

Vermont Psychiatric Care Hospital Procedure

Waived Testing

Revised: X

Date: 04/07/14

DEFINITIONS

- a. **CLIA:** Clinical Laboratory Improvements Amendments of 1988: When an individual other than a representative of the Clinical Laboratory performs a test or interprets the results of a test result, it is an activity that is regulated by CLIA.
- b. **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.

CONSIDERATIONS/REQUIRED STEPS:

a. Certification

- i. Vermont Psychiatric Care Hospital (VPCH) will have a current, valid CLIA certificate of waiver for the following testing: Blood glucose by glucose monitoring devices cleared by the FDA specifically for home use,
- ii. The certificate of waiver will be renewed as directed, and
- iii. The certificate of waiver will be displayed in the Exam Room.

b. Education and skill testing

- i. All direct care staff who have been designated to perform waived testing will be trained during orientation to perform these procedures.
- ii. The direct care staff will demonstrate competency before performing the procedure on their own.
- iii. Continued competency testing will be performed on an as needed basis, but at least annually.
- iv. Education and competency results will be current and maintained with the VPCH Education and Training Department.
- v. All education and competency documentation will be readily available in the Education and Training Department.

c. Process and results of testing

- i. All waived tests will be performed according to procedure dictated by the VPCH Education and Training Department.
- ii. Questions or concerns regarding testing will be addressed by the appropriate supervisor, and the Education and Training Coordinator.
- iii. Results of all waived tests will be documented and kept in the patient's medical record.

d. Equipment performance evaluation

- i. Equipment utilized in waived testing (i.e., glucometer) will be maintained according to the manufacturer's manual, to include quality control checks.
- ii. The manufacturer's manual will be kept in a centralized and easily accessible location.

Approved by VPCH Policy Committee

Approval Date: April 7, 2014