Vermont Psychiatric Care Hospital Procedure	
Waived Testing	
Revised: X	Date: 12/17/2015

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 patient if the test is performed incorrectly.

At the Vermont Psychiatric Care Hospital (VPCH), blood glucose monitoring is the only waived test performed by hospital personnel.

CONSIDERATIONS/PROCEDURE:

1. Vermont Psychiatric Care Hospital (VPCH) shall have a current CLIA certificate of waiver for testing blood glucose by glucose monitoring devices approved by the FDA specifically for home use. The certificate of waiver shall be displayed in the Laboratory and renewed as required.

2. Education and skill testing
   a. All registered nurses (RN) who have been designated to perform waived testing will be trained before performing these procedures (See Blood Glucose Monitoring – Waived Testing Precision Xtra Blood Glucometer Competence Verification Form).
   b. Before performing the procedure independently, an RN will complete the VPCH Blood Glucose Monitoring Competence Verification Form, as directed by the RN preceptor,.
   c. Following initial training, each RN shall repeat Competence Verification at least annually.
   d. Records of Competence Verification shall be maintained by the VPCH Education and Training Department.

3. Process and results of testing
   a. All waived tests shall be performed according to the VPCH Waived Testing Procedure.
   b. Results of waived tests shall be documented in the patient's medical record.

4. Equipment performance and evaluation
   a. Glucometers shall be maintained and control solution tests done as outlined in the Precision Xtra User's Manual.
   b. If necessary, a glucometer may be surface cleaned using alcohol wipes. Glucometers should never be immersed in liquid.

5. Waived testing procedure
   a. Each patient requiring blood glucose monitoring will be assigned a Precision Xtra Blood Glucose & Ketone Monitoring System (glucometer) for use during hospitalization, which they may take when discharged. Patient glucometers shall be stored in a Medication or Treatment Room.
   b. Finger sticks shall be performed as outlined in the Precision Xtra Blood Glucose & Ketone Monitoring System User's Manual. Finger sticks may be performed by an RN or the patient under RN supervision.

c. Prior to the initial finger stick being done by a patient, the RN shall review the correct process with a Nursing Supervisor.
d. Finger sticks shall be done with a disposable lancet. The Easy Touch Lancing Device that comes with the glucometer shall not be used unless so ordered by a physician. Results of each finger stick shall be recorded on the Diabetes Management Flowsheet.
e. Patients who will test their own blood glucose after discharge shall be educated regarding the use of the glucometer. Education shall be documented in the patient's medical record.

6. Control solution testing
   a. Control solution testing shall be done as outlined in the Precision Xtra Blood Glucose & Ketone Monitoring System User's Manual. Control testing shall occur at the following times:
      - When using a new glucometer for the first time
      - When unsure if the glucometer is functioning properly
      - When opening a new box of strips

      Results of the control solution test shall be recorded on the Diabetes Management Flowsheet. If the control solution test does not fall within the acceptable range, a new glucometer shall be issued and tested before use.

7. Glucometer on crash cart
   a. A glucometer shall be kept with the crash cart in the Admissions Treatment Room. This glucometer is to be checked daily with the control solutions and the results documented on a Diabetes Management Flowsheet.
   b. If the crash cart glucometer is used on a patient, the crash cart Diabetes Management Flowsheet currently in use shall be stamped with the patient's name and become part of that patient's medical record. The crash cart glucometer shall then be assigned to that patient or discarded.
   c. Completed crash cart diabetes flowsheets shall be maintained by the Nurse Manager or designee for six months following completion.

Approved by	**Signature**	**Date**
Frank Reed, Commissioner of DMH	Frank Reed	11/29/16