IDAHO NATIONAL LABORATORY (INL) CLINICAL LABORATORY



**STANDARD OPERATING**

**PROCEDURES (SOP)**

 **2021 REVISION**

**STANDARD OPERATING PROCEDURES**

Review Date: April 2021

Revised By: Keri Martin (Technical Consultant)

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| --- |
| Accepted by: Clinical Laboratory Director:Date:Technical Consultant:Date:Nurse Manager:Date: |

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**CLIA Certification**

## CFA CLIA Certificate -- Number – 13D0665090

## MFC CLIA Certificate Number – 13D0711424

## WBC CLIA Certificate Number – 13D0711426

## ATR CLIA Certificate Number – 13D0711427

## SMC CLIA Certificate Number – 13D0711428

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

Phone: 800-323-4040

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

## Scope of Service

INL Moderate Complex Laboratories:

* Central Facilities Area dispensary (CFA)
* Materials and Fuels Complex dispensary (MFC)
* Willow Creek Building dispensary (WCB)

INL Waived Laboratories:

* Advanced Test Reactor dispensary (ATR)
* Specific Manufacturing Capability Dispensary (SMC)

INL has adequate space and facilities to support each of its laboratories.

##  Definitions

1. CLIA ’88: Clinical Laboratory Improvement Amendments (federal law enacted in 1967 and amended in 1988).

## Competency testing: Evaluation of person’s ability to perform the steps of a testing procedure.

1. Waived tests: POCT that is simple to perform with little potential for erroneous results to cause patient harm.
2. Moderate Complexity Testing: A test defined by the Clinical Laboratory Improvement Amendments of 1988 (CLIA) as one requiring basic lab knowledge and training for personnel performing the test.
3. 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.
4. 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 INL clinical laboratories meet the regulatory standards.
	1. 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.
	2. All testing is performed in accordance with CLIA standards.
	3. Staff must demonstrate competency when performing in-house tests in accordance with CLIA standards, under the supervision of the Technical Consultant and the Medical Director.
	4. All laboratory tests at the INL are used for screening and diagnostic purposes.
2. In -house Testing Approval Process:
	1. All tests performed under this policy are reviewed and approved by the Technical Consultant and Medical Laboratory Director.
	2. Approved tests conforming to this policy are included under the laboratory’s CLIA Certificate.
3. Training and Competency Assessment
	1. Testing personnel are trained in the performance of in- house testing.
	2. The Technical Consultant/Lead Testing Personnel orients and provides specific training to staff that perform in-house testing.
	3. Training is documented.
	4. Staff is assessed at defined intervals to show current competence for the moderate complex tests that they perform.
	5. 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.
	6. The following methods are approved to be used to assess the competency of testing personnel:
		1. Participation in the proficiency testing program – performing a test on an unknown specimen.
		2. Technical Consultant periodically observes the performance of In-house Tests.
		3. Technical Consultant/Laboratory Director reviews the quality control results monthly or more often as necessary.
		4. Documentation of competency testing and any required.

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

## Policy: Laboratory shall participate in the INL’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 established 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 with the law.
* laboratory monitors ambient temperature and temperatures of storage devices.
* laboratory collects, compiles and analyzes data to monitor its performance.

##

## Categories of Testing Performed

1. **Waived testing** is performed at all the INL occupational medical facilities and meets standards for the Clinical Laboratory Improvement Amendments of 1988 (CLIA). Waived tests include:
	1. Urine dip stick
	2. Strep A Antigen
	3. Capillary blood glucose
	4. Piccolo Xpress Chemistry Analyzer (lipid profile and comprehensive metabolic profile). (CFA, MFC, and WCB only).
	5. HBA1c (CFA, WCB only).
	6. Influenza A/B
	7. Urine qualitative HCG
2. **Moderate complexity testing** at INL occupational medical facilities meets the standards for CLIA. Testing includes:
	1. A Complete Blood Count (CBC) panel using the Abbott Cell-Dyn Emerald instrumentation.
	2. CBC tests are performed at CFA, MFC, and WCB
3. **Reference Laboratory**--All tests requested that are not performed in-house are referred to Quest laboratories or another approved reference laboratory. All reference specimens shall be sent to a CLIA approved reference laboratory.

