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**Clinical Laboratory Standard Operating Procedure**

**(SOP)**

**2020 Revision**

**STANDARD OPERATING PROCEDURES**

Initial Date: March 2019

Revised By: Dr. Martin A. Mangan

Reviewed by Keri Martin PA-C Technical/Clinical Consultant

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**CLIA Certification**

## Ridgeline Medical CLIA Certificate -- Number – 13D2162278

**Proficiency Program (*College of American Pathologists CAP*)**

Phone: 800-323-4040

Web Address: [www.cap.org](http://www.cap.org)

## 

## Scope of Service

There is currently only one moderate complex lab performed at Ridgeline Medical Clinical Laboratory**.** The space and facilities in the laboratory are adequate for the extent of testing performed.

## Categories of Testing Performed

1. Ridgeline Medical Performs following waived tests: Waived testing meets the Clinical Laboratory Improvement Amendments of 1988 (CLIA)

* Urine Dip stick
* Urine Pregnancy
* Strep A Antigen
* Rapid Influenza A/B
* Rapid RSV
* Capillary blood glucose
* Piccolo Xpress Chemistry Analyzer (lipid profile and comprehensive metabolic profile).
* HgA1c
* FREND NanoEnTek (TSH, Free T4, PSA, Vit D, Testosterone)
* Abbot ID Now – Have not received machine
* PT/INR Mckesson
* Sed Rate

1. One moderate Complexity Procedure, (CBC), is done at Ridgeline Medical CBC testing meets the Clinical Laboratory Improvement Amendments of 1988 (CLIA)
2. All tests requested that are not performed in-house are referred to Express Laboratory or Quest laboratories or another approved reference laboratory.

## Policy Statement

It shall be the policy of the Ridgeline Medical Clinical Laboratory that Waived Testing meets regulatory and professional standards.

## Policy Purpose

The purpose of this policy is to establish and disseminate the standards, methods and responsibilities for Ridgeline Medical Clinical Laboratory to ensure that laboratory testing meets regulatory and professional standards.

## Definitions

1. CLIA ’88: Clinical Laboratory Improvement Amendments (federal law enacted in 1967 and amended in 1988).
2. Competency testing: Evaluation of person’s ability to perform the steps of a testing procedure.
3. Waived tests: POCT that is simple to perform with little potential for erroneous results to cause patient harm.

**Moderate Complexity Testing**:

1. Proficiency Testing: An external program in which blind samples are periodically received from an external agency and processed as patient samples by the usual testing personnel, these results are evaluated by comparison with those of other sites.
2. Quality Control (QC): A set of procedures designed to monitor the accuracy and precision of the test. The term refers to samples of known concentration that are periodically tested like a patient sample in order to validate continued accuracy.

## POLICY STANDARDS

1. The intent of this policy is to provide guidelines to ensure the reliability of testing performed at the Ridgeline Medical Clinical Laboratory meet the regulatory standards.

* The Medical Director & Technical Consultant in accordance with regulatory guidelines establishes policies and procedures that define the context in which test results are used in patient care, treatment and service.
* Confirmatory testing is performed for waived test in accordance with the SOP or Manufacturers Package inserts.

1. Staff must demonstrate competency when performing in-house tests in accordance with CLIA standards, under the supervision of the Technical Laboratory Consultant and the Medical Director.
2. All waived tests at the Ridgeline Medical Clinical Laboratory are used for screening purposes
3. In -house Testing Approval Process

* All tests performed under this policy are reviewed and approved by the Technical Laboratory Consultant and Medical Laboratory Director
* Approved tests conforming to this policy are included under Ridgeline Medical Clinical Laboratory CLIA Certificate

1. Training and Competency Assessment

* Testing personnel are trained in the performance of in- house testing.
* The Technical Laboratory Consultant orients and provides specific training to staff that perform in-house testing.
* Training is documented.
* Staff is assessed at defined intervals to show current competence in the specific waived test that they perform.
* Competency assessment takes into consideration the frequency that testing personnel perform tests, their technical backgrounds, complexity of the test methodology and the consequences of an inaccurate result.
* The following methods are approved to be used to assess the competency of testing personnel:
  + Participation in the proficiency testing program – performing a test on an unknown specimen
  + Technical Consultant periodically observes the performance of In-house Tests
  + Technical Consultant or Staff Supervisor monitors the quality control log
* Documentation of competency testing and any required remedial action is maintained on all testing personnel.

## Reference Laboratory Policy

**Purpose**: To state the guidelines for selecting a reference Laboratory

**Policy**: Leaders, the Medical Director as well as lab personnel shall be involved in the selection of a lab for the referral of specimen not performed in house. The ultimate selection of the reference laboratory shall be the responsibility of the Laboratory Director.

* All reference specimens shall be sent to a CLIA approved reference laboratory.
* The Laboratory Director shall ensure that the performance of the reference lab is acceptable.

## Purpose/Use of In-House Waived and Moderate Complexity Testing

**Purpose:**

To state the purpose for which in house test results are used.

## Policy: Waived test are performed for the purpose of clinical diagnosis and screening. There are times confirmation of a test is required. An example may be in the case when a urine dip test is negative but the symptoms indicate a person has an infection.

## Laboratory Personnel

**Laboratory Director**—Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytical, analytic, and post analytic phases of testing. Provide a safe environment in which employees are protected from physical, chemical and biological hazards. Ensure that the methodologies selected have the capability of providing the quality of results required for patient care. Verify the procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and that laboratory personnel are performing he test methods as required for accurate and reliable results.

Ensure the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed and that the proficiency testing (PT) samples are tested following the CLIA standards. The PT results are returned within the timeframes established by the proficiency testing program. All PT reports received are reviewed by the appropriate staff to evaluate the laboratory’s performance and to identify any problems that require corrective action. Ensure that there is an approved corrective action plan to follow when any PT results are found to be unacceptable or unsatisfactory. Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of the laboratory services provided and identify failures in quality as they occur. Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system. Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory’s established performance specifications are identified, and that patient test results are reported only when the system is function properly. Ensure that reports of test results include pertinent information required for interpretation. consultation is available to their laboratory’s clients on matters relating to the quality of the test results reported and their interpretation concerning specific patient conditions. Employ sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results. Ensure that testing personnel, prior to testing, have the appropriate education and experience, receive the appropriate training for the complexity of the laboratory, and can perform all testing operations reliably and report accurate results. Ensure that policies and procedures are established for monitoring individuals who conduct all phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and be able to identify needs for remedial training or continuing education to improve skills. Ensure the procedure manual is available to all personnel responsible for any aspect of the testing process. And specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of preanalytical, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results.

**Technical Consultant (TC)**—is responsible for technical and scientific oversight of the laboratory. The technical consultant is not required to be onsite at all times testing is performed; however, he or she must be available to the laboratory on an as needed basis to provide consultation. The TC must be accessible by telephone or electronically.

Is responsible for test methodology appropriate for the clinical use of the test results. Must ensure verification for the test procedures performed and the establishment of the laboratories’ test performance characteristics, including the precision and accuracy of each test and test system.

Establish a quality control program appropriate for the testing performed and establish the parameters for acceptable levels of analytic performance and ensure the these levels are maintained through the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of the test results. Resolving technical problems and ensuring that remedial actions are taken whenever the test systems deviate from the laboratory’s performance specifications.

