent recurrence.

In the point-of-care setting, the identity of the testing individual and person notified need not be recorded when the individual performing the test is the same person who treats the patient. In this circumstance, however, there must be a record of the critical result, date, and time in the test report or elsewhere in the medical record.

When critical results are communicated verbally, "read-back" of the results is to be requested and recorded.

NOTE: Transmission of critical results by electronic means (eg, FAX or computer) is acceptable. If critical results are transmitted electronically, the laboratory must confirm receipt of the result by the intended recipient (eg, by a phone call); however, no read-back is necessary.

Records of critical result notification, including read-back as necessary, are evidence of compliance.

Quality Management including Quality Control

Generally, quality control result records, test result records, and instrument records are retained for at least two years.

Any direct-to-consumer testing results, including reference intervals, must be kept ten years Concerning other record retention for waived testing, the following must be retained for at least two years:

a. Specimen requistions (including the patient chart or medical record if used as the requisition)
b. Quality management records
c. Proficiency testing records
d. Discontinued policies and procedures
e. Quality control records
f. Instrument/equipment maintenance and function check records (including temperature charts) Laboratories may wish to retain instrument maintenance records for longer than the two-year requirement (that is, for the life of the instrument), to facilitate troubleshooting.
g. Competency assessment records
h. Training records (But keep if competency assessment records are not available)
i. Instrument printouts (not interfaced with the laboratory computer system) and worksheets. Note that for data directly transmitted from instruments to the laboratory computer system via an interface (on-line system), it is not necessary to retain paper worksheets, printouts, etc., as long as there is a readable electronic record of the data for at least two years. Manual computer entry of patient result data from worksheets, printouts, etc. requires retention of all worksheets, printouts, etc. for at least two years (digitized or photographic images are acceptable). For results that are manually entered into the computer from 1)observation of an electronic display, with no paper print-out available, or 2) manually performed test methods without worksheets, the two-year retention requirement applies to the data within the computer.
j. Patient test results and reports, including original and corrected reports

Record retention for nonwaived testing is the same as for waived testing listed above, with a tew additions:

- Test method validation/verification records need to kept the entire length of time the test is in use, plus 2 additional years.
- Individualized Quality Control Plans (IQCP) including risk assessment and supporting data, and approval, must be kept the entire length of time the test is in use, plus 2 additional years.
- IQCP ongoing quality assessment data must be kept two years.

Verification of new lots and shipments of reagents, competency assessment, proficiency testing, instrument maintenance, calibration verification, precision studies, linearity studies, patient comparison studies, validation studies, and quality control requirements may need to be done regularly and are the responsibility of the trained operators and/or their supervisors of each department/area.

Quality control data are to be evaluated daily to detect instrument or process failure. Acceptable limits are defined for control procedures and entered into the LIS (Laboratory Information System) by the BVHS Laboratory Point of Care Testing Coordinator, when appropriate.

Trained operators should be educated that the results of controls must be reviewed for acceptability and verified before reporting results. It is implicit in quality control that patient test results will not be reported when controls yield unacceptable results. Corrective action should be documented when control results exceed defined acceptability limits.

Quality control data should be reviewed and assessed at least monthly by the laboratory director or designee, the BVHS Laboratory Point of Care Coordinator at the BVHS Findlay Campus and the Bluffton Hospital Laboratory Coordinator or designee at the Bluffton Campus. The review of quality control data must include documented follow-up for outliers, trends, or omissions that were not previously addressed. The QC data for test performed less frequently than once per month should be reviewed when the tests are performed. Evidence of compliance includes records of QC review including follow-up for outliers, trends, or omissions.

Note that the CAP requirements are not the same for waived and nonwaived testing so the assignments made by the BVHS Laboratory Point of Care Testing Coordinator/Bluffton Hospital Laboratory Coordinator will vary based on the CLIA status of each test name/test system.

For non-waived tests, an acceptable control range should be established or verified for each lot of control. Note: For assayed control materials, control ranges supplied by the manufacturer must be verified. The BVHS Laboratory Point of Care Testing Coordinator or designee, will enter the acceptable range of each new lot of controls in the LIS and for wireless analyzers, the control ranges will be linked and reported as pass/fail. The quality control results manually entered by the trained operator will be flagged if out of control. Any failed QC will require the trained operator to document corrective action. These records will be monitored, at least monthly, to ensure control range establishment and/or verification of each lot. Control ranges supplied by the manufacturer may be used without verification for qualitative (positive or negative) testing.

Alternative Control Procedures

If the laboratory performs test procedures for which control materials are not commercially available, there must be written procedures for an alternative mechanism to detect immediate errors and monitor test system performance over time. The performance of alternative control procedures must be recorded.

NOTE: “Performance” includes elements of accuracy, precision, and clinical discriminating power. Examples of alternative procedures may include split sample testing with another method or with another laboratory, the testing of previously tested patient specimens in duplicate, testing of patient specimens in duplicate, or other defined processes approved by the laboratory director. Evidence of compliance includes written procedures for alternative quality control and records of alternative control procedures.

Quality Requirements Specific to Waived Testing

Waived testing requirements include following manufacturer instructions for quality control. The laboratory trained operators must document and review results for acceptability prior to reporting patient results. Note that quality control must be performed according to manufacturer instructions. To detect problems and evaluate trends, testing personnel or supervisory staff must review quality control data on days when controls are run prior to reporting patient results. The laboratory directory or designee, the BVHS Laboratory Point of Care Coordinator at the BVHS Findlay Campus and the Bluffton Hospital Laboratory Coordinator at the Bluffton Campus must review QC data at least monthly or more frequently if specified in the laboratory’s QC policy. If appropriate, quality control results may be located in the patient medical record.

For waived tests, with respect to internal controls, acceptable control results must be recorded at minimum, once per day of patient testing for each device. Acceptable internal control results need not be recorded, if (and only if) an unacceptable instrument control automatically locks the instrument and prevents release of patient results.

Written procedures should be consistent with manufacturer instructions for each waived test and records should show confirmation of acceptable QC results.

For waived test, there needs to be a record of corrective action when control results exceed defined acceptability limits.

Calibration is defined as the set of operations that establish, under specified conditions, the relationship between reagent system/instrument response and the corresponding concentration/activity values of an analyte. Calibration procedures are typically specified in the manufacturer's instructions, but may also be established by the laboratory. Calibration verification is the process of confirming that the current calibration settings for each analyte remain valid for a test system.

For waived tests, the POCT program follows manufacturer instructions for calibration, calibration verification, and related functions. For each waived test, written procedures describing calibration, if indicated, should be consistent with manufacturer's instructions. Records for calibration/calibration verification-related functions as required by the manufacturer should be kept. Also, records of recalibration or other appropriate corrective action when calibration verification is unacceptable must be available as evidence of compliance.

