

**Procedure: Quality Assurance Program****Purpose**

The POCT Quality Assurance Program is designed to monitor the quality of POCT laboratory services provided by medical school personnel including physicians, nursing staff and medical assistants to ensure that problems related to these services are identified and addressed. The monitoring system is designed to be compatible with the standards of the College of American Pathologists, the NJ Department of Health and Senior Services, and CLIA 88.

**Responsibility**

It is the responsibility of the POCT program to:

- Oversee and evaluate the quality of POCT laboratory offerings provided by Robert Wood Johnson Medical School at its various patient practice sites,
- Ensure laboratory compliance with existing federal and state regulations
- Assure continuing compliance with College of American Pathologists (CAP) regulations
- Assist physicians and staff in effectively meeting the clinical laboratory testing needs of their patients

The UDL POCT Committee is responsible for the operation of Point of Care Testing provided at the multiple facilities and sites of Robert Wood Johnson Medical School. It is the committee's responsibility to evaluate the delivery of services provided at these locations. At its discretion, the Committee may assign specific duties for the monitoring of performance and the correction of problems identified by the monitoring system to personnel at various sites.

**Scope of Services**

The UDL provides laboratory support to the activities of our clinical faculty at all of our locations. The offerings that constitute this service may change from time to time to meet the changing needs of the medical school. The Quality Assurance program consists of three elements which collectively insure an organizational commitment to continuously improve quality.

**Elements of the QA Program****1. Participation in Interlaboratory comparison programs:**

- CAP Proficiency testing
- NJ DOH - Proficiency Testing Program
- AAB - American Association of Bioanalysts

**2. Laboratory quality control program:**

- Periodic Meetings of the POCT committee.

**Purpose:**

Review of ongoing technical problems and their resolution  
Review problem cases  
Review of proficiency testing performance  
Review of customer service issues

- Daily procedures, including:

Generation of mandated QC  
Generation of daily patient reports in a consistent, retrievable manner  
Provide for the review of QC data and the proper release of patient results

Provide a mechanism for the review of inconsistent findings by the laboratory subdirector and/or the Bioanalytical Laboratory Director

3. *Quality Assurance Indicator Program*

- A review of all modified reports issued by the division with a classification of errors.
- A review of problematic services
- A review of CAP survey procedures.
- A review of QA indicators

4. *Formal Education and Competency Assessment Program*

**Important Indicators that may be included on the QA report**

**Specimen Collection and Requisitioning**

Demographic errors:

- Incorrect or missing information
- Illegible information misread during the input process
- Transcriptional errors by clerical staff entering information

**Analytical errors:**

Non confirmable results

Interlaboratory proficiency testing

Failed Quality Controls

**Reporting errors:**

Errors on the worksheet - i.e. technologist reporting errors

Errors in the report from transcription mistakes - i.e. clerical errors

**Turn around Time:**

**Indicators and Thresholds**

Will be defined annually by the POCT subdirector and reported to the POCT committee.

**Data Collection and Organization**

The POCT subdirector will identify appropriate indicators and prepare a monthly calendar to permit systematic evaluation of the identified indicators. These indicators may be altered periodically in conformance with the goals of patient-centered quality assurance.

**Evaluation of Services**

Data will be periodically collected and monitored by the POCT committee consisting of the POCT subdirector and the Bioanalytical Laboratory Director. If the designated indicators are found to exceed the threshold for reporting an investigation will take place to determine the possible causes and to develop a plan to correct these problems.

**Action to Improve Services and Resolve Problems**

Problems identified by the monitoring system will be corrected and the appropriate indicator will be re-examined in the next monitoring period to establish adequacy of the solution.

**Education and Competency Assessment**

A formal education program consisting of regular didactic training and 'hands-on' training is provided under the direction of the POCT committee. Formal training is supplemented by 'on-line' programs available through the UDL website.

Regular annual competency assessment is included as a part of the program to evaluate theoretical and practical knowledge of procedures by staff. The assessment includes:

1. Direct observation of performance of routine and quality control procedures. This includes all aspects of sample handling, processing, labeling, testing and instrument preventative maintenance;
2. Monitoring the recording and reporting of test results by reviewing work sheets, quality control records, preventive maintenance records, and other records and entries;
3. Written tests to assess problem solving skills, knowledge of SOPs, and theory; and
4. Assessment of performance using external proficiency test specimens.

