INITIAL WAIVED PERSONNEL TRAINING CHECKLIST

Employee Name: _____ Training Start Date: _____

Lab/Staff Position: _____ Training End Date: _____

Trainer: Document completion by marking: "Date/Initials" in each box for each item the employee has successfully completed. Retain for the personnel file. If an item is not applicable, mark "NA" in each appropriate box

Test Method	**Urinalysis**	**INR**	**Influenza**	**Strep A**	**Phlebotomy**	**EKG**
Manufacturer	**McKesson 120**	**Coag-Sense**	**Binax**	**Binax**		
Read test procedure or methods operation manual	☐ Competent	☐ Competent	☐ Competent	☐ Competent	☐ Competent	☐ Competent
Understands and applies specimen collection and storage requirement for the test method	☐ Competent	☐ Competent	☐ Competent	☐ Competent	☐ Competent	☐ Competent
Appropriately applies manufacturers storage requirements for reagents and control materials employed in testing	☐ Competent	☐ Competent	☐ Competent	☐ Competent	☐ Competent	☐ Competent
Applies knowledge of the inventory control process to all test materials	☐ Competent	☐ Competent	☐ Competent	☐ Competent	☐ Competent	☐ Competent
Performs preventative maintenance, calibration, calibration verification, and quality control procedures for the test method as required by manufacturer	☐ Competent	☐ Competent	☐ Competent	☐ Competent	☐ Competent	☐ Competent
Performs, interprets, documents and accepts or rejects quality control as per instructions	☐ Competent	☐ Competent	☐ Competent	☐ Competent	☐ Competent	☐ Competent
Performs and documents appropriate corrective action as required by QC failure	☐ Competent	☐ Competent	☐ Competent	☐ Competent	☐ Competent	☐ Competent
Notifies appropriate personnel of QC failure that is unresolved with corrective actions	☐ Competent	☐ Competent	☐ Competent	☐ Competent	☐ Competent	☐ Competent
Seeks alternative test methods or delays reporting patient results if QC, calibration or maintenance fails	☐ Competent	☐ Competent	☐ Competent	☐ Competent	☐ Competent	☐ Competent
Verifies specimen identity and performs patient testing as per manufacturer instructions	☐ Competent	☐ Competent	☐ Competent	☐ Competent	☐ Competent	☐ Competent
Reports and verifies completeness and accuracy of patient testing	☐ Competent	☐ Competent	☐ Competent	☐ Competent	☐ Competent	☐ Competent
States and applies knowledge of factors that can affect patient results in test procedure	☐ Competent	☐ Competent	☐ Competent	☐ Competent	☐ Competent	☐ Competent
Verifies, follows physician notification policy, and documents all actions related to critical or questionable values.	☐ Competent	☐ Competent	☐ Competent	☐ Competent	☐ Competent	☐ Competent

This employee has been trained on the above test procedures and has been determined to be competent to perform all laboratory tests and procedures stated above.

Comments: _____

_____

Employee Signature: _____ Date: _____

Trainer Signature: _____ Date: _____

Lab Director: _____ Date: _____

JOB DESCRIPTION
LABORATORY STAFF MODERATE COMPLEXITY

SUMMARY

The laboratory staff is responsible for the performance of patient testing to be inclusive of pre-analytical, analytical, and post-analytical phases of testing. Each staff member must demonstrate minimum qualifications as set forth by CLIA'88 and outlined in "Education and Experience" section below. Established protocols and procedures are provided and will be followed by laboratory staff for insurance of safety and quality of patient care. The laboratory staff is under the supervision of the laboratory director. Laboratory staff will be trained at the time of hire, with each method change, when remediation is deemed necessary by evaluation and at other appropriate times. Competency evaluations shall be performed by the laboratory director or technical consultant as mandated by CLIA'88. All education, training and competency will be documented and recorded in a central location as designated by the laboratory director.

GENERAL DUTIES AND RESPONSIBILITIES

The laboratory staff will be responsible for

Pre-Analytic:

- Reading procedures and completing required training before performing any procedures or protocols
- Ensuring the confidentiality of patient information throughout all phases of laboratory testing. The privacy of each patient must be maintained by preventing any breeches of confidential information by visual, verbal or other means by unauthorized persons, including but not limited to other patients, visitors to the facility and any unauthorized party outside this facility
- Ensuring that all orders received by physicians are documented. If orders are received orally, they must be followed by a written (or electronic) record within 30 days
- Phlebotomy by venous or capillary technique, following proper protocol. Positive identification of the patient prior to collection and complete and proper labeling of the specimen following established protocol
- Receiving specimens collected by other persons (patient, physician, nurse) inclusive of ensuring that the specimens are fully labeled, collected in the proper containers and are sufficient quantity to perform testing. Ensuring that of these specimens are matched to a physician's orders
- Processing specimens for referral testing following established protocol. Ensuring that all essential information is submitted to the referral laboratory and that the specimens are packaged and stored as per reference laboratory protocol prior to courier pick-up or mailing.

