



POINT OF CARE TESTING PROGRAM

POCT PROCEDURES

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Chapter

1

THE UMDNJ - ROBERT WOOD JOHNSON MEDICAL
SCHOOL POCT PROGRAM

CHAPTER 1 THE POINT OF CARE TESTING PROGRAM

The UMDNJ - Robert Wood Johnson Medical School Point of Care Testing Program

DESCRIPTION OF THE PROGRAM:

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 University risks 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, just as a federal DEA number does substitute for a physician's medical license.

To assist personnel within UMDNJ - Robert Wood Johnson Medical School who wish to perform clinical laboratory procedures on-site, the University Diagnostic Laboratories has adopted a POCT program designed:

- To provide quality care to our patients;
- 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 provide additional revenue opportunities for clinical departments;
- To simplify billing procedures within the practice sites; and
- To ensure the highest quality of test performance to all patients.

Under this program, a standard package of Point of Care services can be provided at any RWJMS clinical facility, 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 handled by the Department and clinical oversight responsibilities divided between the Department and a Point of Care Testing Coordinator, usually nursing personnel from UMDNJ - RWJMS administration. Charges will be allocated to departments for these centralized services. Departments will, in turn, be responsible for allocating this expense internally.

This program will:

- Provide each participating nursing unit with a package of standardized procedures which can be performed at any RWJMS facility so long as the requirements for training, competency assessment, quality control and periodic review are maintained within the facility
 - Standardize testing options for point-of-care tests and centralize inventory so that common reagents are used throughout the plan and lot to lot variability is minimized
 - Provide limited troubleshooting 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 point of care testing
 - Provide for monitoring and initial review of testing records
 - Provide for visits to each clinical facility to review compliance efforts with state and federal regulations regarding clinical laboratories at least semi-annually and more frequently if necessary.
 - Ensure compliance with RWJMS billing requirements
-

Reimbursable POCT Testing Included in the Program:

- Glucose by monitoring device FDA cleared for home use
- Urinalysis by dipstick, non-automated
- Urinalysis by dipstick, non-automated with microscopy
- Pregnancy – Urine pregnancy test by visual color comparison methods
- Guiac, stool – Blood occult, by peroxidase activity, feces, 1-3 simultaneous determinations
- Streptococcus, group A
- H. Pylori
- Influenza A & B
- Qualitative HIV-1 antibodies

Physician Performed Microscopy:

- KOH prep
- Wet mount
- Fern test
- Urinalysis by dipstick, non-automated with microscopy

Participation in POCT Testing:

To participate in Point of Care Testing involves three steps:

9. [Completion of a facility POCT survey](#) to delineate all clinical laboratory testing being conducted on premises. Following a physical inspection of the facility, the Department of Pathology and Laboratory Medicine will arrange for licensure of the facility.
10. [Receipt of procedures and subsequent training](#). Upon completion of licensure, the Department will orient the site to proper procedures for providing point-of-care testing from the list of supported procedures. So long as the required training, proficiency testing, quality control procedures, record keeping and validation procedures are performed, the Department will:
 - a. Provide for POCT procedure manuals and log sheets to the unit
 - b. Provide for staff training initially and periodically thereafter
 - c. Review competency assessment of staff, including review of on-going proficiency testing under an appropriate program and direct observation
 - d. Establish POCT approval for billing purposes with site billing operations
2. [Adherence to Point of Care Program Procedures](#): Continued participation in the 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. Periodic inspections of all sites will occur and the results will determine continued participation in the program.

Obtaining necessary supplies:

Supplies, including test and control reagents, may be requested by forwarding a POCT supply request to UDL Central Administrative Offices via fax or email (shihhu@UMDNJ.EDU). Charges for these supplies will be distributed to the Department/Division periodically. Supplies obtained by the Pathology Department on behalf of participating sites will be validated prior to distribution. **If supplies are obtained in any other way, it is obligatory that they be validated prior to use.**

If a facility performs any other procedure aside from those listed above, complete clinical laboratory licensure under the University Diagnostic Laboratories auspices would be required. This too can be arranged by contacting UDL central administrative offices.

Ultimately, the responsibility for successful participation in proficiency testing is the clinical sites'. The Department of Pathology will provide assistance in troubleshooting of a limited nature as a part of POCT oversight. More extensive or complex troubleshooting activities will be charged for on an hourly basis.

