BULLHOOK
Community Health Center

521 4th Street Havre Montana 59501 • Phone: 406-395-4305 • Fax: 406-395-5643 • www.bullhook.com

POLICY

LABORATORY **3014**

PURPOSE:

To provide the highest level of diagnostic care and treatment to all Bullhook Community Health Center patients.

POLICY:

It is the Policy of BCHC to perform laboratory tests ordered by Providers employed by BCHC. No laboratory tests will be performed by outside practitioners due to staffing and Risk Management concerns UNLESS such practitioner or specialist is working in conjunction with the Bullhook Community Health Center Provider for coordination of care.

PROCEDURE:

Laboratory specimens collected at BCHC that do not fall under the CLIA waiver will be sent to outside contracted laboratories for evaluation and interpretation. Upon completion of testing results are then faxed to the Health Center for evaluation by the Provider. After review by the Provider the results are then incorporated into the patient's medical record and plan of care. The patient will then be notified via telephone, if this can be accomplished in a timely manner, or by mail of the results of the tests. Instructions for continues or changes of care and follow up time frames will be included in the telephone call or letter. If at any time the Patient has questions regarding the lab results or care instructions they are welcome to speak with the Provider individually.

Additional laboratory tests that are performed at Bullhook Community Health Center are considered point of care testing and are Clinical Laboratory Improvement Amendments (CLIA) waived. CLIA law specifies that laboratory requirement be based on the complexity of the test performed and established provision for categorizing a test as waived. Tests may be waived from regulatory oversight if they meet certain requirements established by this statute. The following are a list of the current CLIA waived tests performed at BCHC. This may not be a comprehensive list as the list may expand dependent upon the needs of the community.

Specifies tests that are listed in the regulation are:

1. Urinalysis
2. Urine Pregnancy
3. Urine Drug Screen
4. Glucose

5. Hemoglobin
6. Hg A1C
7. INR
8. Lead Testing

Quality control and assurance of the laboratory process is assured through education and annual updates as they relate to laboratory procedures by Medical Coordinators. Initial education is acquired through formal training and education. Upon employment the individual will also undergo training specific to the Policies and Procedures of BCHC. Strict aseptic technique and hand washing guidelines are utilized.

In order to comply with Bullhook Community Health Center Policy:

1. The staff is competent for their assigned tasks.
2. The equipment and reagents are reliable, safe and properly maintained.
3. The methods are modern, accurate, precise and validated.
4. Quality controls for CLIA waived testing are properly performed.

THE FOLLOWING STATEMENTS AND PROTOCOLS REPRESENT THE INTENT OF THE LABORATORY.

PERSONNEL:

The laboratory will staff with those people who have by education, experience, or both the training necessary to perform the tasks assigned to them.

1. Supervisors: The supervisor will oversee the technical and quality control aspects of the laboratory. It will be his/her responsibility to see that the clinical data is accurate, precise and delivered in a timely manner.
2. Records and Rosters: Personnel records will be maintained by the Chief Executive Officer and contain authentication of education and/or experience, continuing education documentation, periodic performance evaluations and job descriptions.
3. Quality controls will be recorded as indicated and performed per individual protocol.

SPECIMEN – COLLECTION AND STORAGE:

The first step in quality laboratory work is proper specimen collection, processing and storage. To this end, the laboratory will maintain a procedure manual that clearly details the processes necessary to obtain the proper specimen for the procedure requested. The following is an outline of the protocols used in this laboratory regarding specimen collection, processing and storage.

1. Specimen Collection: The laboratory procedure manual will contain information concerning the following specimen collection information.
    a. Patient Preparations (i.e., fasting status)
    b. Collection Procedures
    c. Specimen Preservatives
    d. Review of Phlebotomy Procedures
    e. Accessing and Labeling Criteria

   f. Transportation Requirements
   g. Mislabeled Specimen Policy
   h. Labeling of Hazardous Specimens
2. Specimen Rejection Criteria: The individual procedure found in the procedure manual contains information regarding the acceptance or rejection of specimens for that procedure. Information should also be included as to interferences caused by specimens deemed adequate but not ideal. (i.e., turbid, lipemic, slightly hemolyed). Those specimens that have been accepted but are not ideal should have comments explaining those problems on the final charted report.
3. Specimen Storage: Policies regarding the storage of specimens prior to analysis are detailed in the procedure manual.

EQUIPMENT:

The laboratory will maintain records of validation, maintenance, and repair on all instrumentation in the laboratory.

1. Preventative Maintenance and Service: Schedules, charts and other documents pertaining to the maintenance of laboratory equipment is to be kept in the laboratory. Those instruments that are to be serviced under contract by the manufacturer or other designate will have records kept indicating the time, date, and nature of any work performed on them. Copies of work orders will be maintained and kept in a maintenance manual.
2. Instrument Function Checks: The only instrument is the centrifuge.
3. Instrument Safety: Safe operation of the centrifuge.

METHODOLOGY:

All CLIA waived testing will have a procedure attached to the Policy and Procedure Manual.

These procedure manuals will be reviewed on an annual basis by the laboratory director and show their initials or signature on any revisions of the original procedure.

1. Panic Lists: A critical or panic list will contain those lab results that are so abnormal that they indicate that the patient may require immediate medical attention. When results are generated on the patient that falls into the panic list criteria, the results must be personally transmitted by phone or in person, directly to the Provider who can evaluate the test results without delay and take appropriate action.
2. Control Limits: Since different lots or types of control material can be used within the framework of a given procedure, the defined limits for controls need not be given in the procedure manual. Control limits will, however, be posted in clear view, stating the type, lot number, outdate of that particular material.

REAGENTS:

The quality, specification, and disposal of materials in this laboratory shall be monitored to assure that those materials perform as expected and offer no health hazard to employees or patients.

1. Sterilization and Decontamination: Procedure for the decontamination and sterilization of contaminated materials in the laboratory can be found in the Laboratory Safety Manual.

REPORTS:

The final report represents the culmination of a considerable effort on the part of everyone in the laboratory. This document should be clear and precise. The report will be delivered to the Provider in a timely manner.

The final report issued to the Provider will contain the following information:

1. Patient name
2. Date and time specimen was obtained, if applicable
3. Test requested
4. Reporting units (where applicable)
5. Reference intervals (if applicable)
6. Date and time finalized
    a. Prior to the charting of any laboratory results, a review of those results must be accomplished. This review will include a check for clerical errors, incompatible results.
    b. Copies of all laboratory reports will be maintained within the electronic medical record systems.
    c. It is very important that a two-way communication between the Provider and the laboratory staff be maintained. Questions and comments from the laboratory, the Provider and the staff are strongly encouraged.
    d. Confidentiality of all patient information must be maintained at all times.

PATIENT INFORMATION RELEASE POLICY:

Medical records will be available to each patient or in the case of a minor to his/her legal guardian at any time upon the patient's request. Copies of the patient's medical records will only be released to specific parties upon receipt of a signed release for medical information, designating what records may be released and to whom the records may be released.

Cindy Smith Date: 4-21-17
CHIEF EXECUTIVE OFFICER

Carol A Rutherford Date: 4-18-17
CHAIR, BOARD OF DIRECTORS

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