Ensuring that patient test results are not reported until all corrective actions have been taken and the test system is functioning properly. Identify training needs and assure that each individual performing tests receives regular in-service training and education appropriate for moderate complex laboratory services performed.

Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately, and proficiently. The procedures for evaluation of the competency of the staff will include:

Direct observations of routine patient test performance including preparation, specimen handling, processing and testing; monitoring the recording and reporting of test results; review of test results worksheets, quality control records, proficiency testing results and preventive maintenance records; direct observation of performance of instrument maintenance and function checks; assessment of test performance through external proficiency testing samples; and assessment of problem solving skills. Evaluate and document the performance of individuals’ responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. Thereafter, evaluations must be performed at least annually unless test methodology or instrumentation changes occur.

**Clinical Consultant—**Provides consultation regarding the appropriateness of the testing ordered and interpretation of test results. The clinical consultant must be available to provide clinical consultation to the laboratory’s clients; be available to assist the laboratory’s clients in ensuring that appropriate tests are ordered to meet the clinical expectations; ensure that reports of test results include pertinent information required for specific patient interpretation; and ensure that consultation is available and communicated to the laboratory’s clients on matters related to the quality of the test results reported and their interpretation concerning specific patient conditions.

**Testing Personnel—**Must have at least earned a high school diploma or equivalent; and have documentation of training appropriate for the testing performed prior to analyzing patient specimens.

Training must ensure that the individual is able to:

1. Properly collect, prepare, label/process, and handle patient specimens
2. Implement all standard laboratory procedures
3. Perform each test method and operate instruments
4. Perform preventive maintenance, troubleshoot, and calibrate when necessary
5. Have a working knowledge of reagent stability and storage
6. Implement quality control policies and procedures of the laboratory
7. Be aware of factors that influence test results
8. Assess and verify the validity of patient test results through the evaluation of quality control sample values prior to reporting patient test results

Testing personnel are responsible for: Specimen processing, test performance, and reporting test results. Each individual must follow the laboratory’s procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results; Testing proficiency testing samples in the same manner as patient samples; following the laboratory’s quality control policies, and document control activities, instrument and procedural calibration and maintenance performed; Following the laboratory’s established corrective action policies and procedures whenever test systems are not with the laboratory’s established acceptable level of performance; Identifying problems that may adversely affect test performance or reporting of test results and either must correct the problems or immediately notify the technical consultant, clinical consultant, or director; Documenting all corrective actions taken when test systems deviate from the laboratory’s established performance specifications.

In addition, at Ridgeline Medical Clinical Laboratory the moderate complex machine must have at least one lead testing person. The lead will be responsible for the overall operation of the laboratory. Responsibilities will include: ensuring calibration procedures are done at the appropriate times; ensuring controls are being run and are within range before test results are reported; printing and maintaining control records for two years; ensuring logs are being used and are maintained for two years; ensuring that proficiency testing is run samples are tested in the same manner as patients and that all testing personnel have an opportunity to run proficiency samples; and maintaining laboratory supplies.

**WAIVED TESTING**

**PURPOSE:** To state the guidelines for performing laboratory tests procedures.

**POLICY:**

1. Test shall only be performed when requested (written order) by a provider. Staff authorized to order test include physicians, Physician assistants and Licensed Nurse Practitioners. Orders shall be entered into the EMR or written on a lab request form. Laboratory test orders are complete and include the following: Patient’s first and last name - Patient’s sex - Patient’s age or date of birth provider requesting the test, Name of the test(s) ordered - Any special handling required - Date and, when pertinent to the test being ordered, time the specimen was collected.
2. Test shall be performed on appropriate specimen
3. Tester shall ensure that a properly labeled specimen is submitted for testing.
4. Tester shall adhere to manufactures instructions for performing quality control, testing, and reporting results.

## PROCEDURE:

1. Ensure a correctly label specimen has been submitted for the requested test.
2. Cleanse hands and put on gloves.
3. Ensure that recommended Quality Control has been performed, documented and is within acceptable range
4. Perform test according to manufacturer’s package insert or written procedure.
5. Record results accurately, follow test-reporting protocol.
6. Properly dispose of hazardous waste.
7. Remove gloves and cleanse hands
8. Ensure results are transmitted through Relay Med LIS to EMR.
9. Match lab results in patients’ chart in Health Fusion, and maintain copy of results in Relay Med.

**Orientation Outline for Waived Testing**

Purpose: To provide orientation guidelines for Ridgeline Medical Clinical Laboratory employees working in the Clinical Laboratory Department.

* Reading and signing of departmental manual
* Short in-service
* Instruction and demonstrations by manager or designee
* Written materials
* Check off list where applicable

## List of guidelines

1. Standard Operating Policy and Procedure Manual
   * Quality control
   * Panic value
   * Instrument maintenance
   * Specimen rejection/unacceptable
   * Proficiency testing
   * Reagent labeling and storage
   * Specimen collection and storage
   * Specimen referral
2. Use of Relay Med LIS
   * QC log
   * Panic Value log
   * Maintenance log
   * Instrumentation maintenance log

Upon completion of employee’s probationary period, a competency assessment will be performed in all areas he/she is trained for.

## Orientation Outline for pocH-100t

**Purpose:** To provide orientation guidelines for Ridgeline Medical Clinical Laboratory employees working in the Clinical Laboratory Department.

**Policy:** Departmental orientation shall be performed during the employee’s probationary period (which is 90 days). Departmental in-service consists of the following methods:

* Reading and signing of departmental manual
* Short in-service during morning “huddle”
* Instruction and demonstrations by manager or designee
* Written materials
* Check off list where applicable

## List of guidelines

1. Standard Operating Policy and Procedure Manual
   * + - Instrument Overview-System Components
       - Analyzer overview
       - Calibration verification
       - Modes of operation
       - Quality control
       - Reagents and reagent system
       - Maintenance -daily, biweekly, quarterly, as needed
2. Use of forms

## General Quality Control policy

**Purpose**: To state the guidelines for ensuring quality results are consistently obtained. P**olicy**:

* All quality control material shall be stored according to manufacturer’s instructions.
* The laboratory shall implement and maintain a quality control plan based on test current regulatory guidelines, test usage, reagent stability, and manufacturer’s recommendations.
* All testing shall at minimum follow manufacturers guidelines for performing quality control checks.
* When Ridgeline Medical Clinical Laboratory’s Quality Control Protocol for quality control checks exceed the manufacturers guidelines; testing personnel shall follow Ridgeline Medical Clinical Laboratory Quality Control Protocol
* Testing personnel shall note the internal control line when performing a waived test. If the internal control line is not present than the test shall be reported as invalid.
* Corrective actions shall be taken and documented for all out of range QC results as applicable

**INFECTION CONTROL**

## Universal/Standard and Respiratory Transmission Precautions

The use of Universal Precautions/Standard Precautions shall be implemented to reduce the risk of transmission of both recognized and unrecognized sources of infection. Standard precautions apply to:

1. Blood
2. All body fluids, secretions, (except sweat) regardless of whether or not they contain visible blood.
3. Non- intact skin
4. Mucous membranes

Policies and procedures for standard precautions are located in Ridgeline Medical Clinical Laboratory

## DECONTAMINATION OF ENVIRONMENTAL SURFACES

**Purpose:** To state the guidelines for effective Environmental Decontaminations

## Policy:

Staff decontaminating surfaces such as counter tops, exam tables and floors shall use the following guidelines for decontamination:

1. A 10% solution of bleach solution for decontamination in the laboratory.
2. A 10% bleach solution shall be used for decontaminating in all patient areas in the Clinical Laboratory.
3. When mopping floors 10% bleach shall be used to decontaminate.