POCT PROGRAM CONTACT INFORMATION

POCT PROGRAM CONTACT INFORMATION:

Task	Position	Name	Email	Telephone
Ordering of POCT reagents and controls:	POCT administrative coordinator	Vivian Shih	shihhu@UMDNJ.EDU	(732) 743-3630
Reagent or QC failure:	POCT clinical coordinator	Delores Van Pelt		(732) 743-3630
POCT Forms:	See POCT manual Chapter 2	http://www2.umdj.edu/udlweb/		
Proficiency Testing Issues:	Administrative Director, UDL	Eugene Martin, Ph.D.	martineu@umdj.edu	(732) 235-8114
Instrument Failure:	Administrative Director, UDL	Eugene Martin, Ph.D.	martineu@umdj.edu	(732) 235-8114
Regulatory Oversight	UDL Bioanalytical Laboratory Director	Evan Cadoff, M.D.	cadoff@umdj.edu	(732) 937-8586

Chapter

2

CHAPTER 2 – General Procedures

GENERAL POCT PROCEDURES

CHAPTER 2 – GENERAL PROCEDURES

POCT Program**PROCEDURE****Procedure:** General Guidelines for the POCT Program**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 and their timeliness be assured. Proper use of Point of Care 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 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 physicians, nurses (RN or LPN) or other qualified technical personnel may perform testing outside the laboratory, under the authority and licensure of a NJ licensed bioanalytical laboratory director appointed by the Chairman of the Department of Pathology and Clinical Laboratory Medicine.

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

For each testing activity to be performed at each practice site, a procedure specific to the test and site will be developed from these guidelines. Failure to follow the procedures outlined will result in cessation of permission to perform ancillary testing. Specific guidelines are included to allow for the expansion of testing as needed in specific clinical environments.

MAINTENANCE

Regular maintenance procedures on POCT equipment must be carried out by testing personnel at each site. Any preventive maintenance service will be performed by the instrument service representative.

Specific maintenance procedures will be outlined in the procedure manual for each test, and will be summarized for easy reference. Those performing the maintenance checks must document their activity according to the procedure.

QUALITY CONTROL

Following proper quality control procedures is essential. Lack of quality control can result in serious mis-interpretations 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 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 POCT program Central Administration. Materials should be ordered from the Central Administration using forms provided in this manual.

Frequency: The frequency of QC testing depends on the test being performed and may be specific to each site where the testing is being performed. Some testing, such as blood glucose, requires that QC materials be run on daily basis before patient tests are run. In fact, the Medisense PCx will not permit patient testing if the instrument QC has not been performed. Other testing may require QC checks at 8 hour intervals or whenever a lot is new to the facility or even whenever operators change. Specific requirements are noted in each procedure.

Number: For all tests, one QC sample within the reference (normal) range is required, and at least one abnormal sample. Thus a minimum of two, and usually a maximum of three samples must be run each time a QC check is done.

Expected values: For each QC sample, the Point of Care program will establish the *expected range*. These ranges reflect the technical imprecision of the test and the biologic variation that is considered significant. As needed, the laboratory may also establish a flow sheet to aid in interpretation of QC results, to determine whether patient results will be reliable. The POCT clinical coordinator should be 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 coordinator, please contact the RWJMS POCT administrative offices and request assistance.

Record keeping: Results of all QC samples must be logged onto appropriate record sheets that will be kept with each instrument and must indicate who performed the testing. These may be reviewed at any time by the POCT clinical coordinator, laboratory supervisors or representatives from regulatory agencies. They must be sent to the POCT clinical coordinator monthly, and will be kept for at least two years in UDL central administration.

PATIENT 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 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 Point of Care Testing clinical coordinator, and must be retained for at least two years. Any printout provided by the instrument must also be saved with the log sheets for two years.

OPERATOR PROFICIENCY

Each person running the test must be trained according to POCT program policy. Training will be provided by the Point of Care Testing coordinator's direct staff or in limited circumstances by other trainers approved by the coordinator and the laboratory director. The POCT coordinator 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 through the POCT clinical coordinator. 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 POCT site to be run. These samples are purchased from outside regulatory agencies to evaluate the accuracy of the results obtained by the laboratory. These "proficiency testing" samples must be run as patient samples are run, after proper maintenance and quality control procedures have been completed. The results will be reported back to the testing agency for evaluation. Failure to perform adequately on proficiency testing challenges can result in loss of the laboratory's license. Ongoing issues related to proficiency testing results will be cause to prohibit performance of point of care testing at a particular clinical site or facility.

