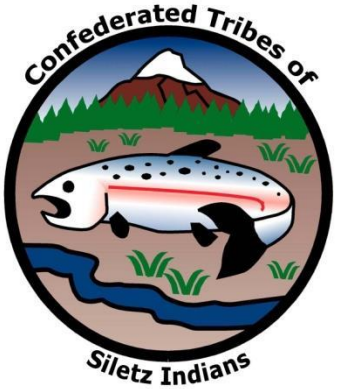
# SILETZ COMMUNITY HEALTH CLINIC POLICY




## Laboratory

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| Date Approved | 08/29/01 |
| Date Revised | 11/05/05; 05/02/09; 05/05/12; 12/21/18; 06/18/21 |

# Part 15A
# General Laboratory

## I. POLICY

It is the policy of the Siletz Community Health Clinic (SCHC) that all laboratory staff adheres to the General Laboratory policy and procedures.

## II. EMERGENCY REDUCTION IN LABORATORY STAFFING

A. If one technologist is available for coverage during clinic hours the delivery of services may be affected. Contingency measures are in place to provide continuing patient care.

1. Every effort will be made to cover requests for STAT PICCALO'S, STAT Urinalysis, and other STAT blood draws.

2. In extreme cases STAT and ASAP requests may need to be referred to the local reference laboratory.

3. The laboratory may request the help of nursing services for phlebotomy and handling of patients.

4. The primary laboratory technologist will work with the Clinical Services Director (CSD) or Medical Director to ensure laboratory operations continue with minimal interruptions to patients.

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## III. LABORATORY DOWNTIME

A. In the event of instrument or test system failure the following steps shall be taken:

1. Log problem in appropriate Problem/ Corrective Action Log.

2. Notify providers of delay in testing.

3. Determine the urgency of test reporting by consultation with provider, and handle appropriately.

4. If it is anticipated that the problem will be resolved in a timely manner (usually by the next day), save the patient specimens for testing at that time.

5. If longer resolution of the problem is anticipated, send specimens to the reference laboratory with other send-out tests.

6. If "STAT" turn-around time is necessary, send the patient to the local reference laboratory at Samaritan Pacific Communities Hospital.

B. In the event of failure of the Lab Module in NextGen:

1. Have the ordering personnel use the Downtime Laboratory Test Requisitions to order all requested tests.

2. Run testing as requested, give a copy of the results to the providers, and keep a copy of the results, and enter manually into the computer when available.

C. In the event of an interruption in power:

1. There are battery backup power sources for all the machines in the laboratory, which allows the on board reagents to remain at their proper temperatures. Most power outages in this area last for less than ten minutes. This provides ample time to activate the secondary backup system handled through the maintenance department.

2. There is a generator backup system which can power the laboratory equipment for approximately eight hours. Any measures required beyond this time frame require a temporary suspension of service.

## IV. LABORATORY TEST MENU

A. The laboratory provides testing which is routinely performed in house. These tests include the following:

1. Chemistries
   Finger Stick Glucose

   BMP (Na, K, Cl, ECO2, BUN, Creat, Glu, Ca, ALKP, AST, ALT, T. Bili. TP, ALB)

2. Urine Drug Screen

   Amphetamine, Barbiturates, Buprenorphine, Benzodiazepines, Cocaine, MDMA, Methamphetamine, Methadone, Opiates, Oxycodone, PCP, Tri-Cyclic Anti-Depressants, THC,

3. Hematology

   Hemocue Hb 201 hemoglobin

4. Coagulation

   INR Point-of-Care

5. Urine

   UA without microscopic

   Urine HCG (Urine Pregnancy Test) Point-of-Care

6. Rapid Strep Screens for Group A Strep Antigen Point-of-Care

7. Lead level testing

8. Influenza A & B RapidPoint-of-Care

9. H.Pylori Rapid Point-of-Care

10. COVID-19 Point-of-Care

11. RSV Point-of-Care

12. Mononucleosis Point-of-Care

13. Tests Available as STAT's

    The following tests are available on a STAT basis. These should be ordered STAT, ONLY when the provider cannot proceed with treatment of the patient without the results. All STAT requests will be handled as emergencies and given priority over any other test.

    a. CMP

    b. INR

    c. URINALYSIS

## V. TURN-AROUND TIME

A. Most in-house test results are reported to the provider within 30 minutes, Turnaround times will be lengthened if there is a staffing shortage or heavier than usual workload.

B. All tests drawn to be sent out to LabCorp (SCHC reference laboratory) will be sent out the same day collected whenever possible.

C. Routine reference laboratory tests are normally returned in one to two days. These are sent electronically to NextGen

D. PAP tests take about one week.

E. Cultures require one to three days.

F. When necessary patients might be sent to another local laboratory to collect and process tests the SCHC laboratory is unable to complete, or per provider preference if STAT laboratory results are required for treatment decision making. Those test results will be obtained by provider's team by logging into EPIC and pulling results to scan into NextGen.

G. State laboratory results are returned in about 1-2 weeks.

## VI. LABORATORY DRESS CODE AND PPE

A. All laboratory personnel are required to dress in appropriate workplace attire. The scope of work in the laboratory requires lifting, squatting, dusting, and decontamination of environmental surfaces and work areas frequently throughout the day. Strict business attire is not conducive to the daily activity requirements. Clothing must be clean and free of holes, tears, stains, etc.

B. Appropriate attire includes items such as:

1. Scrubs
2. Pants or dark jeans on Fridays only
3. Tops which are not revealing
4. Dresses which are at or below the knee
5. Shoes which have closed toes
6. Clean laboratory coats

C. Personnel Protective Equipment (PPE)

PPE such as laboratory coats or gown, gloves, masks, etc., must be worn whenever handling blood and body fluids where the possibility of contamination exists following the Standard Precautions Policy.

D. Gloves

Gloves must be worn when drawing blood and changed after each patient. Gloves must also be worn when handling and processing all laboratory samples. Laboratory personnel will wash their hands between patients following the Hand Hygiene Policy

| SILETZ COMMUNITY HEALTH CLINIC | |
|---|---|
| Program | Laboratory |
| Policy | General Laboratory Equipment and Supply |
| Date Approved | 12/21/18; 06/18/21 |
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## Part 15B
## General Laboratory Equipment and Supply

### I. PURPOSE

To outline the General Laboratory Equipment and Supply policy at the SCHC.

### II. FACILITIES

A. The environment in the working area of the laboratory will be controlled by the commonly used heating, air conditioning, and ventilating equipment used throughout the entire clinic, which will maintain a working temperature of $65^0$ - $77^0$ F.

B. The refrigerator will be in working order in the laboratory to maintain a temperature of $35^0$ - $45^0$F or $2^0$ - $8^0$C. Freezers will maintain a temperature of -$0^0$ to -$20^0$C or lower. Only reagents supplies, biologicals, and specimens will be stored in the refrigerators or freezers. No food or beverages will be stored in the laboratory refrigerator or freezer. A separate refrigerator in the employee breakroom is provided to store food or beverages for personal use.

C. Humidity will be monitored and recorded daily. Normal range is 12-80.

D. Proper lighting will be maintained. Any burnt out bulbs will be replaced as soon as reasonably possible with new bulbs. Maintenance will be notified as soon as possible that a replacement is needed.

E. OSHA regulations and CDC guidelines will be followed in the laboratory. Refer to the infection control policy regarding waste-management, personal protective equipment, and other safety policies. Laboratory coats are to be worn only in the immediate clinic area.

### III. TEST METHODS AND EQUIPMENT

A. The Lab Director will be responsible for making the final decision on the test systems, equipment, and methodologies used in the laboratory.

B. The Lab Director will ensure that proper test validation, if necessary, has been conducted on all tests performed in the laboratory before reporting any patient results. The Lab Director will decide the number of tests performed to validate the instrument or test system. To do this, the laboratory supervisor will consult with the manufacturer or its representative for guidance, seek the reference laboratory technical consultant, and determine the clinical pertinence and clinical requirements for accuracy to determine the scope of test validation. The Lab Director will also determine the performance specifications for all tests performed in the laboratory after consultation with the instrument or test system manufacturers.

