|  |  |  |  |
| --- | --- | --- | --- |
| MID-COLUMBIA MEDICAL CENTER  1700 East 19th Street  The Dalles, OR 97058 | |  | SCOPE:  Laboratory - Point of Care |
| SUBJECT/TITLE: MCMC WAIVED TESTING POLICY | | | |
| DEPARTMENT: Laboratory | OWNER: POCT Technical Supervisor | | |

**Table of Contents:**

1. [[Purpose/Policy] Statement](#Purpose)
2. [Definitions](#Definitions)
3. [Equipment](#Equipment)
   1. [Reagents and Materials](#Equipment_RM)
   2. [Reagent Tracking](#Equipment_RT)
4. [Procedure](#Procedure)
   1. [Specimen Collection](#Procedure_SC)
   2. [Unacceptable Specimen](#Procedure_US)
   3. [Quality Control](#Procedure_QC)
   4. [Calibration](#Procedure_CAL)
   5. [Calculations](#Procedure_Clc)
   6. [Test Procedure](#Procedure_TP)
   7. [Troubleshooting](#Procedure_Tbs)
   8. [Expected Values](#Procedure_EV)
   9. [Critical Values](#Procedure_CV)
   10. [Specimen Storage](#Procedure_SS)
   11. [Reporting Results](#Procedure_RR)
   12. [Limitations](#Procedure_Lim)
   13. [Linearity](#Procedure_Lin)
   14. [Contact Information](#Procedure_CI)
5. [References](#References)

**[Purpose/Policy] Statement:**

The goal of the waived testing policy is to provide a standard for CLIA Waived Laboratory testing by listing testing performed at Mid- Columbia Medical Center (MCMC) and affiliated facilities, asserting requirements for testing procedures, stating minimum requirements for quality control(QC), providing requirements for the reporting of results, identifying qualified personnel certified competent to perform testing using MCMC established competency guidelines.

**Definitions:**

1. Waived Tests- Laboratory Tests which meet the Clinical Laboratory Improvement Amendments of 1988 (CLIA88) requirements to be classified as CLIA waived tests.
2. Abbreviations- POCTS-Point of Care Technical Supervisor, CLA-Clinical Laboratory Assistant, RN-Registered Nurse, LPN-Licensed Practical Nurse, MLS- Medical Laboratory Scientist, MT-Medical Technologist, MLT-Medical Laboratory Technician, MA- Medical Assistant, CNA-Certified Nursing Assistant, RT-Radiologic Technologist, Practitioners-Licensed Independent Practitioners, RD,CDE-Registered Dietitian, Certified Diabetes Educator
3. Point of Care(POC)- see MCMC Point of Care Testing Policy
4. Certified Competent- All personnel performing testing must be identified as certified or deemed competent to perform Laboratory Tests prior to testing patient samples.
   1. Performance and documentation of initial competency and recertification is the responsibility of a Technical Supervisor, designee, or Nurse Educators for Point-of-Care Blood Glucose.
5. Competency guidelines
   1. Initial Competency:
      1. Review of Laboratory Procedure and Manufacturer's Product Insert.
      2. Demonstrate knowledge of Quality Control requirements and expected values.
      3. Direct observation confirming satisfactory test performance and result interpretation.
      4. Adherence to result documentation polices; including manual logs and LIS as applicable.
   2. Recertification/Competency must be assessed at a minimum of once a year. Evaluations to include at least two methods of evaluation per Waived Test:
      1. Test performance as defined by lab (previously analyzed samples, Proficiency testing, blind samples)
      2. Direct Observation of routine patient testing
      3. Performance, monitoring, recording and reporting Quality Control
      4. Verification of required knowledge as demonstrated by written exam performance

**Equipment:**

Equipment, as listed per individual Waived Test MCMC Procedure/Policy, to include maintenance and functional checks as required by manufacturer.

**Reagents and Materials:**

Per each Waived Test Procedure/Policy, Reagents, Quality Controls, Operator Manuals or Guides, and all necessary materials for testing are listed. Product Inserts and Quick Reference Guides are readily accessible at the testing site.

