Point of Care Testing Policy
**Policy Title:** Point of Care Testing

**Executive Summary:** East Cheshire NHS Trust is committed to the health safety and welfare of all of the patients it treats. The safe and appropriate use of point of care devices is vital to ensure that accurate and correct test results are obtained when used in diagnosis. This policy provides guidance on the safe and correct use of point of care devices in the Trust.

**Supersedes:** V2

**Description of Amendment(s):**
- Policy statement updated to identify actions required in the future
- Updated responsibilities
- Section 2.2 – update reference to accreditation to ISO 15189
- Section 3 – Pathology will continue to provide EQA for current equipment, but not new POCT
- Medical Devices Group replaced with Risk Management Sub-committee

**This policy will impact on:**
This policy will be applicable to all service lines and departments in the Trust where Point of Care Testing devices are used.

**Financial Implications:**
Not applicable

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<thead>
<tr>
<th>Policy Area:</th>
<th>Clinical</th>
<th>Document Reference:</th>
<th>ECT/POCT/2/03</th>
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<tbody>
<tr>
<td>Version Number:</td>
<td>3</td>
<td>Effective Date:</td>
<td>15/05/17</td>
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<tr>
<td>Issued By:</td>
<td>Medical Director</td>
<td>Review Date:</td>
<td>01/04/20</td>
</tr>
<tr>
<td>Author:</td>
<td>Jane Clarke, Deputy Service Lead Biochemistry</td>
<td>Impact Assessment Date:</td>
<td>December 2016</td>
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**APPROVAL RECORD**

<table>
<thead>
<tr>
<th>Committees / Group/ Trust Officers</th>
<th>Date</th>
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<tbody>
<tr>
<td>Trust Medical Devices Safety Officer, Deputy Director of corporate Affairs and Governance, Clinical Director for Allied Health and Clinical Support Services</td>
<td>December 2016</td>
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<table>
<thead>
<tr>
<th>Approved by:</th>
<th>Date</th>
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<tr>
<td>Medical Director</td>
<td>April 2017</td>
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<table>
<thead>
<tr>
<th>Ratified:</th>
<th>Date</th>
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<tbody>
<tr>
<td>Risk Management Sub-committee</td>
<td>May 2017</td>
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<table>
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<tr>
<th>Received for information:</th>
<th>Date</th>
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</thead>
<tbody>
<tr>
<td>Associate Directors General Managers</td>
<td>April 2017</td>
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</tbody>
</table>
An Equality Impact Assessment has been undertaken and no adverse impact has been identified. The assessment is available on request from: ecn-tr.PolicyCoordination@nhs.net
Policy Statement
This document covers all Point of Care Testing undertaken within East Cheshire NHS Trust and outlines the procedure to be followed when introducing, managing or performing any Pathology tests outside the laboratory environment by non-laboratory personnel.

No near patient testing can be introduced without prior agreement of the Medical Director and the Medical Devices Group. Going forward, a separate group needs to be developed to discuss POCT due to its expansion throughout the trust and Primary care, as this has a wider scope than medical devices.

All areas undertaking Point of Care Testing must have received training and be enrolled on an approved External Quality Assurance (EQA) scheme where available.

1. Organisational responsibilities

Chief Executive
Has ultimate responsibility for the implementation and monitoring of the policy in use in the Trust. This accountability is delegated in line with the trust's Corporate Governance Manual and Scheme of Delegation and Reservation as follows:

Medical Director
Has delegated accountability for medical devices and for providing assurance that appropriate systems and processes are in place to support safe and effective use of medical devices, including those that support point of care testing. They have the authority to restrict activity in the event of non-compliance until the problem is addressed.

Director of Corporate Affairs and Governance
Has delegated Trust Board accountability for Clinical and Non-Clinical Risk Management, including ensuring systems and processes are in place with regard to: Risk Management Strategy, Incident Reporting, Serious Incidents Requiring Investigation and Patient Experience (surveys).

Director of Nursing, Performance and Quality
Has delegated accountability for ensuring the delivery of safe practice and the following areas relevant to this policy:
- Performance against standards
- Director of Infection, Prevention Control
- Delivery of Patient Safety
- Professional Practice - competency frameworks & fitness to practice.