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.

Written by: _____ POCT Committee. _____ Date: _____ 01/15/02 _____

Approved by: _____ Evan Cadoff, M.D. _____ Date: _____ 01/15/02 _____

Revised by: _____ Eugene G. Martin, Ph.D. _____ Date: _____ 11/19/03 _____

Revised by: _____ Eugene G. Martin, Ph.D. _____ Date: _____ 06/18/05 _____



Reviewed by: _____ Date: _____ 06/20/2005 _____

*POCT Program**PROCEDURE***Procedure:** Quality Control Program**Purpose**

The purpose of the QC program is to monitor the quality of testing performed by the Point of Care Testing staff and to ensure that problems related to the test systems, reagents or testing procedures are identified and addressed. Quality Control testing is an intrinsic part of any laboratory testing and must be done in order to provide proper patient care and to be in compliance with the standards of the College of American Pathologists, the NJ Department of Health and Senior Services and CLIA 88.

Elements of the Quality Control Program

Quality control is an ongoing process designed to insure that an analytic system is functioning correctly. The basic premise of most quality control systems is that known samples are tested (simultaneously with patient unknowns) and the results compared with expected results. Failure to obtain the expected values is an indication that a problem may exist, and results in a series of actions designed to protect the patient and personnel from treatment based on aberrant and incorrect data.

Responsibilities

1. It is the responsibility of the Point of Care site testing staff to complete quality control on all testing performed. Patient testing may only be performed if Quality Control results are within the limits specified.
1. Periodically, the POCT clinical coordinator will inspect sites to ensure that proper procedures are being followed and documented for patient identification, patient preparation, specimen collection, specimen ID, specimen preservation and processing, and result reporting.
1. Quality Control (QC) specimens will be analyzed at a frequency determined by the laboratory director. In some instances this may be minimum of once per day, on days when patient testing is being performed. The first QC sample must be analyzed before or simultaneously with the first patient sample being tested. Please review the specific test procedure to determine the required frequency.
1. QC specimens will be analyzed on a rotating basis by all testing personnel within a POCT site.
1. It is the responsibility of the Point of Care Testing **site** supervisor to review all POCT quality control on a weekly basis, to assure that testing and troubleshooting is done and documented.
1. The POCT site supervisor will submit QC data to the POCT clinical coordinator on a monthly basis for review and central maintenance of records.
1. At his discretion, the UDL Laboratory Director may assign additional duties for the monitoring of performance and the correction of problems identified by the monitoring system to the POCT clinical coordinator or other designated staff.

Quality Control Failures

In the event of a quality control failure, the POCT testing site must take a series of actions designed to:

- Prevent the release of false data derived from the assay.

- Pinpoint the problem to either assay components, equipment malfunction or assay performance.
- Establish a means to follow-up and review the areas indicated by the QC failures.
- Document corrective action directly on the back of the Testing Log sheet forms provided.

Recommended Range of Controls Used

The recommended range of controls is specified in the Quality Control section of each testing procedure.

Recommended Frequency of Quality Control Samples

- As specified in the specific procedure covering the range of expected results;
- Each time an instrument has been serviced to verify proper operation;
- Each time testing personnel are suspicious of possible testing malfunction, e.g., unexpected patterns of patient results which raise the possibility of malfunction;
- Each time a new reagent lot number or new test kit lot number is introduced. Central validation of all reagent lots prior to release will be performed for any POCT supply obtained from POCT program inventory

Acceptable Limits

Acceptable limits will be defined for each particular assay in the assay procedure protocol.

Corrective Actions

If a QC failure occurs it is essential to determine the cause of the failure.

- The initial step in examining a QC failure is to suspect the quality of the reagents, controls, or the performance of the instrumentation. It is often helpful to utilize a different lot of reagent and repeat the procedure. If a different lot of reagents is not available at the site please contact the POCT clinical coordinator or the UDL Administrative Coordinator.
- **In the face of a QC failure, do not release results without contacting the POCT clinical coordinator for approval.** If the problem can be readily identified and solved internally, indicate the corrective action taken on the QC Log. For example, if you repeat the QC and it is now found to be within range, record the new result and indicate whether you repeated the same QC sample from the same lot of reagent or whether you employed a different QC sample or a different reagent lot.