C. All equipment used in the laboratory will be maintained according to manufacturer's recommendations. Records will be kept on all maintenance functions performed in the laboratory. These records will be reviewed by the Clinical Services Director on a quarterly basis and will be signed and dated by the Lab Director at least once a year.

## IV. METHOD VERIFICATION

The laboratory will verify any new test methodology instituted, unless waived by the manufacturer. It must perform validation studies, including reproducibility studies and split sample testing. The results of these studies must be comparable to those stated by the manufacturer before patient test results will be reported. The Lab Director will review the data generated by these studies and make the final decision as to the adequacy and comparability of the data. All these activities will be documented and records maintained for the life of that specific methodology plus at least two years.

## V. TEMPERATURE LOGS

A. Temperature logs will be maintained for ambient temperature, refrigerator, and freezer temperatures.

B. Temperatures will be taken each day an employee is in the laboratory and recorded in the appropriate log. If a temperature is outside the desired range, the Clinical Services Director is notified. If the temperature must be adjusted at the beginning of the workday, it must be checked at a later time of the day to assure proper temperature is maintained. Appropriate corrective action will be taken and documented if the temperature continues to be out of range. It is the responsibility of the CSC to determine the severity of the problem and the effects of the testing process. Laboratory reagents may be moved to another refrigerator or freezer within the clinic if the problem persists or until the problem can be solved.

## VI. REAGENTS, MATERIALS, AND SUPPLIES

A. The lead laboratory technologist will maintain an inventory accounting system to ensure that sufficient supplies are always on hand in the laboratory, a system is in place to monitor current dating of supplies, and supplies are stored properly. Flammable materials will be limited to only working quantities.

B. All reagents, solutions, culture media, control materials, calibration materials, and other supplies must be labeled with the following information:

1. Identity

2. Recommended Storage Requirements

3. Preparation and Expiration Date

4. Safety Data

5. Date Received

6. Date Opened

7. Other Pertinent Information

C. Reagents, solutions, culture media, control materials, calibration materials, and other dated supplies will not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. Once they have exceeded their expiration date, they will be disposed of properly. Components of reagent kits with different lot numbers will not be interchanged unless the manufacturer specifically allows this procedure.

## VII. EQUIPMENT PREVENTATIVE MAINTENANCE

A. It is the general responsibility of all laboratory personnel to ensure that preventative maintenance schedules are followed. The schedule must be contemporaneously completed and appropriately dated and initialed. The manufacturer's schedule must be adhered to.

B. It is the specific duty of the lead technologist to:

1. Perform all scheduled preventative maintenance

2. Identify any problem areas and report them to the Clinical Services Director or Medical Director

3. Ensure that any problems are adequately resolved

4. Document the solutions to the problem

5. Document that preventative maintenance has been performed

C. It is the specific responsibility of the Clinical Services Director to:

1. Ensure that periodic equipment maintenance and function checks are performed as required by the manufacturer or determined by the technical consultant.

2. Ensure that all preventative maintenance schedules are followed and documented.

3. Make sure that all instruments have maintenance records containing at least the minimum amount of maintenance required by the manufacturer's recommendations.

4. Solve problems as they arise.

5. Document how problems are resolved.

6. Provide documentation showing that these checks have been performed. These records will be maintained for the life of the instrument plus two years. The specific requirements will be delineated in the instrument maintenance section of the policy manual.

7. Any deviations and corrective actions shall be documented and reviewed by the Lab Director.

D. Facilities management, on their own or with an outside contract, shall be responsible for maintenance such as:

1. Electrical checks for proper grounding

2. Eyewash station checks

E. Miscellaneous equipment not covered by the manufacturer's warranty or service agreement will be checked on an annual basis by a certified Bio-Medical Inspector. Documentation of these inspections is located in the Quality Improvement Coordinator's office.

F. Thermometers are continuous logging and cloud based. The Clinical Services Director monitors all temperature data loggers and has access to the cloud storage website. Data loggers are re-calibrated every two years and by the Clinical Services Director.

## VIII. PREVENTATIVE MAINTENANCE LOGS

A. The Preventative Maintenance Logs (PM Logs) of all equipment in the laboratory are intended to contain all the information and forms to verify the proper functioning and maintenance of all instrumentation.

B. Any preventative maintenance, including manufacturer recommended procedures for daily start-ups and shut-downs, must be logged in the PM Logs. Corrective actions and periodic troubleshooting will also be documented in the PM Logs.

C. Records of scheduled maintenance programs provided by the distributor/manufacturer as well as service records (to include problems, corrective actions, parts, service contracts, repairs made by company representatives, and bills) must be kept on file. In-house repairs made by facilities management may also be kept with the PM Logs.

## IX. INVENTORY MANAGEMENT

A. A system for monitoring inventory and a routine schedule for checking supplies (reagents, solutions, culture media, controls, calibrators, and other laboratory supplies) on hand are assigned to all personnel. A contingency plan identifying the back-up supply source is in place to ensure availability of appropriate materials in case of an emergency.

B. The supervisor should be notified anytime a shortage is anticipated. All laboratory personnel are responsible for this notification in their assigned work areas.

| SILETZ COMMUNITY HEALTH CLINIC | |
|---|---|
| Program | Laboratory |
| Policy | Laboratory Quality Assurance |
| Date Approved | 08/29/01 |
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## Part 15C
## Laboratory Quality Assurance

## I. PURPOSE

A. The purpose of the Siletz Community Health Clinic Laboratory Quality Assurance (QA) Program is to improve reliability, efficiency, and quality of laboratory services. The laboratory program is designed to monitor and evaluate the ongoing and overall quality of the total testing process (pre-analytic, analytic, and post-analytic) activities. The QA program assures the accurate, reliable, and prompt reporting of test results; provides methods to evaluate the effectiveness of its policies and procedures; provides methods to identify and correct problems; and provides methods to assure the adequacy and competency of the staff. A laboratory quality assurance program is an accreditation requirement. The laboratory must meet the standards as they apply to the services offered, complexity of tests performed, and test results reported. The laboratory must also initiate corrective action when problems occur and document all quality assurance activities.

B. The continuous quality improvement (CQI) activities are used in conjunction with the QA Program, and CQI documentation is used to support QA elements.

C. The QA Program covers the following:

1. Selection of test methods approved by the Medical Staff
2. Quality Control (QC) Program to monitor precision of laboratory performance
3. Proof of participation in a proficiency testing program
4. An instrument maintenance program
5. Continuing education for laboratory staff
6. Documentation of laboratory functions
7. Self-assessment of quality laboratory performance

## II. POLICY

It is the policy of the Siletz Community Health Clinic (SCHC) that all personnel implicitly adhere to the policies and procedures regarding the laboratory.

## III. GOALS

A. The goals of the QA Program are to:

1. Assess the effectiveness of the laboratory's policies and procedures.

2. Identify and correct problems.

3. Assure the accurate, reliable, and prompt reporting of test results.

4. Assure the adequacy and competency of staff.

B. The laboratory must revise policies and procedures based on the reviews.

C. Two types of quality assurance reviews are conducted:

1. Routine, scheduled, quarterly reviews of major elements of laboratory functions.

2. Immediate, focused reviews in response to identified problems, complaints, errors or incidents.

## IV. QUARTERLY REVIEW

A. The routine scheduled review will examine 12 major elements of laboratory function that have been determined by their relevance to the three components of the total testing process:

1. Pre-Analytical

   a. Personal performance evaluation and continuing education

   b. Requisitioning of tests

   c. Specimen collection, handling, or specimen rejection

   d. Complaints and communications breakdowns

2. Analytical

   a. Instrument calibration and maintenance

   b. QC corrective action and follow up

   c. Proficiency testing

   d. Appropriate reference ranges

3. Post- Analytical

   a. Result reporting

   b. Critical values

   c. Report format

   d. Turn-around time

B. The Laboratory Supervisor, Lab Director, and Clinical Services Director perform the quarterly QA review. When incidents, problems or opportunities for improvement are identified, a PDSA worksheet is completed to document action taken.

