PROGRAM OVERVIEW

Program Description:

Point of Care testing may seem, on its face, simple and 'fool proof', but in a study conducted by HCFA in Colorado and Ohio, quality problems were identified in more than 50% of Certificate of Waiver labs surveyed. It revealed "glaring quality control problems" and urged the FDA to provide more governmental oversight of these laboratories. The HCFA study cited the following performance problems:

- Obsolete instructions
- Lack of instructions
- Incorrect instructions
- Failing to perform quality control as required by the manufacturer

The laboratories risk intervention by both federal and state authorities if clinical testing is performed in violation of CLIA and NJ Department of Health and Senior Services requirements. Please note that a CLIA certificate does not substitute for licensure by the State.

To assist personnel who wish to perform clinical laboratory procedures on-site, the Robert Wood Johnson Medical School, statewide Rapid HIV Testing Support Program, has adopted a POCT program designed:

- To provide quality care to our patients and clients;
- To meet the standards of quality review organizations;
- To ensure that RWJMS maintains required compliance with state and federal regulations regarding laboratory oversight;
- To provide consistency of test offerings at all clinical sites participating in the program;
- To achieve economies of scale in the acquisition of reagents and instrumentation within the group;
- To ensure the highest quality of test performance to all patients.

Under this program, rapid HIV testing services (Qualitative HIV 1& 2 Antibodies) can be provided at any RWJMS sponsored site, so long as the required training, proficiency testing, quality control and validation procedures are performed. The Department of Pathology and Laboratory Medicine will oversee this program and provide Bioanalytical Laboratory Directorship (BLD) and all necessary state and federal licensing for these sites. The implementation of the program will include administrative functions and clinical oversight responsibilities handled by the Rapid HIV Testing Support Program under the auspices of the Department of Pathology and Laboratory Medicine.

This program will:

- Provide each participating unit with standardized procedures which can be performed at a licensed facility so long as the requirements for training, competency assessment, quality control and periodic review are maintained within the facility.
- Provide training and recertification to all staff performing rapid HIV testing.
- Centralize inventory so that common reagents are used throughout the state, to provide validation of this inventory and to minimize lot to lot variability.
- Provide resource support to insure testing quality including a standardized procedure for reporting testing exceptions and problem resolution.
- Submit and maintain clinical laboratory licensure for any RWJMS site providing rapid HIV testing.
- Provide monitoring and initial review of testing records and ongoing proficiency.
- Provide monthly visits to each clinical facility to review compliance efforts with state and federal regulations regarding clinical laboratories.

Program Participation:

To participate in rapid HIV testing under UMDNJ-RWJMS sponsorship, the following is required:

1. Execution of a Professional Services Agreement (PSA) between UMDNJ-RWJMS and the organization requesting testing. This document legally delineates the responsibilities and requirements of both parties. Following a physical inspection of the facility, the Department of Pathology and Laboratory Medicine will arrange for licensure of the facility.

2. Upon completion of the PSA, the Department of Pathology and Laboratory Medicine will begin the process for licensure to include: a physical inspection of the site and training of site staff to all the policies and procedures for providing rapid HIV testing, proficiency testing, and license application preparation. During this process the Department will:
    a. Provide each site with Rapid HIV Testing procedure manuals and log sheets.
    b. Provide for staff training, retraining and staff support to operationalize site.
    c. Review competency assessment of staff, including review of on-going proficiency testing under an appropriate program and direct observation.
    d. Provide all necessary supplies and reagents necessary to perform rapid HIV testing.
    e. Adherence to Rapid HIV Testing Support Program Procedures: Continued participation in the Rapid HIV Testing Support Point of Care program requires that these procedures be performed in accordance with the instructions described in our manual including those related to quality control, record keeping, proficiency testing and competency assessment. Monthly inspections of all sites will occur.
    f. Submit all license application materials with appropriate fees to the Clinical Laboratory Improvement Service (CLIS) at the New Jersey Department of Health and Senior Services.

Obtaining Necessary Supplies:

Supplies, including test and control reagents, may be requested by forwarding a supply request to the Rapid HIV Testing Support Program via fax at 732-235-9012.Supplies obtained by the Rapid HIV Testing Support Program on behalf of participating sites will be validated prior to distribution.

Rapid HIV Testing Support Program Contact Information

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General Guidelines:

Goal:
The clinical goals of Robert Wood Johnson Medical School are to provide optimal laboratory services to patients and reference clients. To provide such service, it is essential that the quality of results be assured. Proper use of Rapid HIV testing can provide clinical diagnostic information in a timely manner at the time of patient care and can reduce the volume of blood needed for laboratory testing. Quality assurance/performance improvement guidelines for rapid HIV point of care testing are a necessary step in providing standardized testing procedures and complying with the laboratory accrediting requirements of the New Jersey Department of Health and Human Services, the Federal Drug Administration, and the College of American Pathologists.

Policy:
Properly trained and certified personnel may perform testing outside the laboratory, under the authority and licensure of a NJ licensed bioanalytical laboratory director.

In order to assure the clinical reliability of results obtained from such testing and to comply with federal and state regulations, the following guidelines must be followed. These guidelines will be used to establish specific procedures for each ancillary testing site.

