

CHLabs POCT Internal Audit for wards and clinics

LOCATION:	EQUIPMENT:
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NAME & TITLE:	SIGNED: (Principle)
NAME & TITLE	SIGNED: (Auditor)
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1. Quality management system

1.1	Are all staff members who use Point of Care Testing (POCT) processes aware of the existence of the relevant POCT Operators Manual?				
1.2	Have all staff members familiarised themselves with the contents of each POCT Operating Manual?				
1.3	Are all staff aware of the Appendix documents contained in the Manuals?				
1.4	Have all staff members read, signed and dated the acknowledgment page in the front of each POCT Operators Manual?				
1.5	a) Are Quality Control (QC) samples analysed as per determined frequency? b) Are all QC results documented?				
1.6	a) Are staff members aware that calibrations and QC are required for the correct functioning of POCT? b) Are staff members aware that there are preventative maintenance and calibration worksheets? c) Are QC, maintenance, error logs and stock lot number worksheets maintained regularly? d) Are all entries documented and signed?				
1.7	a) Are staff members aware that errors, failed QC and analyser problems must be entered in the Error Log? b) Are all actions documented fully? c) Are staff members aware that the POCT equipment or process must not be used until QC results are successful? d) Do all staff members know how to contact the POCT Coordinator for assistance?				

Comments:

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2. External services and supplies

2.1	Does the ward or clinic maintain an inventory control system for supplies and POCT that includes the recording of: a) Amount of kits or volume received b) lot numbers c) date of receipt in ward or clinic d) date material is placed in use e) expiry date				
2.2	Are the ward/clinic storage conditions appropriate for POCT cartridges, test strips, quality control solutions, etc? For example, room temperature or refrigeration?				
2.3	If consumables are required to be refrigerated, is there a procedure in place for monitoring refrigerator temperature?				

Comments:-

3. Advisory services

3.1	Are staff members of the ward, or clinic able to: a) provide input on the choice of required POCT b) provide feedback on the quality of POCT services c) interpret POCT results appropriately d) recognise action/critical limits e) communicate easily with the POCT Coordinator or laboratory services regarding POCT f) participate in clinical rounds, enabling advice on POCT effectiveness in general and in individual cases				
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4. Continual improvement

4.1	Does the ward or clinic: a) have a policy and practice for the resolution of procedural errors and transcription errors relating to POCT? b) maintain records of errors, investigations and corrective actions taken?				
4.2	Does the ward or clinic monitor results of corrective actions taken, in order to ensure that they have been effective in overcoming the identified problems?				
4.3	Does the ward or clinic audit to see if existing policies and procedures require modification to accommodate those identified problems?				
4.4	a) Is there a review process in place to periodically examine POCT operational procedures and corrective actions in order to improve the quality of the POCT service? b) Is the POCT Coordinator involved or consulted in this review process?				
4.5	Are results of any actions taken following the above processes submitted to the POCT Coordinator and/or POCT Committee for discussion?				
4.6	Does all personnel have access to suitable educational and training opportunities?				

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5. Quality and technical records

5.1	Do procedures exist for the collection, storage and subsequent safe disposal of POCT records?				
5.2	Is there a clear policy that defines the retention time (of at least 12 months) of POCT records and results? <i>(NPAAC guidelines are recommended).</i>				
5.3	Are all lot numbers of reagents, control samples, cartridges and other consumables recorded at the time of usage? <i>(Note- this record is distinct from Item 2.1).</i>				

Comments:-

6. Internal audits and Health & Safety

6.1	Does the ward or clinic have in place a procedure for conducting its own internal audits?				
6.2	Are deficiencies or opportunities for improvement in POCT practices noted on the internal audit documents?				
6.3	Are health and safety issues relating to POCT examined during the internal audit?				
6.4	Are all staff members aware of the need for Universal Precautions when handling patient samples?				
6.5	Are all recommendations of the audit acted upon within an agreed time frame?				
6.6	Is there a process in place to allow findings and actions that arise from management reviews and internal audits to be communicated to the POCT Coordinator or POCT Committee?				

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7. Competency of Personnel

7.1	Have all staff members been informed of the requirement to complete a training and competency program before using POCT?				
7.2	Staff members should have had training specifically in sample preparation, quality control practices, analyser maintenance, result interpretation, action ranges and troubleshooting for the POCT services offered. Do all staff members have relevant up to date competency records for each POCT procedure?				
7.3	Does the ward or clinic have access to data that define POCT operator competency requirements, e.g., the CDHB training and competency database? Data should include training, competency evaluations for POCT and records of continuing education and achievements				
7.4	Are staff members fully aware of the need for using (and not sharing) their password or unique identifier when analysing POCT?				
7.5	Is there a continuing education program available for all staff?				