## V. PROCEDURE MANUAL

A. Written procedure manuals containing procedures for all activities of the laboratory are maintained and readily available at all times the laboratory is in operation. The procedure manual contains procedures for patient preparation, specimen collection, specimen storage and handling, test performance, test result reporting, quality control, calibration, and proficiency testing.

B. The Lab Director approves the procedure manual when first written, with notation of approval by signature and date. The Lab Director will review the procedure manual annually and sign the signature page at that time to indicate all procedures have been reviewed. If the directorship of the laboratory changes, the new lab director will review the procedure manual within 30 days of taking the position and note approval by signature and date. If a procedure requires a change, a new procedure will be written, approved by the Lab Director, Planning and QI Committee, and Health Director, and inserted in the manual. The old procedure will be retained in a file for outdated documents for a period of at least two years. All laboratory personnel will review the procedure manual on a regular basis. New personnel will read the entire manual within 30 days of hire. Notations will be made in the personnel records and on the manual of the reading and review.

## VI. QUALITY CONTROL ASSESSMENT

A. The Lab Director will review all quality control charts and logs on at least a monthly basis. All out-of-control situations not resolved by a simple repeat analysis will be reviewed by the Lab Director as soon as practical after the event. The Lab Director will review the corrective action to ensure that appropriate action was taken and proper procedures were followed.

B. A corrective action will be documented in the corrective action logs whenever a problem arises in calibration or when an out-of-control situation occurs that is not resolved by a simple repeat analysis. All corrective actions will be initialed by the Lab Director and brought to the next quality assurance meeting if deemed appropriate. All corrective actions

will be initialed by the Lab Director upon review. Specific specimen preservation and processing requirements are listed in the procedure for each test performed in-house. For send-outs, this information is provided by the reference laboratory in their procedure manual or on the reference laboratory website.

## VII. COMPARISON OF TEST RESULTS

The Laboratory Supervisor will ensure that instrument correlation studies are performed at least twice a year on tests for which the laboratory has more than one instrument system or methodology. Any test performed in the laboratory for which proficiency testing is not available will be verified at least twice a year and the results will be reviewed by the Lab Director.

## VIII. RELATIONSHIP OF PATIENT INFORMATION TO TEST RESULTS

The Laboratory Supervisor will ensure that all personnel in the laboratory monitor test requisitions for appropriateness to the patient's age, sex, and diagnosis. The results should also be compared to other readily available laboratory data on that patient. If any requisitions or results appear inappropriate, proper consultation should be obtained.

## IX. RESULTS VERIFICATION

A. Technologists are expected to be diligent in their work and to check result entries before results are reported as final. The latter is very important in that manually entered results may have clerical errors, especially at extremely busy times.

B. The Laboratory staff will review abnormal and critical results in the Electronic Health Record (EHR) system. Results will be checked daily to ensure all tests ordered are resulted in patient's EHR. Critical results, cultures, and biopsies will be brought to provider's attention ASAP. Any errors or discrepancies in the EHR will be addressed and any test result requiring a change will be documented and the provider notified.

## X. PERSONNEL ASSESSMENT

A. The Lab Director will conduct and ongoing evaluation of staff competence using most or all of the following methods:

1. Proficiency testing results;

2. Results of quality control charts;

3. Maintenance logs;

4. Instrument function checks and calibration;

5. Recording and reporting of test results;

6. Personal observation of routine patient test performance, including patient preparation;

7. Repeat testing of patient samples, proficiency test samples and/or controls;

8. Observation of trouble-shooting skills on instruments, test methods, and data processing;

9. Concerns from the medical staff on performance.

B. Evaluations will include competency as an element in the staff member's Standards of Performance.

## XI. COMMUNICATIONS

The Lab Director will monitor the requisitioning and results of testing performed in the laboratory to ensure that any communication problems are corrected as soon as reasonably possible. A corrective action form should be completed if a significant incident occurs.

## XII. QUALITY ASSURANCE REVIEW WITH STAFF

The Lab Director will discuss with the staff, on at least a quarterly basis, the results of quality assurance reviews and ways the laboratory can improve the quality of its work. This review can take place on an informal basis.

## XIII. CONTINUING EDUCATION

A. Staff is encouraged to take advantage of continuing education opportunities.

B. In-house continuing education is occasionally offered by the clinic. This training is provided by staff, outside consultants, and others. Laboratory staff is required to participate in the training.

## XIV. COMPLAINT INVESTIGATION

A. If there are complaints or unusual occurrences concerning the laboratory:

1. Incident forms are given to the Quality Improvement Coordinator.

2. The person with a verbal complaint shall be directed to the Medical Director or Clinical Services Director.

3. The Medical Director or Clinical Services Director will investigate the complaint and take corrective action.

B. The Laboratory Supervisor maintains a quality assurance log where information about laboratory operations (problems, incidents, errors) is recorded. Details about problems encountered are recorded initially in that log, and it serves as a useful resource and reminder when completing the quarterly review. Copies of complaints reported to Risk Management shall also be logged here. Reports are tracked by the Quality Assurance/Risk Management Officer.

C. Quality assurance records are retained in the laboratory for two years in a manner that makes them easily retrievable for review.

| SILETZ COMMUNITY HEALTH CLINIC | |
|---|---|
| Program | Laboratory |
| Policy | Laboratory Quality Control |
| Date Approved | 12/21/18 |
| Date Revised | 06/18/21 |

## Part 15D
## Laboratory Quality Control

### I. POLICY

It is the policy of the Siletz Community Health Clinic (SCHC) that the laboratory maintains a Quality Control (QC) program to ensure accuracy of results reported. All laboratory staff must be familiar with and adhere to the Laboratory policy and the Quality Improvement policy.

### II. GENERAL STATEMENT

The quality control program involves following the manufacturer's instructions for instrument or test system operation and test performance; having and using a procedure manual; performing calibration and calibration verification; performing control procedures; performing remedial actions; and documentation of all these activities. Patient results will not be released until quality control is satisfactory.

### III. FOLLOWING MANUFACTURER'S INSTRUCTIONS

Following the manufacturer's instructions includes performing instrument maintenance, using approved reagents and controls; following environmental requirements (proper space, temperature, electrical, etc.); following storage requirements for reagents and other supplies; following calibration procedures; and any other instructions the manufacturer has included in the instruction manual or package insert.

### IV. CALIBRATION AND CALIBRATION VERIFICATION

A. The recommendations of the manufacturer will be followed in the calibration of the instruments in the laboratory. The calibrator material that is used is recommended by the manufacturer.

B. Instruments in the laboratory will be calibrated according to the following guidelines:

1. When a lot number of a reagent changes, if required by the manufacturer.

2. As recommended by the manufacturer.

3. When an "out of control" situation exists and cannot be resolved by other measures.

4. When major preventative maintenance or replacement of critical parts that may influence test performance is done.

C. The recommendations of the manufacturer will be followed in calibration of the instruments in the laboratory. The calibrator material that is used is recommended by the manufacturer. Calibration verification will be performed according to the

recommendations of the manufacturer using calibration materials specified by the manufacturer.

## V. CONTROL PROCEDURES

A. The laboratory will follow manufacturer's recommendations when running control specimens. Only assayed control material meeting the manufacturer's specifications will be used. Control specimens will be treated the same as patient specimens. Control specimens will be run in the time frame outlined in the manufacturer's instructions or as outlined in this policy.

B. When an "Out of Control" situation occurs, the steps delineated in the procedure manual will be followed. Results from control specimens will be recorded in the appropriate quality control log. Control material will be reconstituted (if necessary) and stored according to the manufacturer's directions. No patient test results will be reported unless the test system has produced adequate control results on the day the patient test has been performed. All of the above actions will be documented.

## VI. REMEDIAL ACTIONS

Any remedial action taken by the laboratory will be documented on the corrective action form, in QC logs or the instrument log, and reviewed by the Clinical Services Director and the Lab Director. These records will be kept for the period of time required by the nature of the problem.