For molecular-based microbiology waived tests, the laboratory must monitor for the presence of false positive results (that is, due to nucleic acid contamination) for all molecular microbiology test. Examples of monitoring could include the review of summary statistics such as monitoring percentage of positive results relative to current local and regional rates and increased positive Strep results above historical rate within a run over multiple runs. Also, examples of monitoring could include the performance of wipe (environmental) testing and the review and investigation of physician inquiries. Based on monitoring data, the laboratory may implement additional mitigation strategies to minimize the risk of contamination, such as process controls. Examples of compliance with this requirement include records of data review, wipe testing, statistical data evaluation and corrective action, if indicated.

Quality Requirements Specific to Nonwaived Testing

Nonwaived testing requirements include calibration verification (process of confirming that the current calibration settings for each analyte remain valid for a test system) every six months and semi-annual correlation between more than one instrument/method including correlation between identical instruments. Each Laboratory must define limits for accepting or rejecting results of the calibration verification process. Calibration verification can be accomplished in several ways. If the manufacturer provides a calibration validation or verification process, it must be followed. Other techniques include (1) assay of the current calibration materials as unknown specimens, and (2) assay of matrix-appropriate materials with target values that are specific for the method.

Single-use devices such as i-STAT instruments are exceptions to the rule that calibration verification must be performed on all instruments. Instead, calibration verification can be performed on representative devices every six months.

Another exception is applicable to coagulation testing. Calibration verification is not applicable to coagulation testing/coagulation instruments that report patient results in units of time (i.e., ACT, PTINR). Also, the AMR (Analytical Measurement Range, the range of analyte values that a method can directly measure on the specimen without any dilution, concentration, or other pretreatment not part of the usual assay process) does not apply to clot-based coagulation tests/instruments. The CRR (clinical reportable range) for such instruments can be established using previously analyzed patient specimens, control materials, and/or other standards.

Note that if materials used for calibration or for calibration verification include low, midpoint, and high values, that are near the AMR, and if calibration verification data are within the user's acceptance criteria, the AMR has been verified: no additional procedures are required. If the

calibration and/or calibration verification materials do not include the full AMR, the AMR must be verified by assaying additional materials reasonably near the lowest and highest values of the AMR.

When verifying the AMR, it is required that materials used are near the upper and lower limits of the AMR. Factors to consider in verifying the AMR are the expected analytic imprecision near the limits, the clinical impact of errors near the limits, and the availability of test specimens near the limits. It may be difficult to obtain specimens with values near the limits for some analytes. In such cases, reasonable procedures should be adopted based on available specimen materials. The closeness of sample concentrations and activities to the upper and lower limits of the AMR are defined at the laboratory director's discretion. The method manufacturer's instructions for verifying the AMR must be followed, when available. The laboratory director must define limits for accepting or rejecting verification tests of the AMR.

Calibration Procedures

Calibration is the process of adjusting an instrument or test system to establish a relationship between the measurement response and the concentration or amount of the analyte that is being measured by the test procedure.

For nonwaived testing, calibration procedures for each test system must be appropriate, and the calibration records are to be reviewed for acceptability. Note that calibration must be performed following manufacturer's instructions, at minimum, including the number, type, and concentration of calibration materials, frequency of calibration, and criteria for acceptable performance. Calibration procedures are typically specified in the manufacturer's instructions but may also be established by the laboratory.

Calibration and Calibration Verification Materials

High quality materials with test system and matrix-appropriate target values are used for calibration and calibration verification whenever possible. Note: Calibration and calibration verification must have defined analyte target values and appropriate matrix characteristics for the clinical specimens and specific assay method. Many instrument systems require calibration materials with system-specific target values to produce accurate results for clinical specimens.

Suitable materials for calibration verification include, but are not limited to:

1. Calibrators used to calibrate the analytical system
2. Materials provided by the manufacturer for the purpose of calibration verification
3. Previously tested unaltered patient/client specimens
4. Primary or secondary standards or reference materials with matrix characteristics and target values appropriate for the method
5. Third party general purpose reference materials that are suitable for verification

In general, routine control materials and proficiency testing materials are not suitable for calibration verification, except in situations where the material has been shown to be suitable (specifically designated by the method manufacturer) or no other materials are available. The appropriate calibration and calibration verification materials should be defined in writing.

Recalibration/Calibration Verification Criteria

Criteria need to be established for recalibration or calibration verification, and the acceptablility of results. Compliance should be recorded.

Laboratories must either recalibrate or perform calibration verification at least every six months and if any of the following occur:

1. At changes of reagent lots, unless the user can demonstrate that the use of different lots does not affect the accuracy of patient/client results
2. If QC shows an unusual trend or shift or is outside acceptable limits, and the system cannot be corrected to bring control values into the acceptable range
3. After major maintenance or change of a critical instrument component.

4. As recommended by the manufacturer.

Single use devices, and other test devices that do not allow user calibration, do not require calibration verification.

As evidence of compliance, a policy should be written defining the method, frequency and limits of acceptability of calibration verification for each instrument/test system. Records of calibration verification at defined frequency should be available.

Recalibration
Test systems are to be recalibrated when calibration verification fails to meet the established criteria of the laboratory POCT program and records are to be maintained. Criteria for recalibration needs to be defined and records of recalibration must be kept, if calibration or calibration verification has failed.

AMR Limits Defined
AMR limits for all analytes tested by nonwaived methods are to be defined. Upper and lower limits of all quantitative reportable parameters on the point of care testing instrument are to be defined, and results that fall outside these limits are to be reported properly. Results falling outside these limits are appropriately reviewed and reassayed if necessary before reporting. Note that apparent analyte concentrations that are lower or higher that the AMR do not routinely require repeat analysis if the result is reported as less than the lower limit, or greater than the upper limit, respectively, and the laboratory has evidence that the low result is not due to sampling/dilution errors, immunologic "hook effects," etc. If there is a need to report an actual value, a patient sample should be referred to a laboratory that either has a method with a wider verified analytical measurement range (AMR), or that can perform sample dilutions or concentrations so that the analyte concentration is brought into the AMR of an analytical method.

Again, the AMR does not apply to clot-based coagulation tests. Evidence of compliance includes a written policy defining AMR by analyte and records of actions taken by trained operators when results fall outside defined limits.

AMR Verification Materials
Verification of the AMR is to be performed with matrix-appropriate materials of known analyte value appropriate to the AMR of the instrument and the process documented. At a minimum this must include materials at the low, mid, and high range of the AMR, and appropriate acceptance criteria should be defined.

Note that the matrix of the sample (the environment in which the sample is suspended or dissolved) may influence the measurement of the analyte. In many cases, the method manufacturer will recommend suitable materials. Other suitable materials for AMR verification include the following:

1. Linearity material of appropriate matrix, CAP CVL Survey-based or other suitable linearity verification material.
2. Previously tested patient/client specimens, that may be altered by admixture with other specimens, dilution, spiking in known amounts of an analyte or other technique.
3. Primary or secondary standards or reference materials with matrix characteristics and target values appropriate for the method.
4. Patient samples that have reference method assigned target values.
5. Control materials, if they adequately span the AMR and have method specific target values.

