DEFINITIONS:

**CLIA:** Clinical Laboratory Improvement Amendment (CLIA) regulates laboratory testing and requires clinical laboratories to be certified by their state as well as by the Center of Medicare and Medicaid services (CMS). Facilities and doctor offices must renew CLIA certificates every two years.

**CALIBRATION:** Process by which readings (obtained from an instrument or other measuring device) in an analytical process are related to known concentrations.

**GLP:** Good Laboratory Practice (GLP) is a quality system concerned with organization process and the conditions under which laboratory procedures (non-clinical health studies) are planned, performed, monitored, recorded archived and reported.

**HIPAA:** Health Insurance Portability and Accountability Act is legislation that provides data privacy and security provision for safeguarding medical information.

**OSHA:** Occupational Safety and Health Administration (OSHA) is a federal organization that ensure safe and healthy working conditions. OSHA regulations pertaining to the laboratory address labeling, use and disposal of hazardous materials, required personal safety equipment and safe needle devices.

**QC TESTING:** Quality Control testing are procedures used to detect and correct errors that occur because of test system failure, adverse environmental conditions, and variance in operator performance as well as monitoring the accuracy of test performance over time.

**WAIVED Tests:** Waived tests are simple laboratory examinations and procedures ‘cleared’ by the Federal Drug Administration (FDA) agency for home use. Waived tests include blood glucose, hemoglobin and hematocrit, urine pregnancy test, strep screens, dipstick urine and hemoccult screening. Principles of Waived tests are:
- Methodologies are so simple and accurate that the likelihood of erroneous results is negligible.
- Tests pose no harm to the patient if the test is performed incorrectly.

**POLICY:**

The goal of Healthpoint Laboratory – PRACTICE GUIDELINES POLICY is to outline:
- The basics of GLP (Good Laboratory Practice) Regulations
- Behaviors and Practices that Promote Safety (OSHA)
- HIPAA Standards Related to Laboratory Activities
- Care of the Laboratory Equipment and Environment
- Process for Initial and On-going Staff Education
PROCEDURE:

1. **GLP (Good Laboratory Processes) basics.** The importance of accurate results cannot be overstated.
   - Providers use test results to diagnose disease, determine prognosis and monitor treatment of health status. Medical decisions are based on tests results.
   - To assure accurate testing, Healthpoint utilizes a ‘READY?’ ‘SET?’ ‘TEST!’ approach.

**‘READY?’ components**

- **PREPARE for testing:** **MAINTAIN THE LAB IN A STATE OF READINESS FOR USE.** **Assure:**
  - No food or drink in laboratory area
  - Work surfaces are clean and the lab area is well lit.
  - Temperatures of testing and reagent storage area is recorded daily.
  - Inventory of reagents and supplies is adequate.
  - Reagents and kits are ‘in date’ and expired reagents/kits are removed/discarded
  - Reagents and kits are from the same kit lot (do not mix reagents).
  - Reagents are inspected for damage, discoloration or contamination/discarded if found
  - Time is allowed for refrigerated reagents to come to room temperature prior to testing
  - Equipment is inspected and operational
  - Calibration checks are performed, following package instructions

- **FOLLOW test instructions:** **KNOW HOW TO DO THE TEST THE RIGHT WAY!**
  Perform CLIA lab tests (i.e.; blood glucose, hemoglobin and hematocrit, urine pregnancy test, strep screens, dipstick urine and hemoccult screening) according to the manufacturer’s instructions.
  Manufacturer’s instructions outline:
  - Intended Use / Summary of Health Condition Test Related to Test / Test Principle
  - Precautions / Storage and Stability
  - Reagents and Materials Supplied / Materials Required but Not Provided
  - Sample Collection and Preparation / Test Procedure
  - Interpretation of Results / Quality Control
  - Limitations / Expected Values
  - Performance Characteristics

- **PERFORM Quality control testing:** **ASSURE TEST RESULTS ARE ACCURATE AND RELIABLE!**
  - **Incorrect** quality control results alert the user about potential problems such as reagent/test kit deterioration, equipment failure, environmental conditions or human error.
  - **Internal** quality controls are ‘built in’ to the device and evaluate whether the test is working as it should, enough sample is added, the sample is moving through the test strip correctly and/or whether the electronic functions of the instrument are working correctly.
  - **External** quality controls evaluate whether the testing process is performed correctly and control results are in the expected ranges or values found in the manufacturer’s instructions.
‘SET’ components