**STORAGE OF REAGENTS AND SUPPLIES**

**Purpose**: To outline the procedure for storing immunizations/medications or reagents requiring refrigeration or freezing.

**Policy:** When storing immunizations/medications, reagent or other supplies requiring refrigeration or freezing:

**Procedure**:

* 1. Store at temperature recommended by vendor/manufacturer or regulatory standard.
  2. Perform temperature checks daily and document; if the temperature is not within the acceptable range:
  3. Notify Medical Director/Nursing Manager, and document the problem in appropriate logbook
  4. Remove immunizations/medication, reagents and or other items and place in another refrigerator. If there is no other refrigerator available temporarily place contents of refrigerator/freezer in an ice chest/igloo along with ice packs, until the refrigerator/freezer is repaired. Ensure that the temperature of the ice chest is within the acceptable range.
  5. If the refrigerator/freezer is found to be malfunctioning, the Nurse Manager/RN will place a work order for repair.

## Procedure to Follow During Power Outages

If there is a power outage/power disruption, the Department Director/Nurse Manager/RN will ascertain if the power outage will be for a prolonged period of time. If the power is to be off for an extended period of time, Nursing service/Laboratory Employees at Ridgeline Medical Clinical Laboratory will place the contents of refrigerator/freezer in an ice chest/igloo along with ice packs, until the power is restored and the refrigerator/freezer temperature is within the acceptable range. After the acceptable temperature is reached; contents will be placed back in the refrigerator/freezer. If unable to restore power within 6-8 hours immunizations, medication and reagents requiring refrigeration will be taken to a working refrigerator.

**STORAGE OF SUPPLIES**

**Purpose:** To state the guidelines for storing supplies

**Policy:** Ridgeline Medical Clinical Laboratory shall follow the following guidelines for storing supplies:

1. Inspect supplies prior to storing and to ensure that the package is not torn and is free from, dampness, dried watermarks, excessive dirt or dust and the expiration date has not been reached. If any of these conditions exist the supplies will not be accepted, they will be returned to the vendor.
2. Supplies should be stored in a cabinet/closet free of dust and moisture.
3. Supplies should be dated with received date.
4. Sterile supplies should be separated from non-sterile supplies by a functional barrier such as a drawer or bin.
5. Supplies shall be monitored/inventoried monthly to ensure the availability of par levels and to detect and remove any expired reagents, medications and supplies.

**Storage of Laboratory Specimen, Reagents and Controls Purpose**: To outline the procedure to follow for storing Laboratory specimens.

**Policy:** All specimens will be stored in accordance with protocol as stated in the specimen collection manual.

## Procedure:

* 1. Specimens, reagents and Controls that require refrigeration are stored at temperatures of 20C – 80C.
     1. Temperature checks are performed and recorded on each day that the lab is open.
     2. If the temperature is not within the expected/acceptable range:
     + Immediately notify the RN/Nurse Manager and document problem in appropriate logbook.
     + Remove specimens, reagents and controls and place in another refrigerator.
     + If the problem is related to power disruption/outage and there is no other working refrigerator, remove the specimens, reagents and controls from the refrigerator and place in an igloo/ice chest along with ice packs. Ensure that the temperature of the igloo/ice chest is within 20C – 80C.
     + When the problem has been rectified and the temperature of the refrigerator is within the acceptable range, place specimens, reagents and controls back in the refrigerator and document corrective action(s).
  2. Ambient room temperature shall be monitored to ensure that reagents/supplies room temperature storage criteria are met. Ambient temperature in the laboratory shall be maintained between 700 F- 790F.
  3. In order to allow for repeat analysis /and or correction or results for tests that have been performed in-house specimens will be held for the following time intervals after completion of all tests:
  4. urine for dipstick testing - discarded at the end of the day or after the patient has been dismissed.
  5. blood for CBC will be discarded at the end of the day shift.
  6. Proficiency samples – refrigerated and held until results of proficiency tests are received and reviewed.

## Reagent Recall

**Purpose:**

To state the procedure for ensuring that unsafe reagents/supplies are not used in patient testing/performing patient care services.

## Policy:

All Ridgeline Medical Clinical Laboratory staff shall adhere to the following:

Upon receiving a recall notification the departmental leader/designee shall:

* + - Reagents/supplies

1. immediately check department’s inventory
2. remove recalled reagent/supplies from inventory
3. document/record reagents/supplies that were recalled (include lot numbers) ; maintain record
4. return recalled reagents/supplies to the vendor/company
5. make a report to the, Medical director, Nursing Manager, and Clinical Laboratory Director
6. replenish reagents/supplies

Critical Programs shall be backed-up using an external device i.e., diskette, CD, or flash drive.

Function Checks shall be made to ensure the accuracy of electronic data

Staff passwords shall be deleted immediately when staff resigns of is terminated.

## Internal QC/Procedural Control & External QC for Waived Tests

**Purpose**: To state the guidelines for internal/Procedural controls and External/Liquid Controls for waived tests and moderate complexity testing.

* **Policy**: The laboratory shall perform quality control testing to monitor the accuracy and precision of its testing processes
* Laboratory personnel will perform and document procedural controls and external liquid controls for Siemens Clinitek Urine, Streptococcus, Influenza, RSV antigen, FREND, Siemens HgA1c and Piccolo as follows:

1. Perform and document external liquid controls as follows:

* Laboratory performs quality control testing in the same manner as it performs patient testing according to manufacturer’s instructions
* Monthly (Piccolo only)
* When a new kit is opened
* When there is a lot # change for a reagent or kit
* When the internal/procedural control does not have the expected results (problem with methodology)
  + - Laboratory will perform quality control for moderate complexity testing (in accordance with regulatory standards)
    - Each day of testing every 8 hours, the laboratory shall verify in house CBC test parameters against known standards and controls or controls within the range of clinically significant values
    - The laboratory shall verify test methodology/instruments
    - The laboratory shall perform calibration and re calibration
    - The laboratory shall perform calibration verification
    - The laboratory shall establish its own QC ranges with valid statistical measurements for each procedure

1. Internal/procedural controls are a part of the test kit, therefore, the internal control will be observed.
2. Documentation will be maintained of all quality control testing, documentation shall include: QC test results; kit lot #s; expiration dates and testers initials.

## Package Inserts for QC Control Limits

**Purpose**: To state the guidelines for using package inserts as references for control limits.

**Policy**: Laboratory personnel will keep the package inserts containing the control limits in the QC Log Book. The package insert will be removed and replaced with the new package insert each time the lot number of the control changes. The technical consultant/designee will monitor for compliance when performing monthly QC review.