Medical Devices Safety Officer
Has overall responsibility for matters relating to medical devices, including policies and SOPs, training, reporting, procurement and compliance with standards.

Service line POCT leads
Nominated leads have responsibility for ensuring POCT within their service areas is undertaken in line with this policy, including ensuring that staff have the appropriate competence and training to undertake testing and that assurance is provided in relation to external quality assurance process.
Risk Management Sub-committee
Has responsibility to receive assurance in relation to point of care testing arrangements across the trust. To receive assurance reports from Medical Devices Safety Officer and service line POCT leads on compliance with standards and review all adverse incidents relating to equipment errors and Point of Care Testing (POCT) to ensure remedial action and organisational learning has occurred. To escalate in line with the trust’s risk management strategy issues or risks to the Executive Lead or Safety Quality and Standards Committee.

Clinical Directors of Service Lines
Are responsible for ensuring compliance with this policy and the escalation of risk assessments associated with Point of Care Testing.

Ward Departmental managers
It is the responsibility of the Ward / Departmental manager to ensure that the Point of Care Testing Policy is implemented in their area. It is the responsibility of the Ward / Departmental manager to ensure that Pathology is consulted when consideration is being given to the introduction of any Pathology based tests into a ward or clinic setting. It is the responsibility of the Ward / Departmental manager to ensure that staff, are trained and competent before they are allowed to undertake point of care testing and to ensure an accurate list of competent users is maintained at each site of testing. The Ward / Departmental managers are responsible for ensuring that all Quality control records are retained.

Individuals
Must follow the guidance contained within this policy It is the responsibility of the individuals undertaking the tests to ensure that the manufacturer’s instructions are complied with, that all reagents used are within date and are auditable for quality assurance purposes and that, where allocated, their personal access data is not divulged or passed to any other individual. Users must be aware of the limitations of any test they are performing and when results must be confirmed by Pathology.
Results from POC testing must be recorded in the patients notes along with the date and who performed the test, as required by RCPath guidelines on the Retention and Storage of Pathological Records and Specimens (April 2015).

Pathology Department
The Pathology Department organises and issues External Quality Assurance (EQA) samples for glucose meters, blood gas analysers, and paediatric HbA1C highlighting any areas of poor performance to the ward manager. Any failings or areas of concern will be reported via the Trust Incident Reporting System.

2. Planning and Implementation

2.1. Definitions:
The following terminology is used in this policy:

Point of Care Testing (POCT) is defined as: Any test that is performed near or at the side of the patient with the result leading to possible change in the care of the patient.

Reagent: A substance employed to produce a chemical reaction. Usually provided as part of a commercial testing system.
2.2. Introduction:

Point of Care Testing (POCT) is any laboratory or pathology based test that is performed near or at the side of the patient, be that in a ward environment or in the community, with the result leading to possible change in the care of the patient.

If such procedures are not undertaken correctly there may be risk to patients resulting from incorrect test results. Ensuring the appropriate use of these tests is a clinical governance issue.

All areas of Pathology are accredited to ISO 15189 by United Kingdom Accreditation Service (UKAS). However, no POCT is currently covered by external accreditation.

The Pathology Laboratory provides direction and advice on procurement of appropriate equipment, quality control of testing procedure, staff training, regular audit, competency assessment and the completion of documentation to ensure a robust and traceable system. All wards undertaking such tests must inform the Pathology Department. The laboratory is not involved in funding equipment /preparation of business case or providing staff to undertake testing.

For East Cheshire NHS Trust, there is currently no POCT coordinator or POCT group/committee. A dedicated coordinator is required to comply with POCT ISO 22870:2016 standards, and to oversee the provision and continuity of a quality POCT service to users.

2.3. Safety Rules:

All samples should be handled as potentially infectious. Wear disposable gloves and other Personal Protective Equipment as per manufacturer’s instructions and follow all Infection and Prevention Control and COSHH Guidance.

A single use retractable sharp lancing device should be used for finger pricks, and all blood sampling devices are disposed of into sharps bin as detailed in Safe Handling of Sharps Protocol

All clinical waste should be disposed of in accordance with the ECT Waste Management Policy.