If the problem cannot be readily identified:

- Review the procedure manual for the test. It may help you solve the problem and/or point you in the right direction for the next steps to take.
- Contact the POCT clinical coordinator or the UDL Administrative Coordinator will follow-up as required
- Document ALL QC actions DIRECTLY on the back of the Testing Log sheet to permit rapid review.

QC Review

All QC results must be reviewed on a regular basis.

Each person performing patient testing must first verify that QC was properly performed and documented at the appropriate interval. If QC has not yet been done, patient testing may not be done. All testing personnel must initiate corrective action if QC results do not fall within the expected ranges.

The Point of Care testing site supervisor will review and document QC on a weekly basis. The site supervisor is responsible for instituting corrective action for 'out of compliance' procedures. Resources available to assist the resolution of 'out of compliance' performance include the POCT clinical coordinator, other technical resources within UDL including clinical laboratory scientists within the Department of Pathology and manufacturer's representatives, as needed.

The POCT clinical coordinator will review and document QC on a monthly basis. The maintenance of a central repository for all POCT records complies with CAP accreditation requirements and assists in the provision of high quality testing by allowing trained clinical laboratory specialists to:

- Review ongoing technical problems and their resolution.
- Review problem cases
- Review QC failures

Action to Improve Services and to Resolve Problems

All problems identified by the monitoring system will be corrected, documented and brought to the Quarterly UDL Quality Assurance meeting.

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

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Reviewed by: _____ Date: 06/20/2005

*POCT Program**PROCEDURE***Procedure:** Proficiency Testing Program**Purpose**

The purpose of Proficiency Testing is to monitor the quality of technical services provided by physicians, nursing staff; medical assistants and any other individual trained and competent for Point of Care testing and to ensure that problems related to these 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. Federal regulations, state regulations and deeming authorities such as the College of American Pathologists mandate that all testing facilities must successfully participate in an approved proficiency program for all regulated testing being performed in each specialty.

Proficiency testing is an ongoing part of a process intended to ensure that the analytic system of the testing site is functioning correctly. The basic premise of proficiency testing is that proficiency test specimens are tested simultaneously with patient unknowns and the results compared with results generated in many other institutions. Failure to obtain the expected values results in a series of corrective actions designed to protect UMDNJ-RWJMS and its patients from the generation of aberrant and incorrect data.

Responsibility

It is the responsibility of the POCT program to:

- Oversee and evaluate the quality of technical offerings provided by RWJMS clinical out patient practice sites,
- Ensure laboratory compliance with existing federal and state regulations
- Assist physicians and staff in meeting the clinical laboratory testing needs of their patients

Point of Care Testing staff must participate in the proficiency testing periodically as a requirement for inclusion in the Point of Care Testing program. Such testing is mandated by state and federal regulations.

Procedure

In order to provide central coordination of these activities and to alert the license holder of significant failures in proficiency performance, all proficiency testing is processed through the Department of Pathology. Annually, based upon a review of POCT testing at RWJMS practice sites facilities, the Department elects to participate in a number of Proficiency Test programs from organizations including the College of American Pathologists (CAP), the American Association of Bioanalysts (AAB), and the NJ Department of Health and Senior Services.

In order to insure compliance with state and federal regulations, all POCT proficiency test (PT) specimens are received at the POCT administrative office and are distributed to the individual testing sites. As closely as possible, these specimens must be analyzed in the same manner, using the same testing methods as patient samples, by the same personnel who routinely test patient samples. Results are then forwarded to the POCT administrative offices on appropriate result sheets including reagent and control lot numbers and expiration dates and indicating the testing individual. The license holder or his/her designee will compile the proficiency data and will submit this data for evaluation by the proficiency testing program.

Proficiency testing will be rotated among Point of Care Testing staff to ensure that all personnel performing patient testing are evaluated periodically.

Analysis and Review of Proficiency Testing and Failures

All results from the interlaboratory comparison programs are received and maintained in the office of the

UDL Administrative Director in the Department of Pathology. Proficiency test results are reviewed, dated and signed by the Administrative Director and/or the Bioanalytical Laboratory Director. In the event of a testing failure, corrective actions will be necessary to improve services and to resolve existing problems.