 **Turn Around Times for In-House Testing**

|  |  |
| --- | --- |
| **TEST** | TURN AROUND TIME**ROUTINE**  **STAT** |
| Finger Stick Glucose | 30 minutes |  10 minutes |
| Complete Blood Count – CBC | 2 hours | 30 minutes |
| Strep Screen | 30 minutes |  |
| Urinalysis  |  2 hours |  30 minutes |
| Hemoglobin A1c |  2 hours |  30 minutes |
| Influenza A/B |  30 Minutes |  |
| Metabolic profile | 2 hours |  1 hour |
| Lipid Profile | 2 hours |  |

## 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, analytical, and postanalytical 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. Ensure 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 enough 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 preanalytic, 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.

**Lead Testing Personnel--**In addition, each INL moderate complex laboratory will have 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.

**Testing Policy:**

* Test shall only be performed when requested (written or standing order) by a provider.
* Staff authorized to order test include physicians, Physician assistants and Licensed Nurse Practitioners.
* Written orders are stored in the patient’s EMR and must contain:
	+ First and last name
	+ Date
	+ Sex
	+ Date of birth/age
	+ Provider requesting the test.
* Standing orders are available in the EDMS.
	+ Under each Certification/Surveillance there is written Standing Lab orders authorized by the INL Medical Director.
	+ Wellness Lab Standing Orders; See written order in SOP. All orders have been authorized by the INL Clinical Medical Director.
* Test shall be performed on appropriate specimen.
* Tester shall ensure that a properly labeled specimen is submitted for testing.
* 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. Record results on Lab Report Form.
9. Place a copy of Lab results report in chart and maintain copy of results in the lab.

## Internal QC/Procedural Control & External QC

## 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 tests as follows:
	+ Laboratory performs quality control testing in the same manner as it performs patient testing according to manufacturer’s instructions.
	+ The laboratory shall verify test methodology/instruments.
	+ The laboratory shall perform calibration verification according to the manufactures’ recommendations.
	+ The laboratory shall use the manufacture’s established QC ranges.
	+ The laboratory shall establish its own QC ranges with valid statistical measurements for CBCs as needed.
	+ Internal/procedural controls part of a test kit; will be observed.
	+ Documentation will be maintained of all quality control testing. Documentation shall include: QC test results; kit lot #s; expiration dates and testers initials.

 **Orientation Outline for Waived Testing**

 **Policy:**

* Read procedure (available in a manual and at *medtraining.org*).
* Short in-service
* Instruction and demonstrations Technical consultant or Lead lab person.
* Written materials available to each testing person at *medtraining.org* and the SOP manual.
* Check off list where applicable.

 **List of Guidelines**

## 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

##

## Orientation Outline for Moderate Complex Testing

## CBC -- Cell Dyn Emerald

**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 procedure manual or electronic copy at *medtraining.org*
* Instruction and demonstrations by trained testing personnel of Technical Consultant
* Written materials; available in a manual or electronically at *medtraining.org*
* Check off list where applicable.

## List of guidelines

## Standard Operating Policy and Procedure Manual

* + Instrument Overview-System Components
		- Analyzer
		- Data Module
		- Reagent System
	+ Principles of Operation

## Use of forms

* + QC log
	+ Panic Values
	+ Maintenance log
	+ Instrumentation maintenance log
	+ Corrective Action log

## General Quality Control policy

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 CLIA standards for performing quality control checks.
* Corrective actions shall be taken and documented for all out-of-range QC results.

## Package Inserts for QC Control Limits

Laboratory personnel will keep the package inserts containing the control limits in the QC Logbook. The Technical Consultant/Laboratory Director will monitor periodically for compliance.

 **CBC Calibration Verification and Calibration**

**Policy:** Trained laboratory testing personnel will perform calibration verification at least every 6 months or as needed.