Analytic:

- Ensuring that the procedure manual is complete and updated when necessary, inclusive of but not limited to changes in testing, procedures, instruments, and methodology. Any changes must be adopted by the Laboratory Director.
- Monitoring internal inventory control process inclusive of but not limited to:
  - maintaining an adequate supply of all reagents and consumables to perform quality testing
  - Maintain records of purchasing orders and receipts
  - Dating reagents and supplies upon receipt and at time of opening
  - Periodic monitoring of inventory for expiration dates
  - Discarding expired reagents and supplies and assuring that expired items are not employed for patient testing or specimen collection. Ordering replacement materials for expired or soon to expire items

- Performing and documenting on instrument log sheets or in LIS routine daily, weekly, monthly, and periodic maintenance and function checks following established manufacturer's and laboratory protocol.
- Performing calibration and calibration verification following established manufacturers and laboratory protocols. Notifying Lab Supervisor and/or Laboratory Director of failures. Holding patient testing until calibration or calibration verification can be performed with acceptable outcomes. Verification of calibration by performing Quality Control procedures before beginning patient testing. Documenting all failures and corrective action with printouts and on instrument logs or in LIS
- Performing Quality Control as required by the manufacturer and established protocols in laboratory policy. Inclusive of, but not limited to:
  - Following established protocols for quality control failures to include but not limited to repeating controls or troubleshooting problems
  - Documenting failures and corrective actions by entering electronically into LIS or logging manually
  - Reporting any unresolved failures to the Lab Supervisor and/or Laboratory Director
  - Holding patient testing until Quality Control problems are resolved
- Identifying problems that may adversely affect patient test results. Applying corrective action steps and/or notifying the Technical Consultant or Laboratory Director of issues. Documenting all discrepancies and corrective actions
- Performing Proficiency Testing and/or Split Sample analysis periodically as outlined in laboratory protocol. Retaining all test records and attestation sheets to demonstrate that proficiency testing samples are tested in the same manner as patient samples
- Retaining records of all analytic activities performed for a minimum of two (2) years. These records are inclusive of, but not limited to, inventory control, maintenance, calibration and verification, quality control, proficiency testing records, and instrument printouts.
- Periodically monitoring electronic storage for completeness

Post-Analytic:

- Reporting patient test results by either electronic transmission form interfaced instruments or by manual entry onto a report form. Verifying accuracy of test results prior to releasing reports.
- Verifying critical values by repeat analysis, if possible. Reporting critical values to the physician or specified nurse and recording reporting information action on the appropriate log or in the LIS
- Correcting detected reporting errors by following the established protocol. Retaining copies of erroneous and corrected reports for review.
- Performing all Quality Assessment activities assigned to this position and documenting these activities for periodic review by the Laboratory Supervisor and/or Laboratory Director. Retaining quality assessment records for a minimum of two years
- Recording details of complaints, incidents, or communication breakdowns. Forwarding records and appropriate documentation to the Lab Supervisor or Laboratory Director for review and corrective action documentation
- Retaining records, and providing for inspector review, all patient reports, errors, notifications, and corrective actions for a minimum of two (2) years.

EDUCATION AND EXPERIENCE

Laboratory Staff must possess a current license issued by the state, if required, and provide documentation of one of the following prior to analyzing patient specimens:

- Is a licensed D.O., M.D., or D.P.M. and possesses a current license to practice in this state, OR
- A Doctoral, Master's or Bachelors' degree in a chemical, physical, biologic or clinical laboratory science, OR
- A medical technology degree from an accredited institution, OR

- An associate degree in chemical, physical or biologic science, OR
- A high school diploma or equivalent and successfully completion of an official military medical laboratory procedures course and having held in the military occupation of Medical Laboratory Specialist, OR
- A high school diploma or equivalent AND documentation of training for skills necessary to perform laboratory testing duties in this facility

ACKNOWLEDGEMENT

Each employee must read and sign that she/he understands this job description and agrees to adhere to all requirements commensurate with employee role in the laboratory setting, with documentation of training for all tasks assigned.

Signature of Employee: _____ Date: _____

Signature of Laboratory Director: _____ Date: _____