**PERFORMANCE IMPROVEMENT (/PI)/QUALITY ASSURANCE (QA)**

**Purpose**:

To state the guidelines for lab’s participation in the Centers Quality Assurance/Performance Improvement Program

## Policy:

Laboratory shall participate in the Center’s Quality Assurance/Performance Improvement Program

* laboratory shall monitor pre analytical, analytical and post analytical aspects of testing
* laboratory has a procedure for patient & specimen identification
* laboratory establishes procedures for collecting specimen
* laboratory performs test based upon written test orders/request
* laboratory has a system for identifying person that performed test
* laboratory has a system reviewing test results and detecting clerical errors
* the laboratory conducts surveillance of test results
* laboratory report is complete and is in the patient’s chart
* laboratory retains records in accordance to the law
* laboratory implements a system of standardized abbreviations
* laboratory monitors ambient temperature and temperatures of storage devices
* laboratory has a reagent receipt, storage and inventory policy
* laboratory implements a standardized approach to hands –off communications
* laboratory collects, compiles and analyzes data to monitor its performance

## 

## Patient/Specimen Identification

**PURPOSE:** To state the guidelines for correct/ properly patient and specimen Identification.

**POLICY:** Laboratory staff shall adhere to correct patient and specimen identification at all times.

## PROCEDURE:

1. Greet the patient, use the following two forms of identifiers to correctly identifying a patient before any services are performed for the patient:

* ask the patient to state his/her name
* ask patient to state his/her date of birth

1. If applicable, check this information given by patient or his/her representative with information on request form/ lab paperwork:

* If the information match; proceed to step # 4
* If there is a discrepancy, the discrepancy must be resolved before the specimen is collected

1. Collect the specimen:

* Affix a label or write the patient’s name and order ID on the specimen before the patient is dismissed.
* Write the date and time and collector’s initials on the label
* label must remain on the specimen for the duration in the laboratory
* All aliquots must have a patient identifier.

## SPECIMEN COLLECTION

## Venipuncture Procedure

**Purpose:**

To state to procedure for the proper collection of a specimen by venipuncture.

**Policy:** Staff shall adhere to the procedure as outlined below when collecting specimens by venipuncture.

## Procedure:

1. Correctly identify patient.
2. Identify ordered test(s)
3. Verify diet/drug restrictions/fasting needs etc.
4. Cleanse hands
5. Put on gloves
6. Assemble supplies and inspect equipment.
7. Reassure patient.
8. Position the patient.
9. Verify paperwork and tubes.
10. Perform venipuncture.
11. Fill the proper tubes.
12. Bandage patient’s arm/venipuncture site.
13. Dispose of sharps in proper container.
14. Correctly label specimen(s).
15. Remove gloves and cleanse hands

## Positioning of Patient:

1. The position of the patient is critical in proper blood collection.
2. The patient must be seated or in a reclined position before any attempt is made to draw blood.
3. DO NOT allow patient to sit on a tall stool or stand while drawing blood.
4. There is always the possibility patients will faint (syncope) and injure themselves; therefore, have patients lie down whenever they indicate they are apprehensive or have fainted in the past while having their blood drawn (Use Exam Room, if patient has to lie down).

## Selection of appropriate venipuncture site:

1. The site to check first is the Upper region of the Arm.
2. The Primary Vein used in the upper arm is the Median Cubital Vein, usually the prominent vein in the middle of the bend of the arm.
3. The Basilic, Cephalic or Median veins can be used as a second alternative. (These veins may not be accessible or may not be prominent enough to obtain a blood sample).
4. The next step is to go to the Back of the Hand to obtain venous access.
5. The veins in the back of the hand have the tendency to roll more than the arm veins because they are not supported by as much tissue and are near the surface.
6. To avoid this, hold the Vein in place with your Index Finger and Thumb while you use a smaller gauge needle or a butterfly.
7. The Wrist veins are also an alternative but generally are much more painful than the other sites.
8. The Foot and Ankle veins may also be used. (The patients’ Physician must give permission to use them).
9. These veins are often restricted because the Physician is concerned about clots forming in the legs.
10. The order for checking for the best available site is 1) Upper Arm, 2) Hand 3) Wrist, and
11. 4) Ankle or Foot. The patients’ condition dictates the site to use.
12. Sites that should be avoided are:
    1. Edematous Arms (swollen because of fluid in tissue)
    2. Arms in casts
    3. Extensive Scarring such as burns, hematomas or the arm on the side of a mastectomy.
13. These veins will not be prominent and the tourniquet will be ineffective due to the swelling.
14. Placement of the Tourniquet has the potential for tissue damage and leaves a temporary indentation in the arm.
15. Areas of Scarring are also to be avoided because of possible injury to the patient or excessive pain.
16. Specimens collected from a hematoma area may cause erroneous test results. If another vein site is not available, the specimen is collected Distal from the Hematoma.
17. ecause of the potential for harm to the patient due to lymphocytosis, the Arm on the side of the Mastectomy should be avoided. If the patient has had a double Mastectomy, a Physician should be consulted prior to drawing the blood.

## 

## VENIPUNCTURE TECHNIQUES USING THE VACUTAINER SYSTEM

**Single Sample Collection Technique**

1. Open the needle package but Do Not Remove the needle shield. Thread the needle into the h older until secure.
2. Select the tube appropriate for the sample desired. In case of doubt, consult the sections of the respective Laboratory for the exact specimen requirements.
3. Gently tap the tubes, which contain additives to dislodge the additives trapped around the stopper.
4. Insert the tube into the holder. Push the tube stopper to meet the guidelines on the holder. The tube will retract slightly. Leave tube in this position.
5. Select the site for venipuncture by pa1pation.
6. Apply the tourniquet. Swab the venipuncture site with 70% alcohol. DO NOT palpate the venipuncture site after cleansing.
7. Place the patient’s arm in a downward position.
8. Remove the needle shield. Perform the venipuncture with the arm in a downward position and the tube in a vertical position, stopper uppermost.
9. Push the tube to the end of the holder, puncturing the diaphragm of the stopper.
10. Remove the tourniquet as soon as blood begins to fill the tube. DO NOT allow the contents of the tube to contact the stopper or the end of the needle during the procedure. This may result in backflow from the tube to the patient.
11. If at this point there is no blood flow into the tube or if blood flow ceases before an adequate sample is achieved, the following steps are suggested. Each successive step should be taken until flow into the tube occurs:
    1. Confirm the correct positioning of the needle cannula in the vein.
    2. Remove the tube and fully insert a new tube into the holder. If you are using a single sample needle, this step may result in leakage of blood.
    3. Remove the tourniquet and complete assembly; discard the needle and repeat the procedure starting with Step 1.
       1. When the blood flow ceases, immediately remove the needle from the vein and apply pressure with dry sterile gauze. Keeping the sterile gauze firmly in place until bleeding ceases.
       2. Remove the tube from the holder. It is normal for the tube not to be completely filled.
       3. If the tube contains an additive, gently invert 6 to 8 times to mix the additive thoroughly with the blood. DO NOT Shake. Vigorous mixing could cause hemolysis.
       4. Apply a bandage, if required.

## Multiple Sample Collection Technique:

1. Follow Steps 1 through 10 as described in the subsection entitled “Single Sample Collection Technique”.
2. In collecting multiple samples, attention should be given to the order in which the tubes are filled.

