MCINTOSH TRAIL
COMMUNITY SERVICE BOARD

POLICY NO. 2125
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SUBJECT: WAIVED TESTING

APPROVED BY

EFFECTIVE
DATE: 12-29-06 (replaces 06-07-02)

Medical Director

Reviewed (no changes): 02-13-10 12-13-10

Executive Director

POLICY

It is the policy of McIntosh Trail CSB to insure that waived testing is performed reliably, safely and competently through adherence to approved processes.

PROCEDURE

1. Waived testing is performed in a variety of sites within the organization. Those sites performing waived testing will maintain a notebook or other record to include which tests are performed at that site, purpose of testing, manufacturer's instructions, list of those staff designated and trained and a log of tests and quality controls.

2. Each site performing waived testing will obtain and maintain a CLIA certificate.

3. The director identifies and documents the staff responsible for performing and supervising waived testing.

4. The site maintains records that staff members have been trained for each test they perform and are competent in tests and in maintenance of any equipment.

5. Site director evaluates and documents orientation, training and competency, to include current competencies assessed by at least two methods such as supervision, testing, quality control, and blood specimen testing.

6. The director for each site establishes detailed procedures for how the tests are to be used and how quality control is to be maintained for the specific tests done at that site.

7. Testing related processes and practices adhere to manufacturer's recommendations regarding specimen type, storage consideration, maintenance, quality control, and followup. The site director or designee will maintain records of compliance.

8. Each site performing waived testing will identify methods and monitor compliance, for specimen type, collection, identification, and labeling.

9. Manufacturer's instructions, to include manuals and package inserts, are the basis for testing processes. Associated policies and procedures are located in or readily accessible to the area where testing is done.

10. Quality control checks are conducted according to manufacturer's recommendations for each procedure, documented on site, and retained for at least two years.

11. Test results are documented in the consumer clinical record and retained for at least two years.

12. Test orders should be confirmed including documented standing/routine orders.

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PROCEDURE (Continued)

13. Consumer identification uses two identifiers to insure the specimen is collected from the correct consumer.

14. During specimen collection, the instructions in the product manual or insert must be followed explicitly. Collection devices are properly discarded. Specimens are labeled with consumer name or unique identifier. Labeling is adequate to prevent specimen mix-up.

15. Pre-testing procedures may include preparing a clean area with adequate lighting, and adequate supplies. Check products and reagents/solutions for expiration dates and inspect all components for damage or problems. The person performing the testing should complete any required controls before or concurrent with performing consumer tests.

16. Documentation to be maintained includes controls, corrective action to failed controls, test results, both qualitative and quantitative.

17. Examples of Waived Testing Checklist for Logbook, Waived Testing Tracking Sheet, and Waived Testing Control Log are all included in FormDocs.

18. Medical director or designee will monitor site performing waived testing at least quarterly to assess compliance with policy and procedures.

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