All accidents and incidents must be reported to the Head of the Ward / Department and an ECT Incident report completed as per ECT incident reporting procedures.

All equipment should be maintained and decontaminated as per manufacturer’s recommendations and a decontamination certificate completed by the users before servicing or repair is undertaken. Where equipment cannot be decontaminated this must be clearly explained to any individual using it and the control measures to adopt explained.

3. Ward Management and Point of Care Testing:

Prior to introducing any new test into a ward / departmental area the Manager of that area must contact the Medical Devices Safety Officer or for non-medical POCT the relevant service POCT lead to determine whether it falls under the remit of POCT.

All POCT activity will be linked, to the appropriate department within Pathology. Pathology will then enrol the equipment on the associated External Quality Assurance Scheme. The Pathology Department will continue to cover the POCT equipment currently enrolled on schemes, but will not take on any further POCT equipment or schemes.
The Manager of each area must ensure a risk assessment is carried out to assess the individual issues associated with their area of responsibility. A generic risk assessment for POCT across the Trust is included in this document - Appendix A.

Before undertaking POCT on the wards staff must have attended approved training. For certain tests, staff, whom have been designated as “cascade” trainers will be able to train others in the workplace.

The ward Manager should maintain a list of staff who have completed training and ensure only staff entered on the list undertake testing. Copies of these lists should be forwarded to the Trust Medical Devices Safety Officer.

Attendance at such courses should be at least every 2 years to ensure competency is maintained and assessed.

All kits and reagents must be used before the stated expiry date and controls must be run as dictated by the manufacturer to ensure the equipment is functioning correctly.

All testing will be undertaken in accordance with manufacturer’s instructions using only approved reagents. All documents hardcopy or electronic versions relating to POCT such as Operator Guides should be available on each ward/area where the POCT equipment is used.

Staff will complete audit records that allow full trace-ability of lot number and QC results for each test performed.

All staff will be encouraged to process External Quality Assurance samples to ensure the correct processes are being followed.

4. Pathology management of Point of Care Testing:

4.1. Distribution of Quality Control (QC) samples
Pathology will distribute External Quality Assurance (EQA) samples to the wards/departments at intervals according to the relevant External Quality Assurance Schemes. The wards / department must process the EQA samples as a routine specimen, complete the accompanying documentation, and return it to Pathology within the stated deadline.

4.2. Analysis of results
The Pathology Department will submit the ward / departmental results to EQA to determine whether performance falls within acceptable criteria. Results and performance in EQA schemes will be communicated to the named individuals with responsibility for the POCT equipment in their area.

4.3. Procedure for non-returned results
Wards / departments failing to return results will be contacted by Pathology via the Matron in the first instance and given an informal reminder.

Any area failing to submit results on 2 consecutive occasions will be referred to the relevant Clinical Director and the Medical Director notified.

Any site which fails to return 75% of their samples within a 12 month period will be referred to the relevant Clinical Director who nominate will investigate the matter.
Wards /areas who consistently fail to complete Quality Assurance samples will be investigated by the Pathology Department in conjunction with the Medical Director and may have the facility withdrawn as the final sanction. Such failures will be recorded via the Trust Incident Reporting System.

All non-returns must be recorded on Datix to allow for review/trending.

4.4. **Procedure for sites identified as poor performers**

Whilst it is the responsibility of individual wards to ensure the accuracy of their testing, Pathology will liaise with and support any sites identified by the scheme as failing to meet the acceptable values.

The service line POCT leads will look at the procedure, equipment and training and identify any areas that require improvement. Improvement action will be communicated to Pathology Department, recorded and retained.

5. **Risk Management:**

Any member of staff discovering any variance or deviation from this policy must complete log as an incident/ Near Miss incident on the DATIX incident reporting system in line with trust incident reporting procedure. This also applies when an error is noted.

6. **Monitoring**

Departmental Managers are responsible for monitoring compliance with this policy at a local level.

The Pathology Department will monitor External Quality Assurance, and report back to the ward/departmental manager any problems identified which may have an impact on service provision or patient care.

The ward/departmental manager is responsible for ensuring that any corrective action identified by EQA testing or audit is implemented.

Failure to resolve such issues will result in the issue being escalated to the Medical Director and reported by exception to the Risk Management Sub Committee and testing may be suspended until a satisfactory solution is agreed.