## VII. BACTERIOLOGY QUALITY CONTROL

A. To meet the quality control requirements for bacteriology, the laboratory must check positive and negative reactivity with control organisms:

Rapid Strep Kit QC will be done once a month and when a new box or lot number of kits has been opened. Additionally, for each Rapid Strep test run, performance of the internal "on board" control must be documented in the patient log sheet.

B. Qualitative results must perform expected reactions before patient results are reported.

## VIII. URINALYSIS QUALITY CONTROL

SIEMENS Multistix®10SG Urine Test strips are tested daily with Quantimetrix Dropper Controls 1 and 2, (normal and abnormal).

## IX. CHEMISTRY QUALITY CONTROL

A. External chemistry controls will be performed using human liquid assayed or control serum to monitor the precision of laboratory testing. Controls for the Abaxis Piccolo Xpress will be ran using BRT chemistry control liquid once a month, with each new lot of reagent discs, a new operator, if test results do not match patient symptoms, or a change in

laboratory conditions. When an "Out of Control" situation occurs, the steps delineated in the procedure manual will be followed.

B. For Blood Glucose Testing three levels of True Metrix PRO with every lot change, when opening a new vial of test strips, if vial has been left open or exposed to extreme heat or cold or humidity, or results seem unusually high or low based on patient's condition. When an "Out of Control" situation occurs, the steps delineated in the procedure manual will be followed.

## X. COAGULATION (INR) QUALITY CONTROL

Two levels of CoaguChek XS Pro PT Control Strips are run once a month and with each box of test kits, with each shipment, or with a lot change. When an "Out of Control" situation occurs, the steps delineated in the procedure manual will be followed.

## XI. URINE DRUG SCREEN CONTROL

Two levels of Alere iScreen Urine Drug Controls are run with every new lot number or new shipment of testing devices and monthly to test the reliability of products in storage. When an "Out of Control" situation occurs, the steps delineated in the procedure manual will be followed.

## XII. DCA SYSTEMS QUALITY CONTROL

Two levels of DCA Analyzer controls are run once a month, with each new lot number or new shipment of test cartridges, with new user training, and if results do not match patient's clinical condition. When an "Out of Control" situation occurs, the steps delineated in the procedure manual will be followed.

## XIII. RAPID INFLUENZA A & B

Two levels of controls are included with each kit. Positive and negative controls should be run with each new lot or shipment, each new operator, and monthly. When an "Out of Control" situation occurs, the steps delineated in the procedure manual will be followed.

## XIV. H. PYLORI

H. Pylori kit has internal and external controls. Positive and negative controls are located with each kit. These should be run every 20 tests or once a month, whichever is sooner. They should also be run with each new lot number or shipment.

## XV. HEMOCUE Hb 201+

Hemocue Eurotrol contains three levels of control solution. Three levels of control must be run monthly and with each new lot number of micro cuvettes or shipment.

## XVI. TABLE OF QUALITY CONTROLS

| TEST | INSTRUMENT | QC MATERIAL | QC FREQUENCY |
|---|---|---|---|
| Urinalysis | Clinitek Status | Quantimetrix Level 1 and 2 | 2 levels each day and with lot change |
| Urine HCG | Rapid test kit | Quantimetrix Level 1 and 2 | new shipment or lot change and once a month |
| CMP | Piccolo | BRT Chemistry Control liquid assayed | Each new lot number and once a month |
| HgbA1C | DCA Analyzer | DCA control solution 2 levels | With new lot number and once a month |
| INR | CoaguChek XS+ | Coaguchek XS + controls | 2 levels with every new shipment or lot change and once a month |
| Fingerstick Glucose | True Metrix PRO | True Metrix PRO 3 levels | With each new vial of strips opened |
| Rapid Group A Strep | Rapid test kit | 2 controls located with kit | Monthly and with each new lot or shipment |
| Urine Drug Screen | Rapid test kit | Alere iScreen | Two levels with each new lot of tests and once a month |
| Hemoglobin | Hemocue | | Each new lot of cuvettes and once a month |
| Rapid Influenza A & B | Rapid test kit | 2 controls located with kit | Each new lot or shipment and monthly |
| Lead level | Lead Care II | Included in kit | Each new box, once a month, or question of validity of results, and new users. |
| H. Pylori | Waived | 2 controls located with kit | Every 20 tests or once a month whatever is sooner |
| | | | |
| Covid-19 | Abbott ID NOW | Included in kit | Monthly and with new lot number |
| Covid-19 | Binax | Included in kit | Monthly and with new lot number |

## XVII. CONTROL INTERPRETATION

A. When a control test result is within acceptable limits (2 SD from the mean) it is considered to be "In-Control." Once the control result is acceptable, patient specimens can be tested. When the control result is outside the acceptable limits it is considered to be "Out of Control." When an Out of Control situation occurs, steps must be taken to determine why the result was not acceptable. When a result is out of control the appropriate action is:

1. Check the reagents for proper dating and/or deterioration. All the reagents used in the testing process including the control specimens should be examined to make sure they have not exceeded their expiration dates, to make sure there is no visual evidence of deterioration, and even to make sure that they have been stored properly.

2. Check instrument to make sure it is working properly. Perform a visual check of the instrument to make sure it has been maintained properly, make sure all lights are working properly, that all mechanical parts are working properly, and that there are no error messages

3. Use new controls. If the result is within acceptable limits and if both results are "In-Control," proceed with patient samples. Discard the first vial of control material as it is no longer reliable.

4. If all of the above actions still do not produce acceptable results, there is probably a problem with the test system (instrument, reagents, or technologist) and further investigation of the source of the problem is necessary. This may involve having another technologist perform the test, rechecking the procedure manual for proper technique or troubleshooting, checking the electrical supply, recalibrating the instrument, or contacting the manufacturer. Document all problems in the Problem/Corrective Action Log and notify the supervisor.

5. No patient specimens can be processed until the problem has been resolved. Whatever steps are taken to resolve the problem must be documented in the appropriate log.

## XVIII. PROFICIENCY TESTING

A. The laboratory is enrolled in the American Association of Bioanalysts (AAB) and obtains challenges for all tests performed, when such challenges are available. The laboratory will test proficiency specimens in the same manner as patient specimens.

B. Communication with other laboratories to discuss proficiency results is prohibited prior to cut-off date for submission of the test results. It is also prohibited to send Proficiency Testing samples to another laboratory for analysis.

C. Follow the instructions for sample preparation. Initial and retain the printouts from any instrumentation. Fill out the report form and make a copy for the laboratory file. All printouts should be stapled to the copy and filed in the Proficiency Testing notebook. Record all results exactly as a patient would be entered. All personnel performing the testing will sign and turn the report over to the Lab Director for signature and mailing.

D. Proficiency tests will be reviewed with the technologists and Lab Director. Corrective action for any unsatisfactory test result will be documented on the report from the AAB program with corrective actions listed. The results of any unsatisfactory proficiency testing will be

discussed with the quality assurance committee should the error warrant further action not taken by corrective actions initiated.

## XIX. CORRECTIVE ACTIONS

A. Corrective action must be applied as necessary to maintain the laboratory's operation for testing patient specimens in a manner that assures accurate and reliable results and reports. All corrective actions must be documented for the following conditions:

1. Test systems do not meet the laboratory's established performance specifications as explained in the method verification section.

2. Results of control and calibration materials fail to meet the laboratory's criteria.

3. Patient results cannot be reported within the time frames established.

4. Errors in reported patient results are detected.

B. The corrective action logs are used to document problems and corrective action taken to correct them.

## XX. QUALITY CONTROL RECORDS

All records of quality control activities must be maintained and retained for at least two years.

## Part 15E
## Laboratory Safety

### I. PURPOSE

To ensure the safety of all staff and the community and to be as transparent as possible about conducting high-quality laboratory testing and patient care.

### II. FIRE SAFETY

A. Work site and laboratory fires pose a potential hazard to laboratory staff and patients. All laboratory staff shall follow the general laboratory fire safety guidelines listed below.