Minimum acceptable scores, performance, and remedial measures to correct inadequate performance on competency evaluations are documented and retained in personnel records.

**Error/Accident Reports and Complaints**

Another element in the QA program is the review, evaluation, investigation, and correction of errors and accidents. It is the intent of the UDL POCT QA program to thoroughly investigate all complaints regarding product quality to determine whether the complaint is related to an error or accident occurring in the laboratory.

Knowledge acquired through investigations of complaints, error/accident incidents, and adverse reactions will be conveyed to involved POCT staff and responsible clinicians. The UDL POCT Subdirector will receive copies of error/accident reports and ensure appropriate follow-up actions have been taken. Corrective actions may include system or process redesign, retraining, and procedural changes.

**Quality Assurance Data Review**

The QA schedule and report will be prepared by the POCT Subdirector and communicated to the UDL Bioanalytical Director in a timely fashion. Quality Assurance meetings will be held in July and January to review indicators.

Written by: POCT Committee. Date: 05/7/03

Approved by: Evan Cadoff, M.D. Date: 05/10/03

Revised by: \_\_\_\_\_ Date: \_\_\_\_\_

Reviewed by: \_\_\_\_\_ Date: \_\_\_\_\_

Reviewed by: \_\_\_\_\_ Date: \_\_\_\_\_

Reviewed by: \_\_\_\_\_ Date: \_\_\_\_\_

**POCT Division  
Process Improvement Program  
Calendar of Events  
2003**

<b>Indicator w/ Indic. Threshold</b>	<b>Jan</b>	<b>Feb</b>	<b>Mar</b>	<b>Apr</b>	<b>May</b>	<b>Jun</b>	<b>July</b>	<b>Aug</b>	<b>Sep</b>	<b>Oct</b>	<b>Nov</b>	<b>Dec</b>
All POCT Proficiency Results Unacceptable errors < 4 % <b>Indicator = 4%</b>						√						√
Urine Dipstick Proficiency Results Unacceptable errors < 4% <b>Indicator = 4%</b>						√						√
Blood Glucose Proficiency Results Failure < 5.0% <b>Indicator= 5.0%</b>						√						√
Physician Performed Microscopy Unacceptable results on CAP PPM survey <b>Indicator &lt; 5</b>  <b>Indicator 5%</b>						√						√
CPT Review <b>Unacceptable CPT codes billed</b> <b>Indicator &gt; 2 %</b>						√						√

**UDL**  
**Quality Assurance Program**  
**POCT**  
**6/17/2002 - QA Meeting**

<b>Indicator w\ Indic. Threshold</b>	<b>% Meeting</b>	<b>Finding</b>	<b>Area for Improvement</b>	<b>Actions/Followup</b>
Cumulative POCT Proficiency Results (Year) Unacceptable errors < 4 % <b>Indicator = 4%</b>	Indicator = 4.2% (8/184)	<b>Threshold NOT Met December 2001 -May, 2002</b>	Urine dipstick performance PPM	Increase re-training, on-site observation Initiate PPM Competency Assessment
Urine Dipstick Proficiency Results Unacceptable errors < 5% <b>Indicator = 5%</b>	Indicator = (6/140) Unacceptable error rate = 4.3%	<i>Threshold Met December 2001 - May, 2002</i>		Initiate re-training program Require completion of on-line lab module
Blood Glucose Proficiency Results Failure < .5% <b>Indicator= 5.0%</b>	Indicator = (1/26) Failure rate Indicator = 3.8%	<i>Threshold Met December 2001 - May, 2002</i>	Review instrument linearity of instrument with unacceptable results	Five point (4x) linearity performed. Instrument = OK
Physician Performed Microscopy Unacceptable results on CAP PPM survey <b>Indicator 5%</b>	Indicator = (1/18) Failure rate indicator = 5.56%	<b>Threshold Not Met December 2002 - May, 2002</b>	Feedback to physician. If pattern continues, mandate re-training. Establish on-line competency assessment and re-training	Continue to Monitor On-line PPM training module to be acquired July, 2002
Quarterly CPT Review <b>Unacceptable CPT codes billed Indicator &gt; 2 %</b>	Indicator = 100%	<i>Not completed this cycle</i>		Continue to Monitor.