CLOSENESS OF SAMPLE CONCENTRATIONS OR ACTIVITIES TO THE UPPER AND LOWER LIMITS OF THE AMR
When verifying the AMR, it is required that materials used are near the upper and lower limits of the AMR. Factors to consider in verifying the AMR are the expected analytic imprecision near the limits, the clinical impact of errors near the limits, and the availability of test specimens near the limits. It may be difficult to obtain specimens with values near the limits for some analytes. In

such cases, reasonable procedures should be adopted based on available specimen materials. The closeness of sample concentrations and activities to the upper and lower limits of the AMR are defined at the laboratory director's discretion. The method manufacturer's instructions for verifying the AMR must be followed, when available. The laboratory director must define limits for accepting or rejecting verification tests of the AMR.

A written document for AMR verification defining the types of materials used and acceptability criteria should be available.

AMR Verification Criteria
Criteria should be established for verifying the analytical measurement range (AMR). Records must be retained. Note that the AMR must be verified every six months after a method is initially placed in service and if any of the following occur:

1. At changes of reagent lots unless the laboratory can demonstrate that use of different lots does not affect the accuracy of patient/client results, and the range used to report patient/client test data
2. QC shows an unusual trend or shift or is outside acceptable limits, and the system cannot be corrected to bring control values into the acceptable range
3. After major preventive maintenance or change of a critical instrument component
4. When recommended by the manufacturer

It is not necessary to independently verify the AMR if the calibration of an assay includes calibrators that span the full range of the AMR, with low, midpoint and high values (three points) and the system is calibrated at least every six months. A one-point or two point calibration does not include all of the necessary points to validate the AMR.

Single-use devices are a special case in which a large number of devices may be in use at any time within an institution. The AMR must be verified for each device when placed in service, and following maintenance or repair. The AMR verification may be performed on a sampling of devices, if allowed in the manufacturer's instructions. The sampling procedure must:

- Include a sample of each instrument type and each lot of strips/cartridges in the subset of devices verified if different types of instruments and different lots of reagent strips/cartridges are in use.
- Use an additional approach to infer AMR verification for the devices not sampled, such as: 1) review of external QC result to ensure acceptability: or 2) comparison of POCT results with near-simultaneously collected specimens analyzed in the main laboratory.
- Include a rotation of devices on which reverification is directly performed over time.

AMR verification is not required for clot-based coagulation tests, platelet function tests, and other tests where output is a unit of time or arbitrary reporting unit (rather than measured analyte concentration). AMR verification is not required for calculated test results as long as the Individual results contributing to the calculation have AMR verification.

A document defining the frequency performed for AMR verification should be available as evidence of compliance along with records of AMR verification at least every six months.

Comparability of Instruments and Methods
If the laboratory uses more than one nonwaived instrument/method to test for a given analyte, the instruments and methods are checked against each other at least twice a year for comparability of results.

Note that this requirement applies to tests performed on the same or different instrument makes/ models or by different methods, even if there are different reference intervals or levels of sensitivity. It includes primary and back up methods used for patient testing. The purpose of the requirement is to evaluate the relationship between test results using different methodologies, instruments, or testing sites. This comparison is required only for nonwaived

instruments/methods accredited under a single CAP number. The laboratory must establish a written procedure for this check that includes acceptance criteria.

This requirement is not applicable to:

- Calculated parameters
- Waived methods
- Laboratories with different CAP numbers

The following types of materials may be used to generate data for comparability studies:

- Patient/client specimens (pooled or unpooled) are preferred to avoid potential matrix effects
- Quality control materials for tests performed on the same instrument platform, with both control materials and reagents of the same manufacturer and lot number.
- Alternative protocols based on quality control or reference materials for cases when availability or pre-analytical stability of patient/client specimens is a limiting factor. The materials used must be validated (when applicable) to have the same response as fresh human samples for the instruments and methods involved.

This requirement only applies when the instruments/reagents are producing the same reportable result. More than one sample should be tested between instruments. There should be a written procedure for performing instrument and method comparison and records of comparability studies reflecting performance at least twice per year with appropriate specimen types.

Comparability Criteria

Acceptability criteria are defined for comparability of nonwaived instruments and methods used to test the same analyte, with records of corrective action when the criteria are not met. Note that the acceptability criteria are determined by the laboratory and can vary based on the specific analyte and clinical impact of its measurement variation. Examples of data that can be useful to establish these criteria include, but are not limited to:

- Method validation or verification data
- Clinical significance of the variation between methods
- Biologic variation data
- Data from external proficiency testing providers.

These criteria may be developed from in-house data or published literature and must be vetted by the laboratory director to ensure that they are appropriate for the clinical application of the test.

Records of comparability studies with evidence of review and corrective action taken, as appropriate, must be kept.

Precision Checks

Concerning precision checks, ordinarily precision checks are only required as a component of the initial instrument and method validation that is performed at the time of an instrument's installation. There may be a need to perform precision studies for the purpose of troubleshooting, or to investigate possible changes in the precision of an instrument. As part of the ongoing quality control program, monthly QC statistics should be reviewed for accuracy and precision. Accuracy and precision are usually determined by analyzing the percent coefficient of variation and the standard deviation of the data.

IQCP

CMS (Centers for Medicare and Medicaid Services) launched a new quality control option for laboratories performing **nonwaived testing,** that is a risk-based model. Starting January 1, 2014, IQCP (Individualized Quality Control Plan) allows labs to customize quality control policies and procedures based on risk management principles, the test systems in use, and the unique aspects of each laboratory. IQCP applies to all nonwaived testing performed, including existing and new test systems. All CLIA specialties and subspecialties are eligible for IQCP except Pathology. In certain cases, IQCP will allow labs to run fewer external liquid controls as long as

the instrument manufacturer's instructions are followed. With IQCP, labs are required to carefully review all phases of the testing process and perform a thorough risk assessment, the results of which may not necessarily lead to fewer external QC runs. The IQCP can be customized based on patient population, environment, test system, personnel, and test uses. This QC option allows labs to adapt to future technology, as manufacturers continually improve their instruments.

Note that IQCP is **voluntary**. The laboratory director retains overall responsibility for ensuring that QC programs are established and maintained to assure the quality of laboratory services provided, and to identify failures in quality as they occur. Labs can still abide by the default two levels per day originally required by CLIA. However, if labs wish to reduce external QC runs based on a manufacturer's instructions, they must use IQCP. For example, if the manufacturer says the QC frequency is once a week, IQCP must be implemented to employ QC frequency of once a week. To summarize, if QC is ran at a frequency that is below what CLIA normally requires, IQCP must be used.

Guidelines that lay out the program are available on the CMS CLIA website at http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Individualized_Quality_Control_Plan_IQCP.html, along with other educational material. The education and transition period for IQCP was concluded on January 1, 2016. As IQCP was set up for POCT, the use of the original equivalent quality control (EQC) was discontinued. However, during the educational and transition period for IQCP implementation, building on existing quality practices and using the information, knowledge, and experience gained from EQC studies as a resource, was the foundation for establishing IQCP. This process was driven by two decisions: 1) limits of medically-allowable error and 2) required action when an unacceptable number of patients are exposed to risk.