For rapid HIV testing to be performed at each practice site, a procedure specific to the specific rapid test used and type of site where performed has been developed. These procedures will be modified as needed. Failure to follow the procedures outlined will result in cessation of permission to perform ancillary testing.

Quality Control:
Following proper quality control procedures is essential. Lack of quality control can result in serious misinterpretations of test results.

All test procedures require that a fixed number of quality control (QC) samples be run at pre-determined intervals. QC samples are samples which contain a known concentration of the analyte being measured. If the result of the QC sample is not within its expected range, it is an indication that patient samples would give erroneous results. **If QC results are out-of-range, patient or client samples may not be run!**

The ancillary testing site is responsible for the proper storage and replacement of acceptable quality control materials as specified by the test procedure or the QC manufacturer. An inventory of QC materials will be maintained by the Rapid HIV Testing Support Program. All supplies should be ordered from the Rapid Testing Support Program using forms provided in this manual.

- *Frequency:* The frequency of QC testing depends on the test being performed. For rapid HIV testing, the frequency is delineated in the policy.
- *Number:* QC run for Rapid HIV 1/2 testing consists of one positive HIV 1, one positive HIV 2 and one negative sample. QC run for Rapid HIV 1 testing consists of one positive HIV 1 and one negative sample.
- *Expected values:* If the positive results and the negative result are not achieved, the program coordinator is available to help with interpreting the results of QC samples and to advise whether patient testing may proceed (see contact sheet in this manual). In the absence of the site's program coordinator, any staff listed can be contacted for assistance.
- *Record keeping:* Results of all QC samples must be logged onto appropriate record sheets that will be kept at each testing area, and must indicate who performed the testing. These may be reviewed at any time by the HIV Rapid Testing Support Program coordinator, laboratory supervisors or representatives from regulatory agencies. They must be sent to the Rapid HIV Testing Support Program monthly, and will be kept for at least two years in the Rapid HIV Testing Support Program office.

Testing:
The test procedure will describe the steps necessary to perform testing. It will also include information about proper specimen collection.

Recordkeeping:
Results of all patient/client tests must be permanently recorded. The record must allow for a review of which patients were tested. This would allow tracking of those patients in case a problem occurs, such as a reagent recall by the manufacturer or testing problems discovered at the site. To do this, all results must be entered on the log sheet located at each site and in the patient file. The date and time the specimen was collected (and the date and time of analysis if there is a significant delay) must be recorded along with the identity of the person performing the test. These records are to be sent to the HIV Rapid Testing Support Program monthly and must be retained for at least two years.

Operator Proficiency:
Each person running the test must be trained according to HIV Rapid Testing Support program policy. Training will be provided by the Rapid HIV Testing Support Program staff. The Rapid HIV Testing Support program staff must be notified of all new hires, terminations or resignations. In general, operator proficiency is certified initially for six months. A re-certification process is then completed with subsequent certification for periods of one (1) year.

Recertification: Recertification of individuals performing testing will be established by direct observation, testing and/or documentation of having obtained proper results on daily quality control (QC) samples and proficiency test (PT) specimens provided. Staff from the Rapid Testing Support Program will monitor compliance with these activities. Correct QC results must be performed in accordance with specific procedures, or certification will lapse.

Proficiency Testing:
Periodically, unknown samples will be given to each rapid HIV testing site to be run. These samples are purchased from outside regulatory agencies to evaluate the accuracy of the results obtained by the site. These “proficiency testing” samples must be run as patient samples are run, after proper maintenance and quality control procedures have been completed. PT samples may not be transferred to or discussed with another testing site or lab during the testing period. The results will be reported back to the testing agency for evaluation. These proficiencies are required in order to maintain NJ licensure. Failure to perform adequately on proficiency testing challenges can result in loss of the laboratory’s license.

Competency Assessment:
At the discretion of the laboratory director, a program for on-going competency assessment may be established. In some instances this will involve mandatory testing of unknown specimens at a frequency sufficient to insure continued successful operator performance.

Quality Assurance Indicators:
A series of quality assurance indicators will be established and updated on a regular basis. These indicators will be selected so as to provide monitoring of compliance with the quality procedures of the Rapid HIV Testing Support Program, including: quality control, temperature monitoring, proficiency test results, discordants, patient/client recordkeeping, and operator competency. Findings of these monitors will be evaluated by the director, and will be forwarded to the appropriate committees or boards responsible for the laboratory’s operations.

Delegation of Authority:
Drs. Evan Cadoff, Eugene Martin and Gratian Salaru shall have authority with regard to all policies, procedures and practices of the laboratory in the absence of, or in addition to, the licensed lab director, Dr. Parisa Javidian. This authority shall include, but it not limited to, approving revisions to procedures, enforcing the procedures, and reviewing records—including personnel, patient testing, quality control, and proficiency test records, and any other data that may periodically need to be reviewed.

Written by: POCT Committee Date: 01/15/02
Approved by: Evan Cadoff, M.D. Date: 01/15/02

Revised by: Patricia A Ribeiro, MT(ASCP) Date: 4/12/13
Reviewed by: Joanne Corbo, MBA, MT (ASCP) Date: 10/2/13
Approved by: Gratian Salaru, M.D. Date: 10/2/13
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