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8. Accommodation and environmental conditions

8.1	Is space: a) adequate for workload b) safe for personnel and patients c) sufficient for storage of sampling equipment, documents, files, manuals, equipment, reagents, records and results,				
8.2	Are ward or clinic resources adequate to undertake the POCT required?				
8.3	Is the design of the POCT area: a) efficient for its operation b) of minimal risk of injury and occupational illness c) as such that patients, employees and visitors are protected from recognised risks				
8.4	Does the ward or clinic monitor, control and record environmental conditions, as required by OSH? (attention should be paid to biological sterility, dust, electromagnetic interference, radiation, humidity, electrical supply, temperature, sound and vibration levels)				
8.5	Are work areas clean and tidy?				

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9. Maintenance

9.1	Are all staff members aware that POCT analysers must be calibrated regularly and the calibration confirmed by analysis of a quality control sample?				
9.2	Are all staff members aware that: a) there are documented procedures available for preventative maintenance and QC? b) There is a requirement for preventative maintenance actions and QC results to be recorded regularly?				
9.3	Is all POCT equipment uniquely labelled, marked or identified?				
9.4	Do staff know that each POCT Operators Manual contains the following: a) identity of equipment b) manufacturer's name, type identification, and serial number or other unique identification c) routine instructions for use d) daily maintenance requirements e) quality control values and records f) reference ranges g) critical limits h) cleaning and decontamination i) troubleshooting history (error log)				
9.5	Are brief instructions, e.g., bullet pointed lists available and easily found beside the POCT analyser? (An example might be routine instructions or how to change the printer paper on an analyser).				
9.6	Is POCT equipment maintained in a safe working condition that includes the examination of: a) electrical safety b) emergency stop devices c) safe handling Is there a Technical Services certificate present?				

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9. Maintenance (*continued*)

9.7	Is disposal of contaminated material, consumables, etc done according to specified relevant regulations?				
9.8	Are employees trained to prevent or contain the effects of adverse incidents?				
9.9	Is defective POCT equipment: a) brought to the attention of the POCT Coordinator immediately b) taken out of use immediately c) clearly labelled as such d) decontaminated prior to service, repair or decommissioned e) once repaired, been successfully calibrated and tested to meet specified criteria, i.e., successful quality control results and/or lab correlations				

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10. Pre-analytical procedures

10.1	Are staff members aware of the documented procedure for proper collection and handling of POCT samples? a) purpose of the POCT b) preparation of the patient c) positive identification of the patient from whom a primary sample is collected d) recording of the identification of the POCT operator collecting the primary sample e) primary sample requirements (e.g. plasma, serum, urine) f) type of container and additive g) special timing of collection, if required h) any special handling needs between time of collection and time tested i) label requirements for all samples j) safe disposal of materials used in the collection				
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11. Analytical procedures

11.1	Are staff members familiar with the documentation and procedures pertaining to: <ul style="list-style-type: none"> a) required POCT equipment and consumables, e.g., cartridges. b) checking of lot numbers and expiry dates c) calibration procedures d) quality control procedures e) sample analysis procedures f) test measurement interferences (e.g. lipaemia, haemolysis) g) repeat examinations due to unexpected results, analytical failure or error codes generated during analysis h) biological reference intervals i) alert/critical values j) measurable range of the instrument k) safety precautions 				
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12. Post-analytical procedures and Reports

12.1	Are samples disposed of in accordance with local regulations or recommendation for waste management?				
12.2	Do reports of POCT include: a) identification of the examination procedure and appropriate measurement units b) unique identification and location of patient c) name or other unique identifier of the operator d) type of sample e) date and time of primary sample collection f) date and time of analysis g) Comments (e.g. quality and adequacy of primary sample which may have compromised the result)				
12.3	Are all POCT results and reports included in the patient record?				
12.4	Are Biological Reference Intervals <i>and</i> Alert/Critical Limits: a) documented b) reviewed periodically c) able to be found easily in the POCT Operators Manual				
12.5	Does the ward or clinic have a procedure for immediate notification to medical staff of clinically significant results?				
12.6	a) Are records of actions taken in response to immediate notification maintained? (Records should include date, time, responsible clinical staff member, person notified and examination results). b) Is any difficulty encountered in meeting the above requirements recorded?				

Comments:-