The records of corrective action when control results exceed defined acceptability limits must be kept. Note that patient/client test results obtained in an analytically unacceptable test run or since the last acceptable test run must be re-evaluated to determine if there is a significant clinical difference in patient/client results. Re-evaluation may or may not include re-testing patient samples, depending on the circumstances. Even if patient samples are no longer available, test results can be re-evaluated to search for evidence of an out-of-control condition that might have affected patient results. The corrective action for tests that have an IQCP approved by the laboratory director must include an assessment of whether further evaluation of the risk assessment and quality control plan is needed based on the problems identified (e. g. trending for repeat failures, etc.).

Quality control specimens must be tested in the same manner and by the same personnel as patient samples. QC specimens must be analyzed by personnel who routinely perform patient testing. This does not imply that each operator must perform QC daily, so long as each instrument and/or test system has QC performed at required frequencies, and all analysts participate in QC on a regular basis. To the extent possible, all steps of the testing process must be controlled, recognizing that pre-analytic and post-analytic processes may differ from those encountered with patients. Records should reflect that QC is run by the same personnel performing patient testing.

Daily QC for nonwaived tests includes running controls at least each day testing is performed, or more frequently if specified in manufacturer's instructions, laboratory procedure, or the CAP Checklist, for quantitative and qualitative tests and when changes occur that may impact patient results. The laboratory must define the number and type of quality control used and the frequency of testing in its quality control procedures. Again, control testing is not necessary on days when patient testing is not performed.

Controls must be run prior to reporting patient results, and prior to resuming patient testing when changes occur that may impact patient results, including after a change of analytically critical reagents, major preventative maintenance, change of a critical instrument component, or with software changes, as appropriate. For quantitative tests, two controls at two different concentrations must be run at least daily, except for coagulation tests, or unless otherwise required in the CAP checklist. For nonwaived testing for coagulation tests, two controls at two

different concentrations need to be run every 8 hours. For qualitative tests, a negative control and a positive control (when applicable) must be ran at least daily.

Controls should verify assay performance at relevant decision points. The selection of these points may be based on clinical and analytical criteria.

For daily QC of blood gas instruments, a minimum of one level of quality control for pH, pCO2 and pO2 is to be analyzed at least every eight hours of operation when patient specimens are tested. QC requirements are more frequent if specified in the manufacturer's instructions or laboratory procedure, and when changes occur that may impact patient results. The laboratory must define the number and type of quality control used and the frequency of testing in its quality control procedures. Control testing is not necessary on days when patient testing is not performed. Controls must be run prior to reporting patient results, and prior to resuming patient testing when changes occur that may impact patient results, including after a change of analytically critical reagents, major preventative maintenance, change of a critical instrument component, or with software changes, as appropriate.

If an internal quality control process (e.g. electronic/procedural/built-in) is used instead of an external control material to meet daily quality control requirements, the laboratory must have an individualized quality control plan (IQCP) approved by the laboratory director defining the control process, including frequency and use of external and internal controls. At a minimum, external control materials must be analyzed with new lots and shipments of reagents or more frequently if indicated in the manufacturer's instructions. The tests must be eligible for IQCP and the requirements for implementation and ongoing monitoring of an IQCP must be met. Records of QC results including external and internal control processed, written quality control procedures, and manufacturer product insert or manual are to be kept on hand.

The BVHS organization determined which current instruments used EQC prior to January 1, 2016. Abbott i-STAT in Open Heart and Hemochron in Cath Lab were those POCT instruments that formerly used EQC and were converted to IQCP. When BVHS decided to implement IQCP, it completed the Risk Assessment per Test System and the Quality Control Plan per Test System by location. In addition, the organization had to ensure there was adequate Quality Assurance in place for each Quality Control Plan. Since then, IQCP plans have been implemented for all nonwaived point of care testing to improve efficiency and save money.

Quality control data are reviewed and assessed at least monthly by the laboratory director or designee. The BVHS Point of Care Testing Coordinator, Bluffton Hospital Laboratory Coordinator, clinical managers / educators and other laboratory and non-laboratory personnel can serve as designees. Note that the review of quality control data must be recorded and include follow-up for outliers, trends, or omissions that were not previously addressed. The QC data for tests performed less frequently than once per month should be reviewed when the tests are performed. The review of quality control data for tests that have an IQCP approved by the laboratory director must include an assessment of whether further evaluation of the risk assessment and quality control plan is needed based on problems identified (e.g. trending for repeat failures, etc.) Records of QC review including follow-up for outliers, trends, or omissions must be kept.

Note that the Individualized Quality Control Plan, or IQCP, does not apply to manual microscopic observations. For nonwaived testing, the CAP has defined eligibility requirements for the IQCP. Eligibility is limited to tests that meet both of the following criteria:

- The testing is performed in a discipline other than anatomic pathology or cytopathology. (Exceptions are tests in anatomic pathology or cytopathology that can be assigned to another discipline.)
- The test system has an internal control process (electronic, procedural, or built-in). (Exceptions exist in microbiology for media, identification systems, and susceptibility testing, which qualify for the IQCP even though there is no internal quality control.)

Unusual Laboratory Results

The BVHS Laboratory Point of Care Testing Coordinator or Bluffton Hospital Laboratory Coordinator or designated personnel, if indicated, review results in a timely manner, in order to detect significant clerical and analytical errors, and unusual or unexpected test results. The BVHS Laboratory POCT Coordinator/ Bluffton Hospital Laboratory Coordinator or designee then contacts the manager where the result originated and makes a suggestion for correction. It is the manager's responsibility to make sure that the final result is entered correctly.

Evidence of compliance includes records of review of results or records of consistent implementation of the error detection system defined in the procedure and records of timely corrective action of identified errors.

New Waived Test Implementation

For each waived test, the laboratory follows manufacturer's instructions for the introduction of the instrument or device and there must be records that the test(s) is approved for use by the laboratory director, or designee meeting CAP director qualifications, prior to use in patient testing.

Note that waived testing must be performed following the manufacturer's instructions. If the laboratory modifies a waived test, the checklist requirements for high complexity testing apply, Including the requirements for validation of the method performance specifications.

Tthe laboratory director's signature on the written test procedure may be used to show approval of the test for use in patient testing. Records of test approval are required.

This requirement also applies to tests with FDA emergency use authorization (EUA) specifically designated by the FDA or other entities as designated by the US Department of Health and Human Services (HHS) Secretary for use in patient care settings in the EUA Letter of Authorization. Such tests are deemed to be CLIA waived tests.

Note: After initial approval, the introduction of additional identical waived instruments performing identical previously approved waived tests does not require approval by the director or designee, providing manufacturer instructions for instrument verification are followed and recorded.