## 

## ORDER OF DRAW

Blood collection tubes must be drawn in a specific order to avoid cross-contamination of additives between tubes. The recommended order of draw for plastic vacutainer tubes is:

1. First - blood culture bottle or tube (yellow or yellow-black top)
2. Second - coagulation tube (light blue top). If just a routine coagulation assay is the only test ordered, then a single light blue top tube may be drawn. If there is a concern regarding contamination by tissue fluids or thromboplastins, then one may draw a non- additive tube first, and then the light blue top tube.
3. Third - non-additive tube (red top)
4. Last draw - additive tubes in this order:

* SST (red-gray or gold top). Contains a gel separator and clot activator.
* Sodium heparin (dark green top)
* PST (light green top). Contains lithium heparin anticoagulant and a gel separator.
* EDTA (lavender top)
* ACDA or ACDB (pale yellow top). Contains acid citrate dextrose.
* Oxalate/fluoride (light gray top)

**NOTE:** Tubes with additives must be thoroughly mixed. Erroneous test results may be obtained when the blood is not thoroughly mixed.

1. When the vacuum the first tube is exhausted and blood flow ceases, immediately remove the tube from the holder.
2. Place the second tube in the holder. Puncture the diaphragm of the stopper and withdraw another sample. Follow the recommended order of draw (Red, Blue, Green, Lavender, Gray top tubes and others).
3. While blood is flowing into succeeding tubes, gently invert the previously filled tubes containing additives 6 to 8 times to mix the additives with the blood. DO NOT Shake. Vigorous mixing could cause hemolysis.
4. As soon as the blood stops flowing into the tube of the last sample to be drawn, remove the needle from the vein and apply pressure to the puncture site with dry sterile gauze keeping the gauze ball firmly in place until bleeding ceases.
5. Apply a bandage, if required.

## Failed Venipuncture

1. First, change position of needle. The bevel may be against the wall of the vein.
2. Tube may not have sufficient vacuum. Try another tube.
3. Tourniquet may be too tight, stopping the flow of blood.
4. Re-apply tourniquet loosely.
5. If a blood sample cannot be obtained within 2 attempts, have another phlebotomist attempt to draw.
6. If a second phlebotomist fails, notify the patient’s Physician for a referral to one of the area hospitals or to re-schedule for another day.

## SKIN PUNCTURE

1. Assemble supplies and equipment
2. Greet & identify the patient
3. Position patientin the drawing chair and
   1. Cleanse hands
   2. Put on gloves
   3. Select the site - Puncture is usually made on the 3rd or 4th finger of either hand.
   4. Always stick across the fingerprints.
4. Clean site thoroughly with 70% alcohol preps
5. Puncture site with one deliberate in and out action.
6. Wipe off first drop of blood to prevent any dilution of tissue fluid.
7. Allow blood to flow freely.
8. After collecting specimen, wipe area with alcohol pad and apply bandage
9. Label specimens
10. Remove gloves
11. Cleanse hands

## Specimen Collection Instructions

\*Consult the Quest Specimen Collection Manual or Quest website for correct specimen for requested test and for handling and processing procedures.

FASTING STATE OF THE PATIENT

A 10-12 Hour Fasting state is recommended for Cholesterol, Triglycerides. After eating, glucose and triglycerides are elevated. In addition, lipemia caused by a transient rise in chylomicrons following a meal containing fat, causes interference in many tests.

SPECIMEN TRANSPORT

Certain specimens require special attention when transporting them to the Laboratory, e.g., refer to the Quest Manual or website for special transportation instructions.

SPECIMEN PRESERVATION

The individual handling of Samples will depend on the analysis that is performed. Serum may either remain at room temperature or be refrigerated. Some analytes are photosensitive, i.e. bilirubin, urobilinogen, must be protected from the light to maintain sample quality. Many chemical determinations are affected by glycolysis; therefore, serum or plasma should be removed from the clot or cells soon after collection.

**Specimen Transport**

1. Place specimen in main section of biohazard specimen bag and seal
2. Place request form in the axillary section place request form in side

**Test Requisition**

**Purpose**: To outline the guidelines and procedure for performing requested tests.

**Policy:** Ridgeline Medical Clinical Laboratory Laboratory personnel will only perform test if there are wriitten/electronic/standard orders by an authorized provider

## Procedure:

1. Before performing test:

* Ensure that there are the written /electronic/standing orders by an authorized provider
* Ensure that the orders contain:
  + The name of the authorized physician requesting the test(s)
  + Patient’s name and unique identifier
  + Sex, age/DOB/ or S#
  + Test(s) to be performed
  + Date/Time of specimen collection where appropriate
  + Any additional; information relevant and necessary for a specific test
  + Ensure that private insurance patients & self-pay patients have requisition/request form stamped “paid”.

1. Incorrectly completed request will be rejected, and taken/returned to the requesting physician for correction before performing the test(s).

## 

## 

**SPECIMEN REJECTION POLICY**

The Lab Department will use the following criteria and take the following actions for specimens that are deemed unacceptable.

## 

|  |  |
| --- | --- |
| **Criteria for Rejection** | **Action** |
| Specimen not labeled or mislabeled | Specimen will be rejected and returned to collector, corrections or recollection. |
| Unsatisfactory specimen, wrong specimen | Specimen with be rejected and re-collected. |

## Prevention, Detection and Correction of Clerical Errors

**Purpose**: To outline the procedure to follow for the prevention, detection and correction of clerical errors

**Policy:** Laboratory personnel performing CBC tests and waived testing procedures will follow the procedure below to prevent, detect and correct clerical errors when reporting results.

## Procedure:

1. Take the following action for questionable results (results that exceed predefined limits):

* The testing personnel will repeat these results for verification before reporting.
* The testing personnel will immediately take/give these results to the requesting physician, and inform the physician that the results were repeated

1. Results from manual test procedures will be recorded on the test log/test request and/or entered into the EMR.

* Results will be compared to pre-defined limits; tests with abnormal results will be repeated/rechecked and immediately reported to the requesting provider.

1. Changes to results that have been seen by a provider are clearly identified as corrected results.

* If the reference laboratory corrects results to corrected results report is printed; this report is immediately given to the requesting provider.

**Calibration Verification Purpose**:

To ensure that the pocH-100i is Correctly calibrated.

**Policy:** Laboratory personnel will perform calibration verification each time a calibration is performed.

## Procedure:

1. Follow the procedure as outlined in the standard operating procedure manual
2. Compare the means to the means that is stated on the insert that is contained in the box with the calibrator:
   * + 1. If each parameter is within the + tolerance limits stated on the calibrator insert the calibration is correct.
       2. document calibration verification
3. If parameter(s) is/are not within tolerance limits re-calibrate, then do steps 1-2 again.
4. If parameter(s) is/are still not within tolerance limits, perform trouble shooting according to pocH-100i Standard Operating Procedure Manual (SOPM). Repeat calibration and calibration verification.
   * 1. If parameter(s) is/are still out of expected tolerance range, notify the Technical Consultant.
     2. Document problem in appropriate log book
     3. Send test to reference lab until problem is rectified.

**In- Run Precision**

**Purpose**: To outline the procedure to follow to ensure that in run precision is acceptable.

**Policy:** Laboratory personnel performing CBC testing procedures using the pocH-100i will periodically perform in-run precision testing.