B. Guidelines

1. Smoking is prohibited in the laboratory (SCHC campus is smoke free).

2. Flammable or combustible liquids and chemicals will be stored in approved containers.

3. Laboratory exits will be unobstructed by equipment, supplies, or trash in order to provide adequate escape routes.

4. Flammable solvents will be disposed of in metal containers.

5. Trash will be segregated from heating instruments and open flames.

6. Flammable liquids will not be used in the presence of ignition sources.

### III. ELECTRICAL SAFETY

A. Unsafe electrical use and maintenance may result in serious injury or other dangers for patients and staff. A preventive approach to electrical concerns maximizes safety. All laboratory staff shall follow the general laboratory electrical safety guidelines listed below.

B. Guidelines

1. Assure proper wiring, permanent or temporary, is installed for all equipment. If doubt exists, consult with maintenance.

2. Assure that all 3-wire equipment is properly grounded. Plug adapters (three-prong to two-prong adapters) known as "cheaters" will be avoided.

3. New electrical equipment and installations must be installed and maintained by maintenance before put into use.

4. Flexible extension cords will be used only as temporary extensions for portable equipment and will be approved by maintenance prior to use.

5. Extension cords will be examined periodically. Extension cords will not be arranged so as to impose an impediment or hazard to personnel movement.

6. Two-wire extension cords will be avoided.

7. Do not use extension cords in wet locations.

8. Extension cords must not be plugged into multiple adapters or other extension cords.

9. Grounding and voltage checks of all electrical outlets, along with an electrical safety inspection, are done by maintenance.

10. Electrical instruments will be unplugged before attempting to repair them.

11. Avoid handling an electrical device that is connected to a power line while hands are wet.

12. Unplug electrical equipment that causes a vibratory or tingling sensation when touched. Notify maintenance to evaluate the origin of this potential malfunction.

13. Blown fuses will be replaced with the same type and size fuse. Investigate the possibility of a short circuit or overload if the instrument fuses blow frequently. Never insert fuses in a live circuit.

14. Surge protection features will be used on computerized equipment and will be approved by the IS department.

15. Cube taps (plug in multiple adapters not affixed to an outlet) and multiple outlet adapters attached to a receptacle, but not fused internally, will be avoided.

## IV. ELECTRICAL SHOCK

The appropriate and rapid response to an electrical shock accident may save the life of another individual. Frequently, the victim may be unable to free himself from contact with the "live" electrical source. The victim should be promptly removed from the electrical source, but only if precautions are taken to ensure the responding staff member is not shocked also. Do not touch the victim until the current/circuit has been shut off. If the current cannot be turned off, a wooden stick or other insulated device may be carefully used to push the victim from the electrical contact. Take caution to refrain from contacting the wires. Once safely removed from the electrical source, assess the victim, call for help, and initiate basic CPR if necessary.

## V. CHEMICAL HAZARDS AND SAFETY

A. Laboratories may contain many caustic, toxic, flammable, and unstable reagents. A basic knowledge of the potential hazardous chemicals used in the laboratory is a first step to maintaining a safe work site. Proper disposal of these used chemicals is also important to protect staff, other individuals, and the environment. All laboratory staff shall follow the general laboratory chemical hazards and safety guidelines listed below and will refer to OSHA or the CDC for the most current guidelines.

B. Guidelines

1. Staff has a right to receive information about the hazardous chemicals to which they may be exposed. The employer has the obligation to inform employees about potentially hazardous chemicals ("Right to Know" legislation).

2. Federal regulations require all chemical containers to be labeled with a health hazard rating, a flammability rating, a reactivity rating, and a category or instructional message. A diamond-shaped placard or danger sign, informing of the type of hazard, may be used to alert individuals of potential hazards.

3. Chemical labels must include the name, statement of health hazards, precautions, effective overexposure, and pertinent first aid procedures. Laboratory staff will be instructed how to properly identify and interpret chemical labels.

4. Federal and state laws require all hazardous chemical manufacturers to provide the purchaser with a safety data sheet (SDS). The SDS provides information about the product, hazardous ingredients, physical data, fire and explosion data, potential health hazards, reactivity, spill/leak and disposal procedures, protective information, and handling and storage precautions.

5. All laboratory staff will be instructed about the availability and proper use of SDS forms.

6. All SDS forms must be kept on file in the laboratory and is freely available to all staff. Information is obtained by phoning the company or visiting their website and supplying the product name, manufacturer, and product number.

7. Suitable personal protective equipment (gloves, eye and face shields, laboratory clothing, etc.) must be worn by staff when handling potentially hazardous chemicals.

8. An eye wash station is available to staff.

9. Bottles of acid, caustic materials, or other reagents will be held firmly around the body of the container with both hands.

10. Mouth pipetting must never be performed in the laboratory.

11. All broken skin (cuts, abrasions, etc.) must be suitably covered for protection with gloves, gowns, eyewear, or laboratory coats.

12. Eating and drinking are not permissible in the laboratory except in designated clean, non-patient care areas.

13. Smoking is not allowed in the laboratory.

14. Always add acids slowly to water while mixing when diluting acids. Water will never be added to concentrated acids because thermal generation may result.

15. When pouring water-soluble reagents into a drain, flush with large amounts of water.

16. Never pour several reagents into the sink simultaneously.

17. Never pour ether or other petroleum solvents into the sink. Flammable substances must be disposed of in a safety container labeled as "organic solvent disposal container."

18. Carefully flush solutions containing sodium azide with large quantities of water.

19. Highly toxic, reactive chemicals will be neutralized prior to sink disposal.

20. Accidents happen and precaution will be exercised when cleaning up a chemical spill. Appropriate personal protective equipment and cleaning materials must be readily available. Neutralizing agents, such as sodium bicarbonate or sodium bisulfate, vermiculite, sand, or other substances may be helpful. A spill kit is kept in lab at all times.

21. Follow these steps when cleaning up a chemical spill.

    a. Notify co-workers, Clinical Services Director, and Lab Director immediately.

    b. Use appropriate personal protective equipment (gloves and protective clothing).

    c. Eliminate all sources of ignition if the substance is flammable.

    d. Maintain proper ventilation in the area.

    e. Cover the spilled chemical with an appropriate neutralizing agent. Chemical spill kits are located in a labeled cupboard or available from maintenance.

    f. Absorb all liquid with appropriate agents found in spill kits.

g. Dispose of neutralized waste by bags provided in the spill kits.

h. The area of the chemical spill will be washed with soapy water and dried.

## VI. EYE SAFETY

A. Eyes may be the most important sensory organ. Care should be taken to protect the eyes while working in the laboratory. Use appropriate Personal Protective Equipment (PPE) following the Standard Precautions Policy

B. Standard Precautions

1. Eye protection or face shields must be worn when working with chemicals, potentially aerosolized fluids containing infectious organisms, or when there is risk of being struck by a flying object, spray, or splash of other materials. Goggles or face shields should be made available to each employee.

2. All staff will have knowledge of the location and operation of eye wash stations.

3. Eye wash stations must be available for use in the emergency flushing of the eyes if a chemical, caustic, corrosive, or other hazardous solution is accidentally splashed into the eyes. There is an eye wash station in the laboratory.

4. If a substance enters your eye, proceed to the eye wash station and obtain assistance. The upper and lower eyelids will be held open and the eyes will be flushed with water for a period of not less than 15 minutes. Topical ocular anesthetics may comfortably facilitate this procedure.

5. Eye wash stations will be activated once a month to clean debris or accumulated rust from the pipe.

## VII. CENTRIFUGE SAFETY

A. Interference with an activated centrifuge by an impatient staff member can result in bodily injury in the form of direct trauma or aerosolization of hazardous droplets. All laboratory staff shall follow the general laboratory centrifuge safety guidelines listed below and shall refer to the instrument manual for additional information.

B. Guidelines

1. Centrifuges must never be operated without a cover in place.

2. Uncovered specimen tubes must not be centrifuged.

3. Centrifuges must never be slowed down or stopped by grasping the device with your hand or by applying another object against the rotating equipment.

4. Be sure the centrifuge is appropriately balanced before activating. If an abnormal noise, vibration, or sound is noted while the centrifuge is in operation, immediately stop the unit (turn off the switch) and check for a possible load imbalance.