New Nonwaived Test Implementation

Prior to clinical use of each new nonwaived (unmodified FDA-cleared or approved) test, the laboratory must perform a verification study and prepare a written assessment of each of the following test method performance specifications, as applicable, using a sufficient number (determined/approved by the laboratory medical director) of characterized samples:

1. Analytical accuracy
   Accuracy is verified by comparing results to a definitive or reference method, or an established comparative method. Use of matrix-appropriate reference materials, patient specimens (altered or unaltered), or other commutable materials with known concentrations or activities may be used to verify accuracy. The use of routine quality control materials or calibrators used to calibrate the method is not appropriate.

2. Analytical precision
   Precision is verified by repeat measurement of samples at varying concentrations or activities within run and between run over a period of time.

3. Reportable range

> The reportable range of an assay is the range of test result values over which the laboratory has verified accuracy of the instrument or test system measurement response.

This requirement also applies to tests with FDA emergency use authorization (EUA) in moderate or high complexity testing laboratory settings.

Note that if multiple identical instruments or devices are in use, there must be records (data and written assessment) showing that the method performance specifications have been separately verified for each test and instrument or device.

If a method is verified by someone other than the laboratory's personnel (manufacturer's representative), the laboratory must have records to show that the verification correlates with its in-house test performance by showing confirmation of performance specifications by the laboratory personnel testing known specimens.

For tests implemented after June 15, 2009, the written assessment must include an evaluation of each component of the verification study, including the acceptability of data. All nonwaived tests must at least have records of completed analytical verification, if implemented prior to 2009. If data include discordant results, there must be a record of the discordance and investigation of any impact on the approval of the test for clinical use. Evidence of compliance includes a written procedure for verifying test method performance specifications and records of verification and written assessment of each component of the test method performance specifications for each test.

Prior to clinical use of each nonwaived test, the laboratory director, must sign the laboratory's written assessment of the validation or verification study (accuracy, precision, etc.) to confirm the acceptance of the study data and written assessment, and to approve each nonwaived test for clinical use. The approval must include: 1) review of the written assessment of the validation or verification study, including the acceptability of the data and investigation of any discordant results; 2) signed approval statement, such as, "I have reviewed the verification (or validation) data for accuracy, precision, reportable range, and reference interval studies (insert other components, as required) for the (insert instrument/test name, and the performance of the method is considered acceptable for patient testing."

If multiple identical instruments or devices are in use, there must be records (data and written assessment) showing that the method performance specifications have been separately validated/verified for each test and instrument or device. There must be permanent records of approval of validation and verification studies and approval for clinical use available for inspection.

Analytical Interferences

The laboratory has to understand the analytical interferences for each test, and have an appropriate plan of action when they are present. Note that interfering substances may pose a significant problem to the clinical laboratory and healthcare providers who may be misled by laboratory results that do not reflect patient clinical status. The laboratory must be aware of common interferences by performing studies or referencing studies performed elsewhere (such as by the instrument-reagent manufacturer. There should be a written procedure for determining method performance characteristics, including analytical interferences. There should be documentation listing known interferences for each test and plan of action when they are present.

Reference Interval Verification or Establishment

The laboratory needs to verify or establish its reference intervals. Note that reference intervals are important to allow a clinician to assess patient results against an appropriate population. The reference intervals must be established or verified for each analyte and specimen source, such as blood, urine, and cerebrospinal fluid, when appropriate. For example, a reference interval can be verified by testing samples from 20 healthy representative individuals: if no more than two results fall outside the proposed reference interval, that interval can be considered verified for the population studied.

If a formal reference interval study is not possible or practical, then the laboratory should carefully evaluate the use of published data for its own reference intevals, and retain records of this evaluation. For many analytes, such as cholesterol, literature references or a manufacturer's package insert information may be appropriate.

The laboratory should have a record of the reference interval study or records of verification of manufacturers stated interval when a reference interval study is not practical (that is, unavailable normal population) or other methods approved by the laboratory/section director.

Reference Interval Evaluation
The laboratory should evaluate the appropriateness of its reference intervals and take action if necessary.

Note that criteria for evaluation of reference intervals include:

1. Introduction of a new analyte to the test menu
2. Change of analytic methodology
3. Change in patient population

If it is determined that the range is no longer appropriate for the patient population, corrective action must be taken. Records should be kept of any evaluations and corrective action, if indicated.

Clinical Claims Validation
For FDA-cleared/approved tests, the laboratory should validate clinical claims not included in the manufacturer's instructions. A clinical claim is a communication from the laboratory to its users (including but not limited to clinicians and patients) regarding a test's sensitivity and specificity, predictive values for a disease or condition, clinical usefulness, cost-effectiveness or clinical utility.

To adequately support a clinical claim the laboratory must perform a clinical validation study, unless the clinical validity of the test is documented in peer-reviewed literature or textbooks. The clinical validation study must include at least 20 samples and must include both positive and negative samples. If the laboratory uses fewer samples, the laboratory director or designee meeting CAP director qualifications must record the criteria used to determine the appropriateness of the sample size.

Software and Middleware Upgrades
The BVHS Point of Care Coordinator will determine the date and time of software upgrades on point of care testing instruments, as required by the manufacturer. Middleware upgrades for TELCOR QML and Novanet, both production and test sides, will need to be done periodically as determined by the each company. Coordination with other department associates, including LIS and IT, along with Bio-Med, may be necessary. Bio-Med staff members will be contacted for assistance to perform software upgrades on instruments located at other physician office laboratories, including Physicians Plus Urgent Care, BV specialty clinics, and BVMP sites.

Guidelines for Physician Office Laboratories with a Certificate of Provider-Performed Microscopy Procedures (PPMP)

A Certificate of Provider-Performed Microscopy Procedures (PPMP) permits a laboratory to perform a limited list of moderate complexity tests, as well as any waived tests. Compliance with CLIA regulations is required. CLIA is a federal program that establishes quality laboratory standards to protect patient safety and improve health care. The final CLIA regulation was published in the Federal Register on February 28, 1992 and became effective on September 1, 1992 as 42 CFR Part 493 Laboratory Requirements. This law established uniform quality standards for all laboratory testing to ensure accuracy, reliability and timeliness of patient test results regardless of where the test was performed.

In Ohio, the Ohio Department of Health (ODH) is responsible for monitoring all clinical laboratories for compliance to these federal requirements through its Laboratory Certification

Program. Generally, each separate location or address is required to have a separate CLIA number but there are exceptions for not-for-profit/government-owned laboratories or hospitals. The application for a CLIA certificate, Form CMS-116, can be located at the ODH website.

For PPMP, some quality and administrative requirements must be addressed. The policies, procedures, and practices need to ensure accurate testing and positive patient outcomes. The PPMP procedures must be personally performed by a physician or midlevel practitioner (nurse practitioners, nurse midwives, and physician assistants) and are categorized as moderately complex. The laboratory may also perform any test classified as waived but the laboratory staff must follow the manufacturer's instructions.

The primary instrument for performing the PPM procedures is a microscope, limited to bright field or phase-contrast microscopy. The PPMP specimens are labile and a delay in performing the test could compromise the accuracy of the test result. Limited specimen handling or processing is required. The specimen examination must be performed during the patient visit on a specimen obtained from the provider's patient or a patient of the group practice.