 **Procedure:**

* 1. Follow the pre-calibration and calibration procedure as outlined in the CBC operation manual.
	2. Compare the results and limits as is stated on the insert that is contained in the box with the calibrator:
		+ If each parameter is within the tolerance limits stated on the calibrator insert the calibration has been verified.
		+ Run all 3 levels of controls (if they are in, the verification is complete, if not troubleshoot until the problem is resolved).
	3. Place all Calibration Verification Documents in the CBC Calibration binder.
	4. If a parameter(s) is/are not within the tolerance limits, input the new calculated calibration factor and re-peat the calibration verification procedure.
	5. If parameter(s) is/are still not within tolerance limits, perform troubleshooting following the CBC operating manual direction. Repeat calibration and calibration verification procedure.
	6. If parameter(s) is/are still out of expected tolerance range, notify the Technical Consultant.
		+ Document the problem on the corrective action log.
		+ Send all CBC tests to Quest Laboratory until the problem is resolved.
		+ Document how the problem was resolved on the corrective action log.

**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.
	* PM must be performed on all instruments according to the manufactures’ recommendation.
	* Instructions for instrument checks must be available and checks must be documented.
	* Instructions for minor troubleshooting and repairs of equipment/instruments must be easily accessible. All repairs and service must be documented.
	* 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.
	* In the event of equipment failure, the instrument/equipment will be labeled “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.

## Patient/Specimen Identification

**Policy:** Laboratory staff shall always adhere to correct patient and specimen identification.

## 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.
	* View patient’s INL ID card or driver’s license.
	* Ask patient to state his/her date of birth or S#.
	* 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 # 2
		+ If there is a discrepancy, the discrepancy must be resolved before the specimen is collected.
2. Collect the specimen:
	* Affix a label or write the patient’s name, time, and S# on the specimen before the patient is dismissed.
	* Collector places initials on specimen.
	* Label must remain on the specimen for the duration in the laboratory.
	* All aliquots must have a patient identifier.

##  Specimen Collection

## Venipuncture Procedure

**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)
5. Selection of appropriate venipuncture site:
* The site to check first is the Upper region of the Arm.
* 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.
* 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).
* The next step is to go to the Back of the Hand to obtain venous access.
* 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.
* To avoid this, hold the Vein in place with your Index Finger and Thumb while you use a smaller gauge needle or a butterfly.
* The Wrist veins are also an alternative but generally are much more painful than the other sites.
* The Foot and Ankle veins may also be used. (The patients’ Physician must give permission to use them).
* These veins are often restricted because the Physician is concerned about clots forming in the legs.
* The order for checking for the best available site is 1) Upper Arm, 2) Hand 3) Wrist, and

4) Ankle or Foot. The patients’ condition dictates the site to use.

* 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 (due to lymphocytosis).
* Placement of the Tourniquet has the potential for tissue damage and leaves a temporary indentation in the arm.
* Areas of Scarring are also to be avoided because of possible injury to the patient or excessive pain.
* 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.

##

## 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 holder until secure.

1. Select the tube appropriate for the sample desired.
2. Gently tap the tubes, which contain additives to dislodge the additives trapped around the stopper.
3. 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.
4. Select the site for venipuncture by palpation.
5. Apply the tourniquet. Swab the venipuncture site with 70% alcohol. DO NOT palpate the venipuncture site after cleansing.
6. Place the patient’s arm in a downward position.
7. Remove the needle shield. Perform the venipuncture with the arm in a downward position and the tube in a vertical position, stopper uppermost.
8. Push the tube to the end of the holder, puncturing the diaphragm of the stopper.
9. 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.
10. 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.
11. When the blood flow ceases, immediately remove the needle from the vein and apply pressure with dry sterile gauze/cotton ball. Keeping the sterile gauze/cotton ball firmly in place until bleeding ceases.
12. Remove the tube from the holder. It is normal for the tube not to be completely filled.
13. 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.
14. Apply a bandage.
15. Tourniquets will be:
	1. Wiped periodically with an alcohol pad.
	2. Discarded when visually or knowingly contaminated with blood.
16. Needle holders will be disposed of after each draw.
17. Instruments will be contaminated with 10% bleach (or a comparable disinfectant) when there is known or visual contamination.

## 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.
	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:
		1. SST (red-gray or gold top). Contains a gel separator and clot activator.
		2. Sodium heparin (dark green top)
		3. PST (light green top). Contains lithium heparin anticoagulant and a gel separator.
		4. EDTA (lavender top)
		5. ACDA or ACDB (pale yellow top). Contains acid citrate dextrose.
		6. 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.