5. Clean the centrifuge periodically with an EPA approved disinfectant. Broken tubes or liquid spills must be cleaned immediately.

6. Do not disconnect the centrifuge cover safety interlock for any reason.

7. Jewelry, hair, clothing, and hands must be kept away from the centrifuge when activated.

## VIII. WASTE MANAGEMENT

A. The responsibility for proper waste management belongs to the laboratory producing the waste. Recent OSHA guidelines direct the proper techniques of waste management. The Environmental Protection Agency (EPA) also has regulations concerning waste management.

B. Consult safety data sheets (SDS), reagent manufacturers, local health departments, or safety officer for additional information about waste disposal.

C. The laboratory will adhere to specific waste disposal procedures to minimize the risk to employees in the laboratory and those individuals disposing of the waste materials.

D. Waste will be segregated by specific type and will be suitably labeled. The labels will indicate the specific potential hazards and contact person to notify in case of a hazardous spill.

E. Waste segregation categories include paper and domestic waste, hazardous non-chemical solid waste (sharp items like glass, needles), bio-hazardous waste (infectious or potentially infectious specimens, blood contaminated products, or microbiology cultures), and chemical waste (by-products of diagnostic reactions and equipment drainage).

F. Paper or domestic waste may be handled by local trash disposal procedures and buried in a landfill or incinerated.

G. Hazardous non-chemical solid waste (broken glassware, slides, needles, or any sharp item) must be collected separately from domestic (paper) waste and packaged in rigid sharps containers to prevent accidental injury. Waste of this type is collected by the maintenance department. This waste is boxed and stored for contractor to pick up and incinerate.

H. Regulated or bio-hazardous waste contains blood or pathogens with sufficient virulence and quantity that exposure could result in acquiring an infectious disease for a susceptible individual.

1. Warning "Biohazard" labels must be affixed to containers of blood or other potentially infectious material. The label must be fluorescent orange or orange-red, with lettering or symbols in a contrasting color. Labels will be secured to the container in a manner to prevent unintentional removal. Red bags or red containers may be substituted for labels. Note: Waste that has been previously decontaminated need not be labeled or color-coded.

2. Any contaminated sharps will be placed in a rigid sharps container and incinerated or buried in a landfill. The container will be a closable, puncture-resistant, labeled or color-coded red, and leak-proof on the sides and bottom.

3. The sharps container must be easily accessible and positioned near the location where sharps are used.

4. The container must be maintained upright and replaced routinely when full.

5. Prior to moving the sharps container for disposal, close the container to prevent spillage or protrusion of contents during handling and transport. If leakage is probable, the sharps container will be placed into a larger second container. If contamination occurs on the outside of the initial sharps container, it will be placed into a second container. The second container should be designed and suitably labeled as the initial container.

6. Materials normally excreted by patients may be disposed of into the sewer system.

I. Chemical waste or hazardous waste must be disposed of in compliance with EPA regulations. Hazardous chemicals are not normally used in the laboratory; however, many low hazardous chemicals are in use. Many liquids, such as acid solutions, peroxide, or reagent solutions may be disposed of in a landfill or by the sanitary sewer provided they are flushed with large amounts of water.

J. All laboratory personnel must:

1. Identify and classify waste.

2. Determine the appropriate collection and packaging methods.

3. Follow and abide by local, state, and federal waste management regulations.

4. Ensure safe handling and proper disposal of all laboratory waste; based on existing regulations.

## IX. SAFETY INSPECTIONS

The laboratory will be surveyed or inspected regularly by the Infection Control Officer and Safety/Infection Control Committee to ensure proper safety practices and procedures have been

implemented and complied with fully. Noncompliant safety practices must be identified, documented, and corrective action taken to attain complete laboratory safety compliance. The Infection Control Officer is responsible for conducting inspections in the facility.

## X. INFECTION CONTROL

The laboratory will follow the Infection Control Policy and will participate in all infection control trainings required by the SCHC.

| SILETZ COMMUNITY HEALTH CLINIC | |
|---|---|
| Program | Laboratory |
| Policy | Laboratory Specimens |
| Date Approved | 08/29/01 |
| Date Revised | 11/05/05; 05/02/09; 05/05/12; 12/21/18; 06/18/21 |

## Part 15F
## Laboratory Specimens

### I. PURPOSE

To provide an overview of specimen collection, processing, accessioning, rejection, and reference testing.

### II. SPECIMEN COLLECTION

Appropriate patient preparation and specimen collection are performed for each test ordered. Specific requirements are a part of written test procedures. Only adequately trained individuals may perform venipuncture procedures or capillary punctures.

### III. SPECIMEN LABELING

All patient specimens are labeled at the time of collection. Label blood tubes with the appropriate computer generated label. Labels will show the patient name, DOS, and PRO number. Perform dual patient verification prior to labeling specimen tubes.

### IV. REFERENCE LABORATORY PROCESSING

A. All specimens referred to the reference laboratory must be ordered and accessioned in the Electronic Health Record (EHR).

B. A hard copy of the requisition is required to accompany each test request with complete patient information including chart number, date of birth, patient's sex, test requested, specimen source, date and time of collection, and the provider requesting the test.

C. Specimen collection requirements are checked on an as needed basis for variances in handling, storage, and requirements for appropriate tubes, etc. as specified in the Lab Corp Reference Laboratory Guide or the LabCorp Website.

1. Specimens, which require freezing, are frozen completely and then placed into a frozen storage transport container, which is provided by the reference laboratory.

2. Specimens, which require refrigeration, are double bagged with an ice pack.

D. All specimens are placed in the appropriate container located in the employee entrance stairwell at the end of each workday. These specimens are then picked up between 5:30 pm-6:00 pm by the LabCorp courier service.

E. LabCorp has an interface with the EHR. LabCorp automatically sends results across the interface twice daily. LabCorp also sends the patient test results to the laboratory printer. These results are verified and checked to ensure they are in the EHR.

F. All laboratory results are screened for critical values and referred directly to the provider who ordered the test for appropriate action as soon as possible. If the primary provider is unavailable, the results will be given to the Lab Director and/or Medical Director.

G. The laboratory staff will ensure all reportable results involving positive STD's, HIV related testing, or other reportable diseases are given to the ordering provider's registered nurse as soon as possible.

H. A "Sendout Requisition Log" will be reviewed daily to keep track of the specimens that have been sent to LabCorp. Tests that have been incomplete for more than three days will be followed up on by a phone call to LabCorp.

I. Cytology specimens, including tissue biopsies and PAP smears, are referred to LabCorp. They must be accompanied with a hard copy of the test requisition with all of the patient information listed above. In addition, these types of specimens should also include clinical information appropriate to the site.

## V. REFERENCE LABORATORY INTERFACE

A. The Laboratory / Reference Laboratory Interface is monitored daily for completeness of data retrieval, as well as any problems with the interface. The interface is monitored by Information Services staff. They will notify laboratory staff of any test results not coming through and work with LabCorp to resolve the issue. Test results are verified in NextGen by laboratory staff.

B. Scanning of Esoteric Test Results into EHR

While most tests are already built into the laboratory interface, occasionally an esoteric test will not cross the interface. In order to minimize the delay in receiving the results, contact LabCorp to fax the result. Use the Medical Records fax # 541-444-9695. The faxed results will be submitted to Medical Records and scanned into the patient's EHR.

## VI. APPROVED REFERENCE LABORATORIES

A. Below is a list of reference laboratories that have been approved by the Medical Staff to perform tests:

1. LabCorp, Seattle, Washington

2. Oregon State Health Laboratory, Portland, Oregon

3. Samaritan Pacific Communities Hospital, Newport Oregon

4. MD Laboratories, Reno, Nevada

B. The reference laboratories are accredited and licensed under CLIA '88. Proof of current accreditation is filed in the Quality Improvement Coordinator's office.

C. All tests performed by the approved reference laboratories shall have the name and address of the reference laboratory on the test report which is transmitted electronically into the patient's EHR. Results which are faxed copies are scanned into the EHR by medical records staff.