**Reagent Tracking:**

At each CLIA licensed Laboratory testing location:

1. Reagent lot numbers and expiration dates are recorded on associated Test Logs with record of associated testing performed, are recorded in conjunction with Patient Results, or in related software applications.
2. Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following:
   1. Identity and when significant, titer, strength or concentration.
   2. Storage requirements.
   3. **Preparation and expiration dates.**
   4. **Other pertinent information required for proper use.**
3. Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

**Procedure:**

A procedure approved by the Hospital Laboratory Director/Pathologist or designee must be readily available to all testing personnel. This procedure must follow the manufacturer’s instructions and current Test manufacturer package insert content to include:

* 1. Principle of test and clinical usage.
  2. List of equipment and maintenance\*.
  3. List of reagents and materials to including storage, handling, and stability information.
  4. Procedure:
     1. Specimen collection
     2. Unacceptable Specimen
  5. Quality Control
     1. Frequency and type
     2. Corrective action when quality control is unacceptable
  6. Calibration, if applicable
  7. Test Performance Procedure
  8. Troubleshooting\*
  9. Expected Values/Reference ranges
  10. Critical values, if applicable
  11. Specimen storage
  12. Reporting results
      1. Includes not reporting patient results unless quality control is acceptable
      2. Includes any units as described in Test package insert
      3. Includes directions to send specimens for confirmatory tests when required by manufacturer
  13. Limitations of test
  14. Linearity

**NOTE:**  \***Reference to manufacturer’s manual for listed requirements is acceptable if contents of manual reflect the testing needs of MCMC.**

**Specimen Collection:**

Only unprocessed samples are used for Waived Testing. Sample collection types, handling and storage are described in individual MCMC test procedures/policies for manufacturers intended use only.

**Unacceptable Specimen:**

Specimens are ineligible for testing and are to be rejected if they meet any of the criteria described below:

1. Specimen is not properly labeled with two unique patient identifiers - such as name, date of birth, medical record number, etc...
2. Specimen stored for a duration exceeding those described in "[Specimen Storage](#Procedure_SS)" for specimen type.
3. Specimen volume is insufficient for analysis.
   1. Minimum specimen volume described per test method:
4. Specimen is not collected as described in "[Specimen Collection](#Procedure_SC)".

**Quality Control:**

1. Quality Control (QC) checks will be performed in accordance with manufacturer’s requirements at a minimum. QC testing materials, intervals and procedure will be described in each individual MCMC Waived Test Procedure/Policy.
   1. External QC must be acceptable prior to Patient Testing.
   2. Internal QC must be acceptable (noted as PASS) for a Patient test result to be valid. Invalid test results will not be documented in a Patient Record.
2. Documentation of all QC results, instrument problems and QC problems must be kept at the location of testing unless managed remotely via a software program i.e., Cobas IT 1000 for Blood Glucose.
3. Review of QC results and Test logs must be completed by a Technical Supervisor or designee monthly.

**Calibration:**

Calibration checks of test methods are performed as needed following manufacturers instruction and per individual MCMC Waived Test Procedure/Policy.

**Calculations:**

Waived Testing personnel are not required to perform Test result calculations. Percent allowable difference for an acceptable repeated test value i.e., repeat critical values for blood glucose and hemoglobin, may be described per Test Procedure/Policy.

**Test Procedure:**

All Waived Testing will be performed by trained personnel in accordance with current approved MCMC Procedure/Policy and manufacturer’s waived testing instructions. Waived Tests performed at MCMC include the following tests. Additional Test Systems may be added by following all guidelines of Waived Testing Policy.

|  |  |  |
| --- | --- | --- |
| **Test** | **Location of Testing** | **Testing Personnel** |
| Beta Ketone, Whole Blood | Hospital | MLS, MT, MLT |
| CLO Test | Hospital | MLS, MT, MLT |
| Blood Glucose, Whole Blood POC | Physician Offices, Hospital | POCTS, CLA, MA, RN, LPN, CNA, RT |
| HCG, Urine Qualitative POC | Physician Offices, Hospital | MLS, MT, MLT, CLA, MA, RN, LPN, RT |
| Hemoglobin A1c, POC | Physician Offices | POCTS, MA, RN, LPN, RD,CDE |
| Hemoglobin, POC | Physician Offices | POCTS, CLA, MA, RN, LPN, RT |
| Influenza A&B Rapid (swab) | Physician Offices, Hospital | MLS, MT, MLT, CLA, MA, RN, LPN, RT |
| Mono (Whole Blood) POC | Physician Office | POCTS, CLA, MA, RN, LPN, RT |
| Occult Blood, Fecal Guaiac | Physician Offices, Hospital | MLS, MT, MLT, CLA, MA, RN, LPN, RT |
| Occult Blood, Fecal Immunochemical | Physician Offices, Hospital | MLS, MT, MLT, CLA, MA, RN, LPN |
| Occult Blood, Gastric | Hospital | MLS, MT, MLT |
| pH Nitrazine | Physician Office, Hospital | MLS, MT, MLT, MA, RN, LPN, RT, Practitioners |
| Rapid Strep A | Physician Offices, Hospital | MLS, MT, MLT, CLA, MA, RN, LPN, RT |
| RSV | Physician Office, Hospital | MLS, MT, MLT, CLA, MA, RN, LPN, RT |
| Rapid SARS-CoV-2 (swab) | Physician Offices, Hospital | MLS, MT, MLT, CLA, MA, RN, LPN, RT |
| Urine Dipstick Analysis, POC | Physician Offices, Hospital | POCTS, CLA, MA, RN, LPN, RT |
| Urine Drug, Instant 12 POC | Physician Office | POCTS, CLA, MA, RN, LPN |