## Procedure:

1. Run a normal patient replica ten (10) times in an empty replica file.
2. Compare the CV% to pocH-100i Procedure Manual.
3. If CV% is within the expected range in–run precision is acceptable.
4. If CV% is not within the acceptable range see trouble shooting guide, follow procedure as outlined until in line precision is within acceptable range.
5. If CV% is still not within tolerance limits notify the Supervisor.
   * + - 1. Document problem in appropriate log book
         2. Send test to reference lab until problem is rectified.

## Patient Report

**Purpose**:

To state the guidelines for reporting patient test results

## Policy:

Test result information will be maintained as part of the patient chart/medical record. The report will include:

The patient’s name and identification number

The name of the laboratory performing the test

Test report date

Result of test(s) performed

Specimen Source Where Applicable

Reference range and units of measure of requested test where applicable/pertinent

Name/identity of authorized physician requesting test

Identity of person performing the test(s)

1. Laboratory results for CBC will be generated by the pocH-100i and transmitted to Healthfusion by cloud based LIS Relay Med. Lab personnel performing the test will review the electronic results and match them to the patients order requisition generated by the provider.

* Report will be electronically submitted to the physician.
* Log panic/critical results and immediately take to the requesting physician
* Maintain a duplicate copy of the results.

1. Results for waived tests performed in the laboratory will be stored on the Cloud Based LIS Relay Med and individual Machines and electronically transmitted to Healthfusion and and results matched with the proper patient's chart and order requisition.

* give the report to the physician if the patient is still with the physician.
* Inform physician of abnormal results

1. Verbal Reports

* Before taking action on a verbal report of a test result, staff uses a record and "read back" process to verify the information

1. Lab reports from Express or Quest or any other facility will be electronically transmitted to Health Fusion EMR and individually matched with their proper order requisition.

## 

## Corrective Actions

**Purpose**: To state the guidelines for performing corrective actions

## Policy: To ensure accurate and reliable test results and reports, laboratory personnel will perform and document corrective actions when any of the following occurs:

1. Test systems do not meet the laboratory’s established performance specifications

* Equipment that perform outside of established parameters
* Methodologies whose performance is outside the specifications
* Proficiency testing results that are outside expected specifications

1. Control values are outside the expected range
2. The criteria for proper storage of reagents and specimen are not met
3. Errors in reporting patient test results

## Procedure:

1. Initiate and perform corrective action as specified by specific standard operating procedure manual, Instrument’s trouble shooting guidelines, laboratory policy/procedure.
2. Document using designated form.

* Errors in patient report test dataWhen errors in the reporting of patient test results are detected the laboratory will:

1. Promptly notify the physician ordering the test.
2. Issue a corrected report

* Use the corrective action form for any other corrections

## CLEANING/ DECONTAMINATING THE LAB

**Purpose:** To state the guidelines cleaning /decontaminating the lab

**Policy:** To prevent the spread of infections due to contamination; the Lab surfaces shall be cleaned/decontaminated daily

## PROCEDURE

1. Clean countertops/ environmental surfaces at the end of the working day of when a spill occurs/visual contamination is evident with one of the following:

* 10% bleach/commercial (the 10% bleach must be prepared daily. the date of preparation and the preparers initials must be on the label) or
* Use 10% bleach for cleaning biohazard spills.

1. All laboratory counter tops will be decontaminated daily, and when there is known or visual contamination with blood or body fluids using 10% bleach.
2. All instruments/equipment will be cleaned/decontaminated as outlined in the instrument’s/equipment’s Standard Operating Procedure Manual. Documentation will be made on the instrument’s/equipment’s PM Log.
3. Instrument(s)/equipment that have been in patient testing must be decontaminated as appropriate before being serviced/repaired. If decontamination of any part or module is impossible a biohazard warning must be affixed to the instrument.
4. Any equipment or instrument used in a procedure that must come in contact with any part of the patient’s body will be decontaminated as appropriate.
5. Tourniquets will be:

* Wiped periodically with an alcohol pad.
* Discarded when visually or knowingly contaminated with blood.

1. Needle holders will be disposed of after each draw.
2. Glucometers will be contaminated weekly with 10% bleach or when there is known or visual contamination.

## 

## Decontamination Agents

**Purpose**: To state the guidelines for effective decontamination in the laboratory

**Policy**: A 10% solution of bleach will be used as the decontaminating agent in the laboratory. The solution will be prepared weekly. The solution will be labeled with the appropriate hazard label, date of preparation, and initial of preparer.

## Procedure:

* + - 1. Prepare a 10 % solution of bleach as follows:

## Bleach Water

1ml 9ml

5ml 45ml

10 ml 90 ml

20 ml 180 ml

25ml 225 ml

50 ml 450 ml

100ml 900ml

* + - 1. Pour in appropriately labeled squirt/spray bottle
      2. Date and initial

\* The solution must be made up daily to be effective

**Hand Hygiene & Prevention of Nosocomial Infections**

**Purpose**: To state the guidelines for minimizing/preventing nosocomial infections using effective hand hygiene

**Policy**: Laboratory personnel will:

1. Follow all established Ridgeline Medical Laboratory safety and infection control policies and procedures as stated in the state OSHA plan.
2. Keep fingernails trimmed short to prevent tearing/puncturing gloves at fingertips
3. Frequently wash hands with an approved liquid antimicrobial soap or cleanse hands using an alcohol based hand rub gel

* Wash /cleanse hands before gloving and after de-gloving
* Before and after the care of a patient/collecting blood

**Hand Washing Procedure**:

1. Wet hands, and wrist, lather using vigorous friction, starting at the fingertips and work toward the forearm for at least 15 seconds
2. Dry the hands
3. Turn of the faucet with a paper towel and discard
4. Clean up any spills around the sink

## 

## Nail Hygiene

Health care personnel should keep natural nails less than one quarter of an inch long if they care for patients at high risk of acquiring infections (i.e., patients in intensive care units).

## Decontamination of Equipment Before Repair:

Equipment is to be decontaminated with a 10% solution of bleach before being sent for repairs. If decontamination is not feasible a Biohazard Label will be affixed.

**Housekeeping:**

* + Clean and decontaminate equipment, the environment and work surfaces daily and after contact with blood and body fluids. Use the disinfectant or germicide required by the Center. Use utility gloves, brushes, brooms, and dustpans to avoid contact with contaminated material.
  + Remove and replace red bag trash can liners daily if any regulated waste is noted. Place red bags in hard-sided, leak proof, closeable containers with biohazard label and place in secured area for the regulated waste removal process. If any red bag container
  + becomes contaminated by a tear or puncture in the red bag, decontaminate the container before placing in a red bag.
  + To clean up broken glass, use a broom and dustpan or scoop and paper towels. Use tongs or forceps to pick up glass particles, not hands. Dispose of the glass in a sharps container, not the red bag. Clean and mop the area with disinfectant.
  + Contaminated needles and sharps are to be discarded into impervious labeled biohazard sharps containers. The Sharps Container must be closed and sealed prior to disposal.