D. Laboratory staff will enter reference laboratory results into EHR and verify that all the tests, which were sent out, have been completed.

## VII. TRANSPORTATION OF SPECIMENS TO THE REFERENCE LABORATORY

A. Specimens which are sent out will be ready and placed in the lock box located in the staff entrance at the end of each workday (5:00 pm-5:15 pm). These specimens are then picked up between 5:30 pm- 6:00 pm by the LabCorp courier service. If there are no specimens for a particular day or if the clinic will be closed, laboratory staff will call LabCorp at 1-800-598-3345. SCHC has two accounts with LabCorp to process and bill for tribal and non-tribal patients.

B. All specimens with corresponding paperwork will be placed in the appropriate biohazard bags provided by LabCorp, which are properly labeled with biohazard information. If there are any problems with leaks or spillage, notify LabCorp for further instructions.

C. Specimens requiring room temperature storage will be placed in the "ROOM TEMP" labeled insulated lockbox without any ice bags.

D. Frozen specimens will be labeled as such and placed in a frozen specimen transport bottle provided by LabCorp then placed in a biohazard bag and placed in the Styrofoam insulated refrigerated/frozen labeled lockbox.

E. Refrigerated specimens will be labeled as such, double bagged with an icepack and placed in the insulated refrigerated/frozen labeled lockbox.

F. For security, the storage containers are behind key card locked door only accessible with authorized key card.

## VIII. UNACCEPTABLE SPECIMENS

Specific specimen requirements are listed for each analyte tested in the test procedures. The condition and disposition of unacceptable specimens is reported to the provider and recollection is requested. If the reason for rejection is known, that information should be documented in the comments section of the original order. If a specimen is reported unacceptable from LabCorp or other reference laboratory, the test is cancelled in the computer with a comment indicating recollection is necessary. If the test is performed and results are reported on less than optimal

specimens, the condition of the specimen is also recorded on the patient's report form and in the computer.

## IX. STANDARD PRECAUTIONS FOR SPECIMEN COLLECTION

A. All specimens must be handled as potentially infectious. Practice standard precautions provided in the Infection Control Policy.

B. Standard precautions apply to:

1. Blood
2. Semen and vaginal secretions
3. Fluids (CSF, synovial, peritoneal, amniotic)
4. Tissues
5. Feces and vomitus, unless visibly bloody
6. Nasal secretions, sputum, urine, saliva, and tears, unless visibly bloody

C. Use appropriate Personal Protective Equipment (PPE)

1. Wear gloves for all blood specimen collection
2. Wear gowns, masks, and eye wear when splatters, sprays, and aerosolization are possible

D. Wash hands following the Hand Hygiene Policy using soap and water or an alcohol based hand rub:

1. Before having direct contact with patients.
2. Between patients.
3. When hands are visibly dirty or are visibly soiled with blood or other body fluids.
4. Before eating and after using a restroom.
5. After providing care to a patient with a diarrheal episode or with known or suspected C. difficile infection.
6. When moving from a contaminated body site to a clean body site during patient care.

7. After removing gloves.

8. When leaving the work area.

E. Safely dispose of contaminated waste and sharps.

F. Keep work surfaces, counter tops, and drawing stations clean.

1. Wipe down all counters and surfaces with an approved EPA registered disinfectant daily and when surfaces become soiled.

2. Wipe down the drawing station and phlebotomy chair in between patients with an EPA registered disinfectant.

3. Wipe down any surface with an approved EPA registered disinfectant if it becomes visibly soiled or contaminated.

## X. SPECIMEN TYPES AND VOLUMES

For specimen types refer to the "Test Description Information" in the manufacturer's instructions or machine manual provided by the manufacturer. Citrated plasma is used for Coagulation. For reference laboratory testing, refer to the LabCorp Reference Guide

## XI. VENIPUNCTURE

Blood is the most frequent body fluid used for analytical purposes. The relative ease of obtaining venous blood makes this a primary source of specimen for clinical laboratory analyses. Venipuncture is accomplished via a syringe or a vacutainer needle attached to vacuum-pressurized plastic tubes. All venipunctures shall be performed following Standard Precautions

## XII. FASTING AND GLUCOSE TOLERANCE SPECIMENS

A. Fasting specimen means no oral ingestion from midnight to the time the specimen is drawn. Ingestion of water is allowed in most cases. For lipid studies, periods of fasting for 12 hours are ideal. If the patient is fasting or not, make a note in the string questions in order module.

B. Glucose Tolerance Specimens

1. Patient must be free of recent surgery, trauma, or illness for two weeks

2. Normal carbohydrate intake three days prior to testing is recommended

3. Patient should be fasting for no less than eight hours and no more than 16 hours

4. Test should start between 7:30 am and 9:00 am

5. During test, patient must not smoke, drink coffee, or exercise

C. Test specific requirements

Specific specimen requirements depend on the test ordered. Refer to each individual test procedure for specific specimen requirements.

## XIII. GENERAL GUIDELINES FOR NON-BLOOD SPECIMEN COLLECTION

All non-blood specimen collection done by the nursing staff (Paps, throat swabs, GC cultures, etc.) shall be properly labeled with the patient's information and transported to the laboratory for processing in biohazard labeled containers.

## XIV. GENERAL GUIDELINES FOR HANDLING AND STORAGE

A. Serum specimen: Allow blood to clot for 20-30 minutes in a non-additive tube or for 15 minutes if a serum separator tube is used.

B. Plasma or serum: Centrifuge for five minutes at 4000g.

C. Refrigerate specimen if testing cannot be done within two hours or more.

D. Freeze serum for longer delays (more than 24 hours).

E. Refer to test procedure and the reference laboratory book or website for specific specimen handling requirements for send out tests.

| SILETZ COMMUNITY HEALTH CLINIC | |
|---|---|
| Program | Laboratory |
| Policy | Retention of Records and Specimens |
| Date Approved | 08/29/01 |
| Date Revised | 11/05/05; 05/02/09; 12/21/18; 06/18/21 |

## Part 15G
## Retention of Records and Specimens

### I. POLICY

It is the policy of the Siletz Community Health Clinic (SCHC) to ensure laboratory records and specimens are maintained in accordance with accrediting and regulatory agency requirements, using the schedule set forth in this policy.

### II. RECORD KEEPING

A. Record keeping is critical to providing quality patient care. Records will be kept complete and up to date. The staff member performing the work is responsible to document corrective actions and maintain daily logs to complete necessary records.

B. Results of laboratory testing will be retained permanently in the patient's Electronic Health Record. This includes outside reference laboratory results. A printed copy of the order requisition will be kept in a file organized by day of week until laboratory staff has verified results have been received.

C. Quality Control (QC) will be reviewed on a weekly basis and evaluated.

1. Quality control logs will be kept for three years.

D. Proficiency test results are filed in binders by year. These will be retained for the current year plus two years.

E. Maintenance logs and records will be maintained with the instrument binders for the life of the instrument plus two years.

F. Instrument calibration verification records are maintained for two years.

### III. RECORD REVIEW

Laboratory records will be reviewed by the Clinical Services Director completely each quarter. The Lab Director shall review all records on a regular basis with the lead laboratory technologist and Clinical Services Director. All QC records will be initialed by the Clinical Services Director along with comments. Both the Lab Director and lead laboratory technologist will review and initial proficiency test results along with corrective action or comments.

### IV. DISPOSAL OF CONFIDENTIAL RECORDS

A. All records which contain patient information or test results must be handled in a confidential manner. These records must be discarded in a manner which leaves them indecipherable.

B. Papers and labels to be discarded, which contain patient information and/or laboratory results, are placed in a special shred pile after removing any staples or paper clips. These papers are removed at least weekly and taken directly to the shredder for shredding. Examples of such records are patient lists, incomplete reports, messages with patient information, extra copies, labels, etc.