1. All Test results will be recorded with associated testing material lot numbers, expiration dates, and QC performance via:
   1. Interfaced software program
   2. Test logs, to include: Testing Location, Test Name, Lot numbers of testing supplies (Kit test or single test devices), expiration dates, External QC Lot numbers and expiration dates, External QC test results, date of testing, patient name, patient date of birth, Internal QC results, Patient test result, and testing personnel identification.
      1. Test Logs are to include any optional **PROFICIENCY TESTING** or blind sample testing performed for testing personnel competency evaluation (Proficiency samples or blind sample testing are assigned to Testing Personnel by Lab Technical Supervisors for competency compliance).
2. Patient Test logs and analyzer printed results are kept at the CLIA licensed Laboratory location of testing for two full calendar years.

**Troubleshooting:**

Below are common problems. Suggested corrective action is identified in individual Test Procedure/Policies. For all unresolved problems outside assistance must be used. See [Contact Information](#Procedure_CI) to seek technical assistance.

1. Equipment failures- Contact Technical Supervisor

**Expected Values:**

Expected Valuesare listedas described by manufacturer’s instruction and per individual MCMC Waived Test Procedure/Policy.

**Critical Values:**

Testing personnel are responsible for identifying and notifying all critical values to the appropriate health care provider or entity requesting the test. Critical value notification will be performed and documented in accordance with MCMC "[Critical Values](https://mcmc.ellucid.com/manuals/binder/267)" Policy.

**Specimen Storage:**

Specimen Storage requirements are listed inindividual MCMC Waived Test Procedure/Policies as described by manufacturer’s instruction.

**Reporting Results:**

1. Patient test results manually documented in the patient’s chart or entered into the electronic medical record are to include specimen source when appropriate, test report date, any units of measurement, interpretation or both and pertinent reference intervals or normal values.
2. Point of Care Blood Glucose test values will result through a middleware program, Cobas IT 1000. An interface sends results to a patient electronic record.
   1. Point of Care Testing Technical Supervisor (POCTS) monitors and will resolve any issues with Cobas IT 1000.

**Limitations:**

The following may adversely affect parameter values:

1. Failure to follow Testing Policy/Procedures or Manufacturer’s exact instructions for a testing system.

**Linearity:**

Linearity checks of test methods are performed as needed following manufacturer’s instruction and as described per individual MCMC Waived Test Procedure/Policy.

**Contact Information:**

The following organizations may be contacted concerning instrument/device performance:

|  |  |  |  |
| --- | --- | --- | --- |
| **Contact information by organization** | | | |
| **Organization** | **Instrument/Device** | **Phone Number** | **Fax** |
| Laboratory Technical Supervisor |  | 541-296-7225 |  |

**References:**

1. CMS Title 42 part 493, Subpart A 493.15, 493.1256, 493.1291, 493.1299, October 01,2019
2. The Joint Commission, WT, January 1, 2020

|  |  |  |
| --- | --- | --- |
| **Review/Revision Date** | **Type** | **Description of Change** |
| 01/08/2009 | Created |  |
| 03/05/2012 | Review |  |
| 01/28/2013 | Review |  |
| 12/19/2013 | Review |  |
| 06/16/2016 | Review |  |
| 04/18/2017 | Revision |  |
| 06/07/2018 | Revision | Edited Test List test names and testing personnel, deleted column Type/definitive. Changed Certification terminology to assessment, deleted Physicians added licensed independent practitioners. Detailed specifics of Patient Test log. |
| 3/12/20 | Revision | Rearranged wording in Purpose  Purpose: replaced proficiency with competency  Added definitions, certified competent responsibilities and competency guidelines  Added: Reagent tracking labeling  Added: Procedure to follow manufacturers insert instruction Changed Procedure items as listed in new format  Deleted certification requirements do not apply to Licensed independent practitioners  Edited testing personnel list  Edited test list to remove Mod Complex tests, amended to POC, added Hb A1c  Edited Test Procedure record keeping, to include remote software.  Added Specimen Collection: only unprocessed samples allowed  Amended Quality Control: added per Manuf. requirement, external and internal QC performance requirements prior to patient testing and resulting  Added remote QC monitoring for QC recorded in a software program  Added Limitations statement  Added References |
| 9/30/2021 | Revision | Add Rapid SARS-CoV-2 Antigen to "Test Procedure" test system table. |
| 12/28/21 | Revision | Added RD,CDE to testing personnel for HbA1c  Edited IT 1000 to Cobas IT 1000  Added RN, LPN to Instant Urine Drug |