- **CONFIRM the Test Ordered:** BEFORE COLLECTING A SAMPLE, CONFIRM THE FOLLOWING:
  - **Test Order** – If there is a question whether order is correct, confirm with provider
  - **Patient Identification** – Use full name and date of birth, picture ID is also acceptable

- **PREPARE the patient:** PREPARING THE PATIENT IS AS IMPORTANT AS PERFORMING THE TEST
  - **Verify** pretest instructions (such as fasting for a glucose test) were followed
  - **Discuss** factors such as medical conditions, medications that can affect test results with the patient. (This information can be found in the ‘Limitations’ section of the manufacturer’s instructions.)
  - **Explain** the test procedure and the reason for the test.

- **UNDERSTAND type of sample needed for the test:** QUALITY PATIENT SAMPLES ARE CRITICAL FOR ACCURATE AND RELIABLE TEST RESULTS.
  - **Review** the manufacturer’s instructions for collection, handling and storage instructions.
  - **Follow rules** related to one time use of collection devices needles and lancets, using materials that come in kits and not ‘substituting’ or ‘mixing’ supplies.
  - **Label promptly** as soon as sample is collected, with patient name and/or affix label as appropriate.

- **FOLLOW OSHA guidelines:** PROTECT YOURSELF AGAINST OCCUPATIONAL EXPOSURE
  - **Follow work practices that limit risk of exposure to bloodborne pathogens.** Handle all blood and body fluids as if they are infectious, never recap needles, dispose of used sharps in puncture proof containers, report any hazards or exposures to supervisor, do not eat or drink in lab area, participate in training related to infection prevention, obtain hepatitis B vaccine.
  - **Use appropriate Personal Protective Equipment (PPE) such as gloves**
  - **Sanitize hands** before and after procedures and after removing gloves

- **MAINTAIN a safe environment:** FOLLOW RECOMMENDED BIOHAZARD CONTROLS
  - **Place** biohazard bags and sharps containers as close as possible to the testing area
  - **Utilize** biohazard containers for sharps or contaminated items, Do Not Mix biohazardous material with regular trash
  - **Replace** biohazard bags daily, replace sharps containers when 2/3 full
  - **Use appropriate disinfectant** and sanitize work surfaces before performing any test procedure, **whenever contamination** is visible, and at **end of the day**. (Bacteria and viruses can be present in high concentrations in a few drops of blood or body fluid. Dried material can remain infectious for at least one week if left on countertops and doorknobs.)
‘TEST!’ components

- **PERFORM tests:** DO NOT TEST SAMPLES THAT ARE IMPROPERLY COLLECTED OR HANDLED

- **FOLLOW Manufacturer’s instructions:** MAINTAIN INSTRUCTIONS AT THE WORK STATION
  - Follow the **exact order and timing** for testing: (Use of timers is recommended)
    - Reading results **TOO SOON** can cause **INVALID** or **FALSE NEGATIVE** results due to incomplete reaction of sample and reagents.
    - Reading a test **AFTER THE TIME** given in manufacturer’s instructions can lead to **FALSE POSITIVE** results due to overdevelopment of color, **FALSE NEGATIVE** results due to fading reaction or color or **INVALID** results when reaction moves past visible area.

- **FOLLOW PHLEBOTOMY Policy and Procedure for blood collection:** SECTION 4 OF LAB MANUAL
  - Follow Collection Methods outlined for blood samples: Venipuncture, Fingerstick, Heelstick
  - Use Anatomical **Landmarks**
  - Avoid venipuncture on same side as mastectomy or arm with cannula, fistula or vascular graft
  - Follow Correct **Order of Draw**
  - Follow instructions when using **Centrifuge**
  - **Label** and **Package** specimens promptly.

- **INTERPRET results:** FOLLOW GUIDELINES FOR DETERMINING ACCURACY OF TESTS RESULTS
  - If Quality Controls (QC) results are **inaccurate** (unexpected and do not reflect patient’s clinical history or presentation) or **invalid**:
    - Do NOT report test result to the Provider.
    - Follow **troubleshooting** steps outlined in the manufacturer’s instructions
    - Repeat QC testing once the problem is identified and corrected.
    - Re-test the patient sample(s) if QC results are acceptable
    - Report and **Record** the final accurate (acceptable) results in eCW.
  - Additionally, **repeat testing**:
    - If test results have numerical (quantitative) results **beyond the measuring range** of the instrument (such as reading ‘HIGH’ on glucometer).
    - The test system gives an **invalid** result or prevents display of result.