Action to Improve Services and Resolve Problems


Any failure of proficiency testing must be investigated by the POCT testing site staff. The clinical site supervisor and the POCT clinical coordinator will analyze the PT failure in an effort to identify the source of the failure and to develop a plan of corrective action. The results of the investigation and any corrective action taken must be documented on the appropriate incident form, and be submitted to the UDL Administrative Director and the Bioanalytical Laboratory Director. Additional technical assistance will be provided by the Department of Pathology to insure successful test performance by POCT staff and adequate analysis of proficiency test failures.

Written by: _____ POCT Committee. _____ Date: _____ 01/15/02 _____

Approved by: _____ Evan Cadoff, M.D. _____ Date: _____ 01/15/02 _____

Revised by: _____ E. Martin/E. Cadoff _____ Date: _____ 11/05/02 _____

Revised by: _____ Eugene G. Martin, Ph.D. _____ Date: _____ 06/18/05 _____

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POCT Program

PROCEDURE

Procedure: Result Reporting Procedure

Purpose

The purpose of this procedure is to ensure the quality of technical services provided by the Point of Care Testing staff by establishing a standard for result reporting and reviewing.

Responsibility

It is the responsibility of Point of Care testing staff (including physicians performing microscopy) to:

- Properly identify patients and maintain the identity of the source patient throughout the testing process.
- Sign off on all testing performed by them
- Report and document any critical values immediately to the attending physician.

It is the responsibility of the Point of Care testing site supervisor or designee to:

- Review all patient and quality control testing results weekly and document their review.
- Forward all testing logs to the POCT clinical coordinator on a monthly basis
- Investigate and report back to the POCT coordinator all problems and questions as they occur
- Implement corrective action plans as required

It is the responsibility of the ordering physician to:

- Review all testing results and document their review.

It is the responsibility of the POCT clinical coordinator to:

- Review quality control, proficiency test results and patient logs
- Assist the laboratory directors in identifying significant reporting, QC or PT issues

Procedure

Patient Identification

1. Confirm the identity of the patient verbally with the patient and/or someone accompanying the patient.
1. Label any specimen collection containers (Hemoccult cards, urine cups, blood tubes, throat swabs, etc.) while still at the patient's side. Urine cups should preferably be labeled either before the patient voids, or by the patient in the bathroom.
2. Single use test devices (eg. pregnancy tests, strep tests) should be labeled so as to uniquely identify the patient. HIPAA regulations do not prevent you from labeling with the patient's name, but if you do use the name, you should not leave the test unattended in a public area.

Reporting

1. All patient testing results must be documented on the appropriate Testing Log and reported to the ordering physician.
1. All patient testing results will also be documented in the patient chart.
2. The results of all quality control performed will be documented on the Testing Log
3. All reagent lot numbers and expiration dates will be documented on the Testing Log.
4. If an electronic log of patient testing is kept and readily available, then paper logs of patient results will not be required. As this option becomes available, appropriate policies will be put in place.
5. Normal testing reference ranges will be found on the POCT Program reference range sheet.
6. All testing personnel will initial the Testing Log for any testing performed. A legible signature or printed name is required at least once per Testing Log sheet.
7. The reference range sheets provided must be included in the patient chart of any patient for whom POCT is performed. The reference range sheets will be updated as required.

Result Verification and Unexpected Test Results

If result verification is required by the specific procedure, it will be indicated in the specific procedure. Any unusual or unexpected test results must be assessed. If the result is subsequent to a testing system failure, the results of the investigation and the corrective action must be documented on the back of the Patient Testing Log. Notify the POCT clinical coordinator when repeat testing fails to verify an unexpected test result.

Written by: POCT Committee. Date: 01/15/02

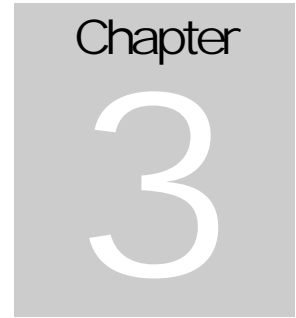
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POCT Forms

CHAPTER 3 POCT FORMS

CHAPTER 3 POCT FORMS