The laboratory must meet all applicable requirements of participation in proficiency testing, patient test management, quality control, personnel, and quality assurance. Because the PPM tests are considered non-regulated, proficiency testing is not specifically required, but the laboratory is responsible for documenting quality assurance. The laboratory must verify the accuracy of PPMP test results at least twice a year. In other words, at a minimum, two split samples for each PPM test should be done yearly.

Quality Control (QC) is an analytic process. QC testing is performed to ensure that the test system and reagents are working properly and the operator is performing the test correctly. Controls must be tested at least as often as recommended by the manufacturer of the kit/reagents. Documentation of results verifies that QC materials were tested and were acceptable.

Control materials are not available to monitor the entire testing process but two levels of controls must be performed if available. Note that two levels of control materials for urine sediment examinations are commercially available. Since most microscopic procedures do not have commercial controls available to verify the reliability of test results, a procedure should be established to confirm that the interpretation of the patient test or microscopic observation is accurate. Besides participation in a proficiency testing program, some methods include a review of permanent slides or a review of photomicrographs in atlases, textbooks, or computer software. Review of the findings by a second trained individual is also an option for confirming results.

Regular maintenance must be performed on the microscope (and centrifuge if used in conjunction with the microscope) and documented accordingly. A current procedure manual must be developed and maintained for all microscopy tests performed in the laboratory. Reagent must be properly labeled and stored. Outdated reagents should never be used. Both the refrigerator and room temperatures must be monitored and documented. Minimum and maximum temperatures, as well as current, must be recorded daily during normal business hours.

All testing personnel in PPM laboratories are required to undergo competency assessment. If a solo practitioner has a PPM laboratory, the solo practitioner must establish a minimal level of proficiency in order to demonstrate competency. Personnel competency must be demonstrated and documented through quality assurance testing or other educational material for microscopy testing. PPM competency assessment should evaluate if the provider performs the test and reports results according to the laboratory's procedure. Other considerations include if the test is actually performed during the patient's visit and if the correct microscope type (bright field or phase contrast) is actually used.

The following tests are classified as PPM procedures and are to be performed by the physician or midlevel practitioner:

1. All direct wet mount preparations of specimens (including vaginal, cervical, or skin) for the presence or absence of bacteria, fungi, parasites or cellular elements.

2. All potassium hydroxide (KOH) preparations
3. Pinworm examinations
4. Fern test
5. Post-coital direct, qualitative examinations of vaginal or cervical mucous
6. Urine sediment examinations
7. Nasal smears for granulocytes
8. Fecal leukocyte examinations
9. Qualitative semen analysis limited to the presence or absence of sperm and detection of motility

NOTE: If microscopy testing is performed by an individual NOT meeting provider requirements, the exams are MODERATE COMPLEXITY and the laboratory needs a different certificate, either Certificate of Compliance or Certificate of Accreditation.

Concerning waived testing, proficiency testing is not specifically required. Some waived tests have quality control requirements. Medical office laboratory personnel should very carefully review the manufacturer's instructions and follow them as written.

The most recent package insert instructions should be used. Waived testing kit instructions may change slightly from time to time. Any posted kit instructions (recipe card format) should be dated. At the beginning of each year, fresh instructions should be posted. Any time the instructions change, fresh instructions should be posted to replace the outdated instructions.

Test kits/reagents must be used in the form they are received. They cannot be altered in order to save money. For example, reagent strips may not be cut in order to test more samples per strip. Outdated reagents should never be used. All test kits should be stored and handled according to the manufacturer's instructions. Both the refrigerator and room temperatures must be monitored and documented.

The laboratory must have a sufficient number of individuals who meet the qualifications to perform the volume and complexity of tests performed. Personnel performing waived testing must have documentation of training appropriate for the tests performed prior to analyzing patient testing. Training for each test and test method is required. Training records must be updated whenever a test method changes. For waived testing, CLIA does not require policies for assessing personnel competency.

Generally, laboratory testing records of quality control, patient results, and quality assurance should be kept on site two years. Daily temperature records should be kept two years. Electronic training and competency records of personnel should be kept permanently in Net Learning. Paper records should be kept on site at least two years. Outdated procedures and instrument maintenance/repair records should be kept for two years after the procedure/instrument is no longer in use.

For laboratories accredited by CAP or JC, the accrediting organization's standards should be reviewed for compliance.

Guidelines for Physician Office Laboratories with a Certificate of Waiver

A Certificate of Waiver permits a laboratory to perform any waived tests. Compliance with CLIA regulations is required. CLIA is a federal program that establishes quality laboratory standards to protect patient safety and improve health care. The final CLIA regulation was published in the Federal Register on February 28, 1992 and became effective on September 1, 1992 as 42 CFR Part 493 Laboratory Requirements. This law established uniform quality standards for all laboratory testing to ensure accuracy, reliability and timeliness of patient test results regardless of where the test was performed.

In Ohio, the Ohio Department of Health (ODH) is responsible for monitoring all clinical laboratories for compliance to these federal requirements through its Laboratory Certification

Program. Generally, each separate location or address is required to have a separate CLIA number but there are exceptions for not-for-profit/government-owned laboratories or hospitals. The application for a CLIA certificate, Form CMS-116, can be located at the ODH website.

The laboratory staff must follow the manufacturer's instructions (procedures) when performing these tests. Laboratories performing only waived tests are not routinely inspected. However, they may be inspected as part of a complaint investigation or on a random basis to determine whether or not only waived tests are performed. The laboratory policies, procedures, and practices need to ensure accurate testing and positive patient outcomes. Proficiency testing is not specifically required. Some waived tests have quality control requirements. Medical office laboratory personnel should very carefully review the manufacturer's instructions and follow them as written.

The most recent package insert instructions should be used. Waived testing kit instructions may change slightly from time to time. Any posted kit instructions (recipe card format) should be dated. At the beginning of each year, fresh instructions should be posted. Any time the instructions change, fresh instructions should be posted to replace the outdated instructions.

Test kits/reagents must be used in the form they are received. They cannot be altered in order to save money. For example, reagent strips may not be cut in order to test more samples per strip. Outdated reagents should never be used. All test kits should be stored and handled according to the manufacturer's instructions. Both the refrigerator and room temperatures must be monitored and documented.

The laboratory must have a sufficient number of individuals who meet the qualifications to perform the volume and complexity of tests performed. Personnel performing waived testing must have documentation of training appropriate for the tests performed prior to analyzing patient testing. Training for each test and test method is required. Training records must be updated whenever a test method changes. For waived testing, CLIA does not require policies for assessing personnel competency.

Generally, laboratory testing records of quality control and patient results should be kept on site at least two years. Daily temperature records should be kept at least two years. Training records of personnel should be kept indefinitely in case the staff member returns to work at a specific laboratory. Outdated procedures and instrument maintenance/repair records should be kept for two years after the procedure/instrument is no longer in use.

