Vermont Psychiatric Care Hospital Policy and Procedure		
Waived Testing		
Effective: April 2021	Revised: August 2024	Due to Review: August 2026

POLICY

The Clinical Laboratory Improvement Act (CLIA) of 1988 requires all clinical laboratories to possess a CLIA certificate in order to perform testing on human specimens. Certain tests are exempted from a waived list. Organizations that collect human specimens but do not perform tests are excluded from this act. When a hospitalized individual performs a test on themself, such as blood glucose testing on their own glucose meter, the action is not regulated by CLIA. The purpose of this policy is to define the Vermont Psychiatric Care Hospital's (VPCH) compliance with waived testing criteria and the need for a certificate of laboratory services.

DEFINITIONS

CLIA: Clinical Laboratory Improvement Amendments (CLIA) of 1988 are United States federal regulatory standards that apply to all clinical laboratory testing performed on humans in the United States, except clinical trials and basic research

Waived Testing: Simple laboratory examinations and procedures that are cleared by the FDA for home use, employ methodologies that are so simple and accurate as to render the likelihood of erroneous results negligible, or pose no reasonable risk of harm to the individual if the test is performed incorrectly.

PROCEDURE

VPCH shall have a current CLIA certificate of waiver which shall be displayed in the Laboratory and renewed as required.

Education and Skill Verification

- Registered Nurses (RN) and other clinical staff who have been designated to perform waived testing will be trained and have their competency verified before performing these procedures independently and at least annually thereafter.
- Records of training and competence verification shall be maintained by the VPCH Clinical Education Department.

Process and Results of Testing

- Waived tests shall be performed according to this Waived Testing Procedure.
- Results of waived tests shall be documented in the individual's electronic medical record.

Equipment Performance and Evaluation

- Waived testing equipment shall be maintained, and applicable functionality testing done, in accordance with the equipment specific user's guide available on the VPCH SharePoint.

- If necessary, a glucometer may be surface cleaned using alcohol wipes. Glucometers should never be immersed in liquid.

Waived Testing Procedure – Point of Care Blood Glucose

- Each hospitalized individual requiring routine blood glucose monitoring will be assigned an individual glucometer for use during hospitalization, which they may take when discharged. Assigned glucometers shall be stored in a designated medication or treatment room.
- Capillary blood collection (finger sticks) shall be performed in accordance with the equipment specific user's guide available on the VPCH SharePoint (search by model number).
- Finger sticks may be performed by an RN, by a trained clinical staff under the supervision of an RN, or by the hospitalized individual under RN supervision. Prior to initial finger stick being done by a hospitalized individual, the RN shall review the correct process.
- Finger sticks shall be done with a disposable lancet. Results of each finger stick shall be recorded in the individual's electronic medical record (usually on the MAR).
- Individuals who will test their own blood glucose after discharge shall be educated regarding the use of the glucometer. Education shall be documented in the medical record.

Functionality Testing

Functionality testing, such as with control solutions for glucometers, shall be done as outlined in the equipment specific user's manual available on the VPCH Share Point. Control testing shall occur at the following times:

- When using new equipment for the first time
- When opening a new bottle of blood glucose test strips
- You left the test strip bottle cap open for awhile
- You dropped the equipment.
- You suspect the meter and/or test strips are not functioning properly
- Every 24 hours (daily) when the glucometer is assigned to individual patients
- Weekly when glucometer is in crash pack (for use in emergencies/not in routine use)

Results of the glucometer control solution test shall be recorded on the Diabetes Control Solution Flow Sheet. Each glucometer will be assigned its own flow sheet. If the control solution test does not fall within the acceptable range, which is listed on each bottle of test strips, a variance should be completed, and a new glucometer shall be issued and tested before use.

Glucometers in Crash Packs

- A glucometer shall be kept in each crash pack. These glucometers will be checked weekly with the control solutions and the results documented on a Diabetes Control Solution Flow Sheet.
- If a crash pack glucometer is used on a hospitalized individual, the Diabetes Control Solution Flow Sheet currently assigned to that glucometer shall be labeled with the

individual's name and become part of that individual's medical record. The crash pack glucometer shall then be assigned to that individual or discarded. A new glucometer shall replace this one in the crash pack as soon as reasonably practicable.

- Completed Diabetes Control Solution Flow Sheets for crash cart glucometers shall be maintained by the Quality Department or designee for three years following completion.

Approved by	**Signature**	**Date**
Emily Hawes, Commissioner, Vermont Department of Mental Health	DocuSigned by: Emily Hawes C50275615A62462...	8/27/2024