## V. SPECIMEN RETENTION

A. Blood and urine obtained for testing will be stored for one week past the day testing was performed.

B. No records should be destroyed without the approval of the Clinical Services Director or Lab Director.

| SILETZ COMMUNITY HEALTH CLINIC | |
|---|---|
| Program | Laboratory |
| Policy | Test Requisition and Order |
| Date Approved | 04/02/12 |
| Date Revised | 12/21/18; 06/18/21 |

## Part 15H
## Test Requisition and Order

### I. AUTHORITY TO ORDER TESTS

A. Tests can be ordered by physicians, dentists, optometrists, and other licensed providers. Nurses, public health nurses, and pharmacists are allowed to order certain tests using written standing order protocols. Providers will coordinate orders from outside providers who are providing a service to clinic patients. Only labs which are approved by an in-house provider will be performed. Contact the Clinical Services Director or Lab Director if there are questions regarding the authority to order tests.

B. Patients and staff outside of those mentioned above are not allowed to order tests. Results of tests are released to those staff members who are authorized to order tests.

### II. REQUISITIONS

A. Requests for laboratory testing, either computer generated or hand written, must include the following legible information:

1. Patient's Name
2. Patient's Chart Number
3. Test Requested
4. Ordering Provider
5. Date of Birth
6. Gender
7. ICD 10 Code

B. Most of the above information is normally provided when tests are ordered in the laboratory module in the Electronic Health Record (EHR).

C. The laboratory staff will ensure that the date and time is on the requisition when the samples are received and accessioned into the computer.

D. Special instructions are sometimes given to fax results or send copies to another physician. The technologist who has performed or processed the specimen will assure that the results are faxed or given to medical record staff for faxing.

E. Specific requisitions are required for each reference laboratory for testing. More information about reference laboratory testing is contained in the section on reference

laboratories in this policy. A complete manual from LabCorp is located in the laboratory along with access to this information on their website at www.labcorp.com .

## III. PENDING ORDERS AND STANDING ORDERS

A. Requests are sometimes ordered in advance for testing to be performed when it is convenient to the patient or for a scheduled appointment. These orders are entered into the laboratory computer via the EHR. On the day the tests are to be performed, the patient must register at the main front desk, and present to the laboratory. The laboratory will review the EHR for requested tests and perform testing as ordered.

B. Occasionally, "Standing Orders" will exist for patient's that require periodic laboratory testing for monitoring of therapeutic procedures, (i.e. Coumadin therapy). Standing orders are good for one year. After one year the order must be reviewed by the ordering provider and if it is to continue an updated standing order must be received by the laboratory.

## IV. TEST ORDERING

A. Tests are performed at the written or electronic request of an authorized person. Oral requests are not permitted.

B. Outside providers who call in test orders should be instructed to fax orders to the clinic fax machine at 541-444-9695.

C. Test requisition forms will include the patient's name, chart number, date of birth, and sex; name and address or other unique identifier of person who ordered the test; date of collection; ICD-10 code; time of collection; source of specimen, if pertinent; test name; and any other relevant and necessary information for a specific test to assure accurate and timely testing and reporting of results.

D. For PAP smears, all the above will be included; in addition, the ordering requisition will contain the date of the last menstrual period, indication of a previous abnormal report, treatment or biopsy, if available, and specimen source.

| SILETZ COMMUNITY HEALTH CLINIC | |
|---|---|
| Program | Laboratory |
| Policy | Reporting Test Results and Error Correction |
| Date Approved | 08/29/01 |
| Date Revised | 11/05/05; 05/02/09; 05/05/12; 12/21/18; 06/18/21 |

## Part 15I
## Reporting Test Results and Error Correction

### I. POLICY

It is the policy of the Siletz Community Health Clinic (SCHC) to ensure that all laboratory tests are performed and resulted in a timely manner, any errors found are corrected as soon as possible, and all tests that are sent to the reference laboratory are tracked.

### II. TEST RESULTS

A. All tests (except those specifically excluded) sent to the reference laboratory will have an acceptable turn around time of 72 hours.

B. A copy of the requisition is kept in the daily tracking folder until results are received.

C. When it has been verified that the test result is in the patient's Electronic Health Record (EHR) the requisition copy is to be discarded in the confidential recycling bin.

D. If test results are not back in 72 hours the laboratory staff will call LabCorp to check the status of results. Any information received from LabCorp about result status will be documented on the order requisition along with the date of the follow up phone call and staff initials. Follow up will continue until results are received.

E. All laboratory test results are reviewed by laboratory staff. A physical copy is printed on the Lexmark lab printer.

F. Test results from the reference laboratory are automatically generated into the provider's acceptance queue.

G. If the results fail to print, first troubleshoot the printer. Usually rebooting it will re-establish the connection to Beacon. If this does not solve the issue and no other issues are found with the printer, LabCorp will be notified and they will remote access the computer to re-establish the interface connection. Laboratory reports should print every day.

H. If you fail to see results coming in, this problem must be corrected within 48 hours. Document the issue in the incident log along with what was done to correct issue.

### III. CRITICAL LABORATORY RESULTS

A. Critical laboratory results will be automatically populated to provider's acceptance queue and printed. The printed copy will be taken directly to the provider or the team's registered nurse (RN.) If the ordering provider's team is not available the critical results will be given to the Medical Director.

B. Critical values are flagged by the reference laboratory (LabCorp).

C. After hours reporting of critical results is done via the after hours answering service. Lab Corp and other outside laboratories are able to reach an on call provider 24/7 to deliver critical results.

## IV. COMMUNICABLE DISEASE AND POSITIVE CULTURES

A. A copy of all positive screening tests for STI's, Strep cultures, and wound cultures are given to the ordering provider's RN.

B. The ordering provider's RN is responsible for reporting positive STI results to the Lincoln County Health Department STI Coordinator.

C. In-house COVID-19 results, negative or positive, must be reported to Oregon Health Authority within 24 hours of test. Reporting is completed via web portal for tests completed on patients not in the EMR or is sent electronically for results entered in EMR.

D. The reference laboratory, LabCorp, is responsible for reporting all communicable diseases to the Oregon State Health Department. Refer to Infection Control Policy "Reportable Diseases and Infections".

E. Lead results are sent to the Oregon Health Authority each week via fax, or the same day for elevated lead level. See Lead Procedure for more details.

## V. FAXING TEST RESULTS

A. Occasionally, requests are made to fax laboratory test results to other providers or facilities. It is the responsibility of the laboratory to ensure that policies for sharing personal health information follow HIPPA guidelines and maintain patient confidentiality.

B. Outside Provider Requests:

1. If the laboratory receives a written request for laboratory testing from a provider outside the clinic, and a request that subsequent test results be faxed to their facility, test results will be faxed from the laboratory, as the outside provider is regarded as the ordering provider.
2. If a verbal request or phone call is received requesting faxed copies of laboratory results, and the requestor is not the ordering provider, the call will be transferred to Medical Records, who can ensure that all proper release of information documents are in order.

3. The laboratory staff may not fax laboratory results to anyone other than the ordering provider, unless the request is in writing and complies with HIPPA requirements.

| SILETZ COMMUNITY HEALTH CLINIC | |
|---|---|
| Program | Laboratory |
| Policy | Reporting Test Results and Error Correction |
| Date Approved | 08/29/01 |
| Date Revised | 11/05/05; 05/02/09; 05/05/12; 12/21/18; 06/18/21 |

## VI. ERROR CORRECTION

A. When an error in a laboratory result is discovered, the provider shall be notified and the result shall be corrected as soon as possible.

B. If a scanned laboratory result is entered into the wrong chart, staff will notify the Health Information Lead immediately. That staff person can refile the scanned document to the correct chart.

C. If an in-house performed lab is entered incorrectly the staff member will go back to the original encounter and make the correction. If the encounter is locked, the NextGen Specialist will unlock the encounter and assist with correction. Ordering provider will be notified as soon as possible of correct results.

D. If a laboratory order is placed in the incorrect chart that order will be cancelled and a note made "entered in error". An order will be made in the correct chart.

E. Results from LabCorp to NextGen will be held in the Rosetta Holding Tank if there are any discrepancies between the order information and the resulting information. Information Services staff will notify laboratory personnel if this occurs.