Laboratory Certification (CLIA) By the Ohio Department of Health

The Laboratory Certification Program at the Ohio Department of Health works to ensure Ohioans receive accurate, cost-effective clinical laboratory testing as a part of their health care. Clinical laboratory testing directly or indirectly affects every Ohio resident from pre-cradle to grave.

Each year, the program inspects and monitors clinical laboratories located in hospitals, independent laboratories, plasmapheresis centers and physicians' offices. The program monitors the performance of approximately 8,500 laboratories and investigates clinical laboratory complaints it receives.

The program monitors all clinical laboratories for compliance to federal (42 Code of Federal Regulations Part 493 Clinical Laboratory Improvement Amendments of 1988 (CLIA)) and state requirements (Ohio Revised Code Chapter 3725 Plasmapheresis Centers). The program conducts on-site inspections for compliance, monitors accuracy and reliability of testing via proficiency review of testing scores/reports, investigates complaints and answers both regulatory and technical questions related to clinical laboratories.

Generally, each separate location or address is required to have a separate CLIA number. To ensure this requirement is met, the Laboratory Point of Care Testing Coordinator at Blanchard

Valley Hospital will yearly inspect the list of CLIA certificates for BVHS laboratories and make recommendations, as needed, to the Laboratory Administrative Director.

Note that there are exceptions for not-for-profit/government-owned laboratories or hospitals. Call ODH to inquire if an organization qualifies for one of these exceptions. The application for a CLIA certificate, Form CMS-116, can be located at the ODH website.

A CLIA certificate can cover multiple sites. The single site CLIA certificate can cover multiple testing locations if any of the following regulatory exceptions applies to the facility's operation. Exceptions:

1. The laboratory is not at a fixed location. This laboratory moves from testing site to testing site, such as a mobile unit providing laboratory testing, health screening fairs, or other temporary testing locations, and may be covered under the certificate of the designated primary site or home base, using its address. For a mobile unit providing laboratory testing, the vehicle identification number(s) (VINs) must be recorded and attached to the CLIA certificate application.

2. A not-for profit or Federal, State or local government laboratory engaged in limited (not more than a combination of 15 moderate complexity or waived tests per certificate) public health testing and filing for a single certificate for multiple sites.

3. A hospital with several laboratories located at contiguous buildings on the same campus within the same physical location or street address and under common direction that is filing for a single certificate for these locations**. Note: Stand-alone buildings on the same campus or on a split campus do not qualify for this exception. Each should have their own separate CLIA certificate.**

Contact Information for CLIA Applications

Mailing Address:
Ohio Department of Health
Laboratory Certification Program
246 North High Street
Columbus, OH 43215

Telephone: (614) 644-1845
Fax: (614) 564-2478

E-mail: CLIA@odh.ohio.gov

For updates on a CLIA Certificate of Waiver, send an email to the above address within 30 days with the following:

1. CLIA ID number
2. Change/update information (such as name of new laboratory director or new address)
3. Effective date

For updates on a CLIA Certificate of Provider Performed Microscopy Procedures, submission of a partial new application may be required.

Note: All laboratories are required to notify the licensing agency (ODH) of a change in laboratory director within 30 days.

Accreditation by College of American Pathologists and/or Joint Commission
For laboratories accredited by CAP and/or JC, the accrediting organization's standards should be reviewed for compliance.

Blanchard Valley Health System Laboratory *CAP and JC* accredited sites:

Blanchard Valley Hospital Laboratory
1900 South Main Street
Findlay, OH 45840
Phone: 419.423.5318
Fax: 419.423.5362
CLIA ID NUMBER: 36D0668023 (CAP Certificate of Accreditation, CAP Number: 1675801)

Bluffton Hospital Laboratory
139 Garau St.
Bluffton, OH 45817
Phone: 419.369.2314
Fax: 419.358.2639
CLIA ID NUMBER: 36D0351534 (CAP Certificate of Accreditation, CAP Number: 1675804)

Blanchard Valley Hospital Respiratory/Cardio-Pulmonary
1900 South Main Street
Findlay, OH 45840
Phone: (55286)
Fax: 419.423.5490
CLIA ID NUMBER: 36D0351697 (CAP Certificate of Accreditation)

Armes Family Cancer Care Center Laboratory
15990 Medical Dr. S.
Findlay, OH 45840
Phone: 419.425.3734 (ext. 33734)
Fax: 419.728.0115
CLIA ID NUMBER: 36D2089401 (CAP Certificate of Accreditation, CAP Number: 382958)

Blanchard Valley Health System Additional *JC* accredited sites:

Bridge Home Health & Hospice
15100 Birchaven Lane
Findlay, OH 45840
Phone: 419.423.5351
Fax: 419.423.8967
CLIA ID NUMBER: 36D0684513 (CLIA Certifcate of Waiver)

Bridge Hospice Care Center
1900 South Main Street
Findlay, OH 45840
Phone: 419.423.5577
Fax: 419.423.5541
CLIA ID NUMBER: 36D2122500 (CLIA Certificate of Waiver)

Bridge Hospice Care Center
1069 Klotz Road
Bowling Green, OH 43402
Phone: 419.353.7802
Fax: 419.728.0304
CLIA ID NUMBER: 36D2016946 (CLIA Certificate of Waiver)

Carey Diagnostic Center

930 Sheriden Drive
Carey, OH 43316
Phone: 419.396.0585
Fax: 419.396.1022
CLIA ID NUMBER: 36D2172255 (CLIA Certificate of Waiver)

Eastern Woods Outpatient Center (EWOC)

15900 Medical Drive South
Findlay, OH 45840
Phone: 419.425.3465
CLIA ID NUMBER: 36D2045658 (CLIA Certifcate of Waiver)

Findlay Surgery Center
1709 Medical Boulevard
Findlay, OH 45840
Phone: 419.429.0409
Fax: 419.429.0410
CLIA ID NUMBER: 36D0967845 (CLIA Certifcate of Waiver)

Infusion Therapy

1900 S. Main St.
Findlay, OH 45840
Same address as Blanchard Valley Hospital.

Ottawa Diagnostic Center

1740 N Perry St
Ottawa, OH 45875
Phone: 419.523.3681
Fax: 419.523.3678
CLIA ID NUMBER: 36D2113466 (CLIA Certifcate of Waiver)

Wound Care Solutions

100 W. Pearl St.
Findlay, OH 45840
Phone: 419.423.5309
Fax: 419.423.5376
CLIA ID NUMBER: 36D2114552 (CLIA Certifcate of Waiver)

Julie A. Cole Rehab 7 Sports Medicine

1721 Medical Blvd. Suite B
Findlay, OH 45840
Phone: 419.425.3199
Fax: 419.425.3012
No laboratory testing performed.

Sak Sleep Wellness Center

1909 S. Main St.

Findlay, OH 45840

Phone: 419.427.2604

No laboratory testing performed.