## Disinfectant – the following may be used for blood and body fluid spill cleanup:

* **Commercial Clorox /Bleach are approved for use at Ridgeline Medical Laboratory.**
  + All spills will be cleaned as soon as possible, using a 1:10 chlorine bleach solution. Clean up of blood and body fluid. Staff shall use gloves to avoid contact with contaminated material.
  + \*The Clorox/Bleach must be a 1:10 dilution and must be prepared fresh each 24 hours.
  + A 10% solution of bleach is used for decontamination. 10% v/v solution contains 10ml of solute per 100 ml of solution. Calculate the desired amount of bleach solution to be made using ratios & proportions:
  + Example: Calculate how much bleach is needed to make 250ml of a 10% solution of bleach as follows:

10ml bleach diluted to 100 ml with water 20 ml of bleach diluted to 200 ml with water 50 ml of bleach diluted to 500 ml with water 100 ml of bleach diluted to 1000 ml with water

The bleach solution should be placed in a squirt/spray container, labeled as “10% bleach”, and have the applicable hazard warning affixed. The label should also contain the date of preparation and the initial of the person that prepared it.

## Biohazard Spill Clean – Up:

**Procedure:**

1. The following PPE should be worn when cleaning a spill: gloves, apron.
2. Goggles/face shield should also be worn if there is a potential for splattering/splashing.
3. Place paper towels over the spill, and then use a squeeze bottle containing the approved decontaminating agent saturate the spill, working from the perimeter to the center.
4. Wait for (5) minutes to ensure that the spill has been decontaminated.
5. Pick- up the material and transfer to a biohazard bag. If there is any broken glass shards they are to be picked up with tweezers/hemostats and placed in the sharps container.
6. Wipe area with paper towels moistened with the bleach solution, place paper towels in the biohazard bag.
7. Clean the area with soap and water, place paper towels in the biohazard bag.
8. Secure bag by taping/tying.
9. Remove PPE and wash hands.

**Laboratory Accidents**

**Purpose:** To state the guidelines for dealing with lab accidents

## Policy: All Laboratory Personnel will document all Lab ACCIDENTS resulting in property damage, personal injuries, patients falls, or involving spillage of hazardous specimens or substances.

## PROCEDURE

1. When an accident occurs IMMEDIATELY Stop what you are doing
2. If injury occurs, Notify Provider and check-in with the front nurse.
3. If injury needs attention, get it.
4. Document the Incident and give to appropriate personnel.
5. When Spills or Breakage occur, clean according to Policy and Procedure, notify site Nurse Manager, or Medical Director.
6. If chemical spill (may need evacuation).
7. Document Spill incident and notify the Nurse Manager.
8. Dispose of infectious materials following Policy and Procedure Guidelines.
9. If patient falls, or is involved in any accident/incident notify, fill out an incident report and notify Site Manager,
10. If Blood is spilled on counter or draw-chair during or after phlebotomy, testing or processing clean IMMEDIATELY with 10% bleach.

**ELECTRICAL SAFETY**

* All Lab instruments should carry a certification mark such as U.L. (Underwriters Lab) or
* CSA (Canadian Standards Association)
* All outlets should be grounded
* There must be no frayed electrical cords
* All centrifuge must be placed and top closed before using
* Electrical safety checks are to be performed and documented annually.

**NOTE:** Cover all specimens that will be centrifuged to eliminate the possibility of contamination from airborne particles (aerosols).

## SPILLS

All spills must be cleaned up IMMEDIATELY using the spill kit or 10 %. bleach (See DIRECTIONS)

1. Secure the area where the spill occurred
2. Put on appropriate PPE
3. Disinfect area with 10% Clorox or another liquid disinfectant or germicidal cloth.
4. Place contents of spill and used cleaning materials in a red biohazard bag.
5. Seal bag, label and dispose of in compliance with Facility Waste and Disposal Policies.
6. Remove gloves and Promptly wash hands thoroughly with soap and water

NOTE: When antiseptic hand-cleaners or towelettes are used, hands should be washed with soap and running water AS SOON AS POSSIBLE.

**REGULATED WASTE**

Regulated waste includes liquids or semi-liquid blood or other potentially infectious materials, contaminated items that would release blood or other potentially infectious materials in a liquid or semi-liquid state if compressed, pathological and microbiological waste. Containing blood or other potentially infectious materials.

**REGULATED WASTE CONTAINERS**

Containers must be leak-proof, labeled with biohazard sticker or color-coded and closed prior to handling, storing, transporting or shipping.

## 

## SECONDARY CONTAINERS

Secondary containers must be provided in situations where the outside of the primary container becomes contaminated.

**NOTE:** Trash containers used to collect regulated waste must be “closable” and not necessarily covered during use.

The Exposure Control program at Ridgeline Medical Laboratory requires the use of the following engineering controls/PPE and work practices to limit the occupational exposure to bloodborne pathogens to employees:

## GLOVES

Gloves shall be worn when the employee has the potential for the hands to have direct skin contact with blood, other potentially infectious body fluids or material, mucous membranes, non- intact skin, and when handling items or surfaces soiled by blood or other potentially infectious materials.

## HANDWASHING

Employees shall wash their hands immediately or as soon after removal of gloves or other personal protective equipment and after hand contact with blood or other potentially infectious materials (See FLYER)

## FOOD, DRINKAND COSMETICS

Eating, drinking, applying cosmetics or lip balm, and handling contact lenses are prohibited in work areas where there is a potential for occupational exposure to bloodborne pathogens. Food and drink shall not be stored in refrigerators, freezers, shelves, and cabinets or on countertops or bench-tops where blood or other potentially infectious materials are present.

Refrigerators, freezers, bins, pails and other receptacles that contain blood or other potentially infectious material should also be marked with the international biohazard symbol.

## SHARPS

Used needles and other sharps shall not be sheared, bend, broken, recapped or re-sheathed by hand (except by approved methods such as re-sheathing devices, forceps, other mechanical means or approved one-handed methods). Used sharps shall be placed in approved sharps containers that are:

1. Closable
2. Puncture Resistant
3. Leak proof on the sides and bottom
4. Labeled or Color-Coded

## MASKING AND EYE PROTECTION

Face shields or masks shall be worn whenever performing a procedure where there is a potential for splashes, sprays, spatters, droplets or aerosols of blood or other potentially infectious materials to be generated.

**PROTECTIVE CLOTHING (PPE)**

Appropriate clothing such as, but not limited to, gowns, aprons, lab coats, clinical jackets or similar outer garments shall be worn in occupational exposure situations. The type and characteristics will depend upon the task and degree of exposure anticipated.

If the garment is penetrated by blood or other infectious materials, the garment shall be removed IMMEDIATELY or as soon as feasible. All personal protective equipment shall be removed prior to leaving the work area.

**Laboratory Equipment**

**Purpose:**

To state the guidelines for Procuring and Maintaining Laboratory Equipment

## Policy:

In order to ensure that all patient results are acquired using instruments/equipment that is reliable/in good working condition and are operated by competent employees the follow is done:

1. Current list of all laboratory equipment, along with the personnel that is competent to operate the equipment is maintained. This list is reviewed/updated annually.
2. PM/function checks are performed at set intervals and documented.

* The temperature of refrigerators and other temperature dependent equipment must be checked and recorded daily or on each day of use.
* Refrigerator maintenance must be scheduled periodically and documented.
* PM must be performed on the pocH as defined in the SOP.
* PM must be performed on the Piccolo Xpress as defined in the SOP
* Instructions for instrument checks must be available and checks must be documented.
* Instructions for minor trouble-shooting and repairs of equipment/instruments must be easily accessible. All repairs and service must be documented.