**UDL**  
**Quality Assurance Program**  
**POCT**  
**December - QA Meeting**

<b>Indicator w/ Indic. Threshold</b>	<b>% Meeting</b>	<b>Finding</b>	<b>Area for Improvement</b>	<b>Actions/Followup</b>
Cumulative POCT Proficiency Results (Year) Unacceptable errors < 4 % <b>Indicator = 4%</b>	Indicator = 2.9% (8/274)	<i>Threshold Met</i> January 2002 - December, 2002		Continue to monitor
Urine Dipstick Proficiency Results Unacceptable errors < 4% <b>Indicator = 5%</b>	Indicator = (220/226) Unacceptable error rate = 2.7%	<i>Threshold Met</i> January 2002 - December, 2002	Automated Dipstick reader Re-certification program	Re-negotiate contract for Urine dipsticks
Blood Glucose Proficiency Results Failure < .0% <b>Indicator= 5.0%</b>	Indicator = (25/26) Failure rate Indicator = 3.8%	<i>Threshold Met</i> January 2002 - December, 2002		Continue to monitor
Physician Performed Microscopy Unacceptable results on CAP PPM survey > 5% <b>Indicator 5%</b>	Indicator = (1/8) Failure rate indicator = 5.56%	<b>Threshold Not Met</b> January 2002 - December, 2002	Automate feedback to physician. Continue to simplify program. Access to re-training modules needs improvement Recruit additional physicians	On-line Competency Module in place Physician compliance improving
CPT Review <b>Unacceptable CPT codes billed</b> <b>Indicator &gt; 2 %</b>	Indicator = 100% 967 Total POCT correct 643 Total POCT 0.399 Error rate  1088 Total UDL correct 169 UDL error 0.134 Error rate	<b>Threshold Not Met</b> November - December, 2002	UDL Errors: Contact dept admin (Medicine billed using RWJUH instead of MEB as testing location for a month.  Revisit in June, 2003 to confirm trend before asking for them to take action?	Continue to Monitor.  Appears to be ineffective controls in UMG billing. Re-assess June, 2003

## POCT Program 2002 Quality Assurance Report Summary

### 2002 Summary

Cumulative POCT Proficiency Results (Year) Unacceptable errors < 4 % <b>Indicator = 4%</b>	Indicator = 4.2% (8/184)	<b>Threshold NOT Met December 2001 -May, 2002</b>
Physician Performed Microscopy Unacceptable results on CAP PPM survey <b>Indicator 5%</b>	Indicator = (1/18) Failure rate indicator = 5.56%	<b>Threshold Not Met December 2002 -May, 2002</b>
Physician Performed Microscopy Unacceptable results on CAP PPM survey > 5% <b>Indicator 5%</b>	Indicator = (1/8) Failure rate indicator = 5.56%	<b>Threshold Not Met January 2002 -December, 2002</b>
Physician Performed Microscopy Unacceptable results on CAP PPM survey > 5% <b>Indicator 5%</b>	Indicator = (1/8) Failure rate indicator = 5.56%	<b>Threshold Not Met January 2002 -December, 2002</b>

### May, 2002

1. Urine Dipstick Proficiency Results. Unacceptable error rate = 3.57%
2. Blood Glucose Proficiency Results Failure. Indicator = (1/9) Failure rate Indicator = 11.0%
3. Unacceptable results on CAP PPM survey. Indicator = (1/8). Failure rate indicator = 12.5%
4. Implement University of Washington Lab Training Library
5. Implement University of Washington PPMP Competency Assessment

### 2003 Modifications to Program

1. Implement CAP Physician Performed Microscopy on the UDL website to increase physician compliance with PT challenges.

### Impact of Quality Assurance Program

1. Focuses attention on critical quality aspects of overall laboratory performance including major customer service issues.
2. Allows us to monitor performance in a regular and consistent manner. Permits us to detect a defect in our system before it gets out of control. A major impact of the QA program this year

was to focus our attention on the control of training processes and the reinforcement of key elements in the handling of POCT materials.

3. The effectiveness of our review processes have been clearly documented throughout the year. We continue to aspire to methodologies and cross-checking techniques which will result in an error rate of zero.
4. Directly interfacing POCT equipment such as glucometers or automated dipstick readers to the reporting programs would further reduce transcriptional issues. A small number of errors will continue to occur using human-based checking methodologies.