- **MANAGE SPECIMENS PROPERLY:** FOLLOW LAB CORP TEST INSTRUCTIONS FOR STORAGE
  - Maintain blood samples at **correct temperature/in correct tubes** prior to Lab Corp pick up.
  - Discard CLIA test biohazardous devices and specimens in appropriate biohazard containers.

- **UTILIZE BEST PRACTICES for safety:** SECTION 5 OF LAB MANUAL
  - Follow Policy and Procedure pertaining to Management of **Biohazardous (Infectious) Waste**
  - Waste Disposal **Guidelines**
  - Protecting Yourself – **Glove** Removal and **Hand Hygiene** guidelines
  - Protecting Yourself – **Hepatitis B** information

- **RECORD AND REPORT RESULTS:** FOLLOW GUIDELINES RELATED TO DOCUMENTATION AND VERBAL NOTIFICATION
  - Ensure patient **confidentiality** is maintained during and post specimen collection, with patient’s physical presence and with tests ordered/specimens collected.
  - **Record accurate results** into eCW as promptly as possible post completion of the test.
  - **Report** ‘Out of Range’ test results to the provider immediately.
2. **General Care of Laboratory and Equipment**
   - **Lab staff** clean counters with antiseptic cleaning solution at the end of each day and after any spills
   - **Housekeeping** mops floor daily with solution containing mixture of bleach and water
   - **Lab staff** clean equipment with aseptic wipes at the following intervals:
     - Clinitek (Urinalysis) – after each use
     - Hemopoint H2 (Hemoglobin) – after each use
     - Centrifuge (spin blood) – end of day and as needed post contamination, filter changed monthly
     - DCA Vantage (A1C) – end of day and as needed post contamination
     - Glucometer – (Blood sugar) – at end of day and as needed post contamination
     - Autoclave (sterilization of instruments) – weekly and monthly
   - **All staff** share in inspection of equipment at the following intervals:
     - Lab staff inspect equipment at start of each shift
     - Facility manager inspects lab environment during monthly environmental rounds
     - The Purchasing and Facility Manager ensures equipment is inspected annually by medical equipment inspection company.

3. **Quality Control (QC): Refer to Section 2 of Lab Manual**
   - **Quality control testing occurs** weekly or monthly and intermittently as required. The schedule for performing tests on laboratory equipment is based upon:
     - Manufacturer’s directions of equipment and testing material.
     - Environmental problems such as power outages or mechanical failure of refrigerator
     - Stability of test related to expired product or new controls
   - Quality Control **testing results** are documented and logs are maintained in the lab area.
   - **Defects** with a machine or calibration results that do not match controls are promptly reported to the facility manager.
   - Waived tests using equipment, requiring control checks with external material are:
     - Clinitek
     - Hemopoint H2
     - DCA Vantage
     - Glucometer
     - Refrigerator temperatures
   - Waived tests that incorporate quality control into the testing procedure are:
     - Influenza A&B
     - Glucose
     - Strep
     - FIT (Fecal Immunochemical Test)

4. **Injury or Exposure Events – Refer to Section 7 of Lab Manual**
   - Staff are to follow first aid instructions as listed within the Bloodborne Pathogens / Body Fluid Exposure Policy and Procedure and/or Safety Data Sheets (SDS) pertinent to chemical involved.
   - Staff are to notify their manager promptly of the injury or exposure event and complete a Variance Report.

5. **Training:**
   - Training is comprised of **new hire** (NEO) training and **ongoing** staff development.
   - Staff proficiency is assessed **prior** to staff assuming lab duties and is reassessed annually.
- Staff development plans are designed and implemented to address performance or knowledge deficiencies.
RELATED POLICY:
Phlebotomy
Biohazardous (Infectious) Materials

REFERENCES:
txtrain@dshs.state.tx.us

REQUIRED BY:
(Leave blank if none)

ATTACHMENTS/ENCLOSURES:
(Leave blank if none)

POLICY/PROCEDURE TRACKING FORM (to be added as last page of each P&P for documentation of changes)

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