1. Equipment malfunctions are reported to the Nurse Manager/Technical Consultant. A repair request is made with the appropriate service department. The equipment will not be used until service has been completed and performance and safety standards met.
2. In the event of equipment failure the instrument/equipment will be **labeled “out of service/do not use”** until the instrument has been repaired and has been certified as accurate/precise by running controls. Testing will be referred to Quest until the instrument has been placed back in service by the Medical Director or designee.

**Needle Sticks/Sharps Punctures**

**Purpose**: To state the guidelines for reporting/documenting needle /sharps sticks.

## Policy: All accidental needle/sharps sticks must be immediately reported and documented.

* 1. All staff who are accidentally stuck with a stuck needle/sharp must follow the procedure as outlined in the EDMS.
  2. If a patient is accidentally stuck with a contaminated needle/sharp:
  3. immediately notify Front RN/Nurse Manager/Medical Director
  4. Check into a dispensary where you can be seen by a provider
  5. follow Ridgeline Medicine Laboratory incident reporting protocol

**Surveillance of Laboratory Reports**

Lab Personnel will retrieve all incoming Lab Reports, sort the Reports, pull Abnormal and Panic/critical Results, and immediately give to the requesting provider.

Laboratory personnel shall:

1. Retrieve all Lab reports from contract Labs
2. Put Reports in provider’s box for review.

Provider

1. Review the Lab results and sign them IF RESULTS ARE ABNORMAL, the physician shall:
2. Have the Admin. recall the Patient.

* The Admin. shall:
* Recall patients
* Make a follow up appointment

1. Sends e-mail to patients who cannot be reached by phone, requesting that they come in for a follow-up visit.

**Laboratory Test Order and Result Tracking Policy**

## Purpose: This policy ensures that ordered tests are completed and results are evaluated by the Ridgeline Medicine Laboratory staff and appropriate patient follow-up occurs.

## Policy: It is the policy of the Ridgeline Medicine Laboratory to improve patient safety and the quality of care a patient receives by ordering relevant laboratory tests and obtaining results in a timely manner.

## Reporting Normal Lab Results

1. All lab results will automatically be given to the ordering/requesting provider for sign-off and instructions for patient notification.
2. Providers will ensure that patients are notified of results of their lab results by one of the following mechanisms:

* scheduling a follow-up visit
* Patient Portal
* HIPAA compliant E-mail

## Reporting Abnormal Lab Results

1. Abnormal/Critical Lab Results will be flagged to bring them to the clinician’s attention by use of codes such as L – Low, H- high and P- Panic. Abnormal/critical lab results will be given to the ordering/requesting provider immediately.
2. Providers and/or clinical support staff will make an effort to contact all patients with clinically significant abnormal lab results within one- three business days of receipt. A clinically significant abnormal lab is defined as a lab result that requires action or follow up.
3. After three business days, if the patient cannot be contacted by phone, notification of abnormal results will be made by letter or e-mail.
4. The lab letter/e-mail will include both the test results and the treatment plan from the provider.

## Reporting of External Critical Lab Results

1. After hours, the referral lab (Quest) will contact the on-call with critical results. A provider will be notified by phone from Quest, or a nurse will take the information and document in the patient’s chart the time the result was given and the provider notified.

**Turn Around Times (In House)**

|  |  |  |
| --- | --- | --- |
| **TEST** | TURN AROUND TIME  ROUTINE STAT | |
| 1) Finger Stick Glucose | 5 Minutes |  |
| 2) Complete Blood Count – CBC  [ not including draw] | Within 1 hour | 15 Minutes w/o problems |
| 6) Strep Screen | 15 Minutes |  |
| Urinalysis:  Dipstick  Microscopic | 30 minutes  30 minutes |  |

**Complete Blood Cell Count in Whole Blood Utilizing the pocH-100i**

**PRINCIPLES OF OPERATION**:

The pocH-100i is a multiparameter automated Hematology analyzer, which integrates the flow cytometry technologies of fluorescence, multi-angle light scatter, and focused flow impedance, with hemoglobin spectrophotometry on a single argon laser instrument platform. The system reports 9 parameters.

## Specimen:

1. Specimen of choice is EDTA whole blood collected in a 4.5 ml. lavender top tube.
2. The tube should be at least one-third full.
3. Stability is eight hours at room temperature and twenty-four hours at 4 degrees C.
4. EDTA blood collected in microtainer from fingers are also acceptable.
5. Clotted or any kind of body fluid cannot be run.

## Supplies: Gloves and Gauze Specimen Racks

## Reagents:

pocH-100i Hematology Blood Analyzer (CBC Machine) REAGENTS:

**CAUTION**: **ALL REAGENTS S SHOULD BE HANDLED WITH CARE. SDS SHEETS ARE AVAILABLE FOR APPROPRIATE REAGENT.**

**ALL REAGENTS ARE CLEARED BY FDA FOR DISPOSAL DOWN PUBLIC DRAIN/SEWER SYSTEMS**.

## Storage: All reagents, should be stored at room temperature, (controls and calibrators are stored in the refrigerator).

## Stability:

All reagents are good until the expiration date noted on the container, even after being opened. Lot# and expiration date are located on each reagent container label.

**pocH-100i** **Tri-level Controls Storage and Stability:**

Store at 2 – 8 degrees C. Do not freeze. Unopened tubes are stable until the expiration date indicated.

## CALIBRATION:

The calibration is the adjustment to make its result match the “true value”, which is defined by measurement results from standards or reference procedures. The goal is to calculate calibration factors, which are applied to data in order to eliminate bias and obtain accurate results.

Frequency:

* Upon installation.
* Every six months.
* After major service procedures

## Quality Control: Schedule for running commercial QC materials:

* At the beginning of the shift before patient testing
* every 8 hours during patient testing

Note: All controls outside acceptable QC range must be repeated and documented.

**Review of QC data**: All commercial QC shall be reviewed on a regular basis by the laboratory technical consultant or Medical Director. The examination will include review of actions logged in response to QC problems.

For the details on how to run specimens **pocH-100i** follow touch screen and Operator’s manual.

**NORMAL RESULTS:**

|  |  |  |
| --- | --- | --- |
| Parameter | Range | Reportable units |
| WBC | 3.9 – 11.1 x 103 | cells/ul |
| RBC | 3.79– 6.21 x 106 | cells/ul |
| Hgb | 11.9 – 18.1 | g/dl |
| HCT | 34.9 – 54.1 | % |
| MCV | 80.0 – 100.0 | fl |
| MCH | 26.0 – 35.0 | pg |
| MCHC | 31.9 – 36.1 | g/dl |
| RDW | 10.9 – 14.6 | % |
| Platelets | 139 – 441 x 103 | cells/ul |

**PANIC VALUES:**

|  |  |  |
| --- | --- | --- |
| WBC | <1000/ul | >30,000/ul |
| Hematocrit – Adult | <21 vol% | >65 vol% |
| Platelet count | <20,000/ul | >2,000,000/ul |
| Hgb | < 6 | >17.5 |

\*All panic values results must be called and documented in the Corrective Action log and taken immediately to the requesting provider.

References: pocH-100i **Operator’s manual.**