Each year the POCT leads will audit areas of POCT activity against an annual audit schedule, which will be decided and monitored by the Risk Management Sub-committee. This may be undertaken in house or may be performed by the supplier of the equipment / reagents if applicable. Any areas of non-compliance will be communicated back to the ward/departmental manager.

7. **Key Performance indicators**

The effectiveness of this policy will be monitored via assurance reports from the Medical Devices Safety Officer and service POCT Leads three times per annum to the Risk Management Sub-committee in relation to the following key performance indicators:

- % staff trained to use any point of care testing devices by the Medical Devices Safety Officer
- Any site which fails to return 75% of their EQA samples within a 12 month period and resulted in escalation to the relevant Clinical Director.
8. Review
This policy will be reviewed every three years by the Medical Devices Safety Officer and service leads for POCT testing.

9. References:
Guidelines to Near Patient or Point of Care Testing: Clin. Lab. Haem 2000, 22,185-188

Welsh Scientific Advisory Committee March 1995 Near Patient Testing: he use of diagnostic Equipment and Procedures outside the Diagnostic Laboratory.


RCPath guidelines on the Retention and Storage of Pathological Records and Specimens (April 2015)
## Appendix A

### Risk Assessment

**Assessment of:** Point Of Care Testing  
**Assessment date:** May 2017  
**Assessor(s):** Risk Management sub-committee

<table>
<thead>
<tr>
<th>Date for review:</th>
<th>Hazard Identified</th>
<th>Person(s) affected</th>
<th>Likelihood</th>
<th>Impact</th>
<th>Risk Rating</th>
<th>Plan/Controls</th>
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<tbody>
<tr>
<td>1</td>
<td>Handling blood, body fluids leading to infection from biological agents</td>
<td>All competent staff encompassing Nursing staff, and Health Care Assistants</td>
<td>Possible (3)</td>
<td>Moderate (3)</td>
<td>Moderate (9)</td>
<td>Use of gloves, competency training, following rules laid down in safety manual and compliance with SOPs and COSHH assessments. Also use of enclosed automated analysers. vaccination</td>
</tr>
<tr>
<td>2</td>
<td>Inoculation injury from single use lancing device or capillary tubes, leading to infection from biological agents, cuts to skin.</td>
<td>All competent staff encompassing Nursing staff, and Health Care Assistants</td>
<td>Possible (3)</td>
<td>Moderate (3)</td>
<td>Moderate (9)</td>
<td>Use of gloves, competency training, following rules laid down in safety manual and compliance with SOPs and COSHH assessments. Use of sharp bins. vaccination</td>
</tr>
<tr>
<td>3</td>
<td>Exposure to bar code scanner – possible damage to eyes, possible blindness</td>
<td>All competent staff encompassing Nursing staff, and Health Care Assistants</td>
<td>Rare (1)</td>
<td>Major (4)</td>
<td>Insignificant (4)</td>
<td>Training in hazards</td>
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<td><strong>4</strong></td>
<td><strong>Electrical Hazards, analysers linked to mains – electrocution loss of life</strong></td>
<td>All competent staff encompassing Nursing staff, and Health Care Assistants</td>
<td>Rare (1)</td>
<td>Catastrophic (5)</td>
<td>Insignificant (5)</td>
<td>Electrical safety checks, safety audits, competency training.</td>
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<tr>
<td><strong>5</strong></td>
<td><strong>Fire due to electrical components</strong></td>
<td>All competent staff encompassing Nursing staff, and Health Care Assistants and patients</td>
<td>Rare (1)</td>
<td>Catastrophic (5)</td>
<td>Insignificant (5)</td>
<td>Electrical safety checks, safety audits, competency training.</td>
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<tr>
<td><strong>6</strong></td>
<td><strong>Incorrect performance of test or machine, increased morbidity of patient</strong></td>
<td>All competent staff encompassing Nursing staff, and Health Care Assistants and patients</td>
<td>Unlikely (2)</td>
<td>Major (4)</td>
<td>Minor (8)</td>
<td>Competency training, daily QC. Restriction to equipment via barcode access where available</td>
</tr>
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Approved by ……Risk Management Sub-committee