## 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
	* + Cleanse hands
		+ Put on gloves
		+ Select the site - Puncture is usually made on the 3rd or 4th finger of either hand.
		+ 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

## Reference Laboratory Specimen Collection Instructions

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

**Fasting**

A 10-12 Hour Fasting state is recommended for Glucose and 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.

Consult Quest Specimen collection manual or website for fasting requirements for all specimens sent out.

**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. Follow the manufacturer’s instructions for tests performed in house. Refer to the Quest Manual or website for specimen’s sent out.

 **Specimen Transport Packaging**

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

**Test Requisition**

Laboratory personnel will only perform test if there are written/electronic/standard orders by an authorized provider.

## Procedure: Before performing test:

* Ensure that there are the written /electronic/standing orders by an authorized by a 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.
		- Incorrectly completed request will be rejected and taken/returned to the requesting provider 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, or mishandled specimen  | Specimen with be rejected and re-collected. |

## Test Report

## 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 (where applicable
	+ Identity of person performing the test(s)

##  Reporting:

## All reports will be reviewed by the testing person before reporting.

## Reports are given to the ordering provider. For standing orders, the report is given a provider who available to review the report or is seeing the patient.

## If a test(s) is/are markedly abnormal or there are panic values:

## Repeat test.

## Document on report form that test was repeated.

## Verified Panic Values:

## document on the corrective action log: patient’s S # and that panic value(s) were verified and reported.

## Immediately give the verified report to a provider.

## Document in the patient’s chart, who reported the result, the date, the time, and the provider the results were given too.

## Reference Lab Verbal Reports/Panic Values -- the result will be given to the provider by the person who received the phone call from the reference laboratory. The result is documented in the patient’s EMR to include:

## Name of person from the reference lab who gave the report.

## Name of the person who received the result.

## The provider who the result was given too.

## Date and time of report.

## Reference Lab Reports: Lab Personnel will retrieve all incoming Lab Reports and distribute the reports to the ordering provider or assign a provider to the report in the case of standing orders.

## Patient’s will receive results after a provider reviews the report. Patient may receive results by:

## Phone call (document in patient’s chart date, time of report)

## E-mail

## Office visit

## 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:

* Test systems do not meet the laboratory’s established performance specifications.
	+ Equipment that performs outside of established parameters.
	+ Methodologies whose performance is outside the specifications.
	+ Control values are outside the expected range.
* The criteria for proper storage of reagents and specimen are not met.
* Errors in reporting patient test results
* Panic values
* Complaints

## Procedure:

## Initiate and perform corrective action as specified by specific standard operating procedure manual, Instrument’s trouble shooting guidelines, laboratory policy/procedure.

## Document resolution on the corrective action form.

**Infection Control**

 **Universal/Standard and Respiratory Transmission Precautions:**

All blood and other body fluids are treated as if they are infectious. All testing personnel will be required to maintain personal hygiene, use personal protective equipment (PPE), engineering controls, and work practice controls to prevent the spread of disease.

Standard precautions apply to:

1. Blood
2. All Body fluids and secretions (except sweat)
3. Non-intact skin
4. Mucous membranes

 **Exposure Control Plan**

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

1. **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.
2. **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, Drink and 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.

1. **Labels --** Refrigerators, freezers, bins, pails and other receptacles that contain blood or other potentially infectious material should also be marked with the international biohazard symbol.
2. **Sharps Containers** -- 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 and Color-Coded (red).
3. **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.
4. **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.
	1. 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.

**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 (red) 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.

## Decontamination and Cleaning Laboratory Surfaces

Use the following guidelines for decontaminating surfaces in the laboratory:

1. A 10% solution of bleach solution (or other INL approved disinfectant), for decontamination and cleaning.
2. A 10% bleach solution (or other INL approved disinfectant) shall be used for decontaminating in all patient areas in the Clinical Laboratory.

## Biohazard Spill

**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.

## Decontamination of Equipment Before Repair:

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

**Laboratory Accidents:**

1. When an accident occurs IMMEDIATELY Stop what you are doing.
2. First take care of any emergent injuries and/or hazardous spills. If an injury has occurred:
	* check-in the patient at the front desk.
	* Document the Injury in patient’s EMR and have patient seen by a provider.
	* Follow INL incident reporting protocol.