Pain Management

1900 S. Main St.
Findlay, OH 45840
Phone: 419.423.5555
Same address as Blanchard Valley Hospital.

Pain Management – Lima Site (2)
801 Medical Drive Suite 300 A
Lima, Ohio 45801

Pain Management – Lima Site
658 W. Market St. Suite 106
Lima, OH 45801

Blanchard Valley Health System Laboratory *CLIA Provider Performed Microscopy Procedures* sites:

Blanchard Valley Obstetrics & Gynecology - Bluffton
559 Harmon Road
Bluffton, OH 45817
Phone: 1.844.OBGYN4U
Phone: 419.358.8856
Fax: 419.358.6780

and

Blanchard Valley Obstetrics & Gynecology – Findlay South Main
1917 South Main Street
Findlay, OH 45840
Phone: 1.844.OBGYN4U
Phone: 419.358.8856
Fax: 567.429.0262

CLIA ID NUMBER: 36D0890803 (CLIA Certificate of PPMP)

Blanchard Valley Obstetrics & Gynecology – Findlay East
(Women & Children's Center at EWOC)
15900 Medical Drive South
Findlay, OH 45840
Phone: 419.425.8131
Fax: 567.525.5326
CLIA ID NUMBER: 36D2057006 (CLIA Certificate of PPMP)

Blanchard Valley Obstetrics & Gynecology (Fostoria)
617 North County Line Street, Suite B
Fostoria, OH 44830
Phone: 1.844.OBGYN4U
CLIA ID NUMBER: 36D2154252 (CLIA Certificate of PPMP)

Blanchard Valley Obstetrics And Gynecology - Ottawa
1740 North Perry St.
Ottawa, OH 45875
Phone: 1.844OBGYN4U
Phone: 419.523.7000
Fax: 419.424.0257

CLIA ID NUMBER: 36D2163176 (CLIA Certificate of PPMP)

Blanchard Valley Obstetrics And Gynecology – Clark
(Center for Women and Children)
301 W. Wallace Street
Findlay, OH 45840
Phone: 1.844.OBGYN4U
Phone: 419.424.0180
Fax: 419.424.0257
CLIA ID NUMBER: 36D2031367 (CLIA Certificate of PPMP)

Carey Medical Center
930 Sheriden Drive
Carey, OH 43316
Phone: 419.396.7683
Fax: 419.396.3312
CLIA ID NUMBER: 36D0867660 (CLIA Certificate of PPMP)

Caughman Health Center
1800 N. Blanchard St., Suite 121
Findlay, OH 45840
Phone: 419.427.0809
Family Practice Fax: 419.427.2840
Pediatric Fax: 419.427.2205
CLIA ID NUMBER: 36D0901133 (CLIA Certifcate of PPMP)
(PPMP but microscope not available at site)

Eastern Woods Family Practice
15840 Medical Drive South, Suite B
Findlay, OH 45840
Phone: 419.425.3780
Fax: 419.425.6781
CLIA ID NUMBER: 36D1067137 (CLIA Certifcate of PPMP)
(PPMP but microscope not available at site)

Fostoria Primary Care
617 North County Line Street
Fostoria, OH 44830
Phone: 419.436.9091
Fax: 419.436.9094
CLIA ID NUMBER: 36D2179141 (CLIA Certifcate of PPMP)

Lake Cascades Primary Care
1721 Medical Boulevard, Suite C
Findlay, OH 45840
Phone: 419.423.7663
Fax: 419.423.7665
CLIA ID NUMBER: 36D0351690 (CLIA Certificate of PPMP)

(Ottawa) Putnam County Primary Care
1740 North Perry St.
Ottawa, OH 45875
Phone: 419.523.0012
Fax: 419.523.3416
CLIA ID NUMBER: 36D1031183 (CLIA Certifcate of PPMP)

Blanchard Valley Health System Laboratory CLIA *Certificate of Waiver* Only sites:

Blanchard Valley Diabetes Center

1816 Chapel Drive, Suite J
Findlay, OH 45840
Phone: 419.429.7901
Fax: 419.429.0265
CLIA ID NUMBER: 36D2105601 (CLIA Certificate of Waiver)

Blanchard Valley Urology Associates
1651 North Lake Court
Findlay, OH 45840
Phone: 419.423.8090 ext: 68023
Fax: 419.423.8902
CLIA ID NUMBER: 36D2097375 (CLIA Certificate of Waiver)

Bluffton Primary Care
161 Garau St.
Bluffton, OH 45817
Phone: 419.369.2280
Fax: 419.358.0792
CLIA ID NUMBER: 36D2136132 (CLIA Certificate of Waiver)

Bridgestone APM Company (Well at Work – Upper Sandusky)
235 Commerce Way
Upper Sandusky, OH 43351
Phone: 419.294.2218
Fax:
CLIA ID NUMBER: 36D2250904 (CLIA Certificate of Waiver)

Gastroenterology Associates of Northwest Ohio
1818 Chapel Dr., Suite C
Findlay, OH 45840
Phone: 419.429.7637
Fax: 419.429.7641
CLIA ID NUMBER: 36D2132570 (CLIA Certificate of Waiver)

Hanco EMS LLC
417 Sixth Street
Findlay, OH 45840
Phone: 419.423.3838
Fax: 419.423.7524
CLIA ID NUMBER: 36D0678534 (CLIA Certificate of Waiver)

Infectious Disease and Travel Medicine
300 W. Wallace St., Suite A-5
Findlay, OH 45840
Phone: 419.420.0100
Fax: 567.429.0214
CLIA ID NUMBER: 36D2214017 (CLIA Certificate of Waiver)

(Leipsic) Putnam County Primary Care
901 E. Main St., Suite A
Leipsic, OH 45856
Phone: 419.943.2130
Fax: 419.943.2146
CLIA ID NUMBER: 36D0670121 (CLIA Certificate of Waiver)

McComb Family Practice
271 South Park Drive
McComb, OH 45858
Phone: 419.293.0601
Fax: 419.293.1912
CLIA ID NUMBER: 36D1002082 (CLIA Certificate of Waiver)

North Baltimore Medical Office- (Family Practice)
209 Brian Hill Road, Suite B
North Baltimore, OH 45872
Phone: 419.257.2992

Fax: 419.257.2112
CLIA ID NUMBER: 36D0916061 (CLIA Certificate of Waiver)

Pediatric Associates of Northwest Ohio
122 N. Jackson St.
Bluffton, OH 45817
Phone: 419-549-5865
Fax: 419-358-0471
CLIA ID NUMBER: 36D2087840 (CLIA Certificate of Waiver)

Physicians Plus Urgent Care Center
3949 North Main St., Suite A
Findlay, OH 45840
Phone: 419.423.3888
Fax: 419.423.4475
CLIA ID NUMBER: 36D0946906 (CLIA Certificate of Waiver)

Well at Work
3949 North Main St., Suite D
Findlay, OH 45840
Phone: 419.425.5121
Fax: 419.425.5738
CLIA ID NUMBER: 36D083467 (CLIA Certificate of Waiver)

Birchaven Health Care
15100 Birchaven Lane
Findlay, OH 45840
Phone: 419.424.3000
Fax: 419.425.3070
CLIA ID NUMBER: 36D0682814 (CLIA Certificate of Waiver)

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