 **Needle Sticks/Sharps Punctures**

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

* + All staff who are accidentally stuck with a needle/sharp must follow the INL lab-wide procedure (LWP-14501), which can be found in the EDMS in the INL Nucleus.
	+ If a patient is accidentally stuck with a contaminated needle/sharp:
	+ immediately notify Front Nurse and check-in patient.
	+ All staff who sustain needle/sharp injuries must be seen by a provider.
	+ follow INL incident reporting protocol.

 **Storage of Laboratory Specimens, Reagents and Controls**

Allspecimens will be stored in accordance with the manufactured recommendations for each testing procedure**.**

 **Procedure:**

1. Specimens, reagents and controls that require refrigeration are stored at temperatures of 20C – 80C.
2. Temperature checks are performed and recorded on each day that the lab is open.
3. If the temperature is not within the expected/acceptable range:
	1. Immediately notify the Nurse Manager and document problem on the Corrective Action Log.
	2. Remove specimens, reagents and controls and place in another refrigerator.
	3. 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 acceptable range for the stored items.
	4. 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).
4. 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.
5. 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:
	1. urine for dipstick testing - discarded at the end of the shift or after the patient has been dismissed.
	2. blood for CBC will be discarded at the end of the shift or after the patient has been dismissed.
	3. Proficiency samples – refrigerated and held until results of proficiency tests are received and reviewed.

## Reagent Recall

Upon receiving a recall notification, the Nurse Manager/designee shall:

1. immediately check department’s inventory
2. remove recalled reagent/supplies from inventory.
3. document/record reagents/supplies that were recalled (include lot numbers) on corrective action log.
4. return recalled reagents/supplies to the vendor/company.
5. replenish reagents/supplies.

 **Electrical Safety**

* + All outlets should be grounded.
	+ There must be no frayed electrical cords.

**Complete Blood Cell Count in Whole Blood Utilizing the Abbott Cell Dyn Emerald**.

**PRINCIPLES OF OPERATION**:

The Cell Dyn Emerald 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 Specimen Rocker, and Specimen Racks

## Reagents:

 Cell Dyn Emerald Hematology Blood Analyzer (CBC Analyzer) REAGENTS:

 Cell Dyn Emerald 18 Cleaner Reagent

 Cell Dyn Emerald 18 Diluent Reagent

 Cell Dyn Emerald 18 CN-Free Lyse Reagent

 Cell Dyn Emerald 18 Whole Blood Calibrator

 Cell Dyn Emerald 18 Plus Whole Blood Controls

 **\* 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.

**Cell Dyn Emerald 18 Plus Tri-level Controls Storage and Stability:**

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

## 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 on Cell Dyn Emerald follow touch screen and Operator’s manual.

## 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

 **Normal Range:**

|  |  |  |
| --- | --- | --- |
| 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  | cells/ul |

**Panic Values:**

|  |  |  |
| --- | --- | --- |
| WBC | <1x103/ul | >30x103/ul |
| Hematocrit – Adult | <21 vol% | >65 vol% |
| Platelet count | <20x103/ul | >2,000x103/ul |
| Hgb | < 6 g/dl | >17.5 g/dl |

\*All panic values results must be verified, given to the provider immediately, documented in the Corrective Action log, and in the patient EMR.

**Reportable Ranges:**

|  |  |  |  |
| --- | --- | --- | --- |
| **Parameter** | **Minimum** | **Maximum** | **Reportable units** |
| RBC | 0.36 x 106 | 6.25 x 106  | cells/ul |
| HGB | 0.98 g/dl | 19.53  | g/dl |
| WBC | 0.83 X 103  | 68.98 X 103  | cells/ul |
| PLT | 10.75 X 103 | 966 X 103 | cells/ul |

References: Cell Dyn Emerald **Operator’s manual.**

**WELLNESS LABS STANDING ORDER**

Date: 01/15/21

BEA Employees who need a physical exam and do not have any Certifications or Surveillances that require lab work may elect to have a metabolic panel, lipid profile, and CBC w/o a written order from a provider.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Clinical Laboratory Director