**NHSGGC CHECK LIST FOR POINT OF CARE TESTING (POCT) SERVICES**

**Section 1- CREATING & ESTABLISHING THE SERVICE**

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| **1** | **What is the name of this POCT service?** |   |
| **2** | **Is there an agreed need for this POCT service?** YES / NO*SUMMARISE:* |
| **3** | **Who holds the funding (budget) for:*** Capital equipment purchase
* Costs of preventative maintenance & repairs
* Costs of consumables
* QC costs (IQC & EQA: Internal Quality Control & External Quality Assessment)
* Laboratory support costs (if applicable)
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| **4** | **Which laboratory (or other service) will provide the following support:*** Training and competence assessment of staff
* Quality Assurance (IQC and EQA)
* Quality Management support (including SOPs & Document control)
* Health & Safety
* Maintenance of equipment
* Order, storage and supply of consumables
* Advice on interpretation of results
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| **5** | **Are the above relationships** (including supporting and budgetary arrangements) **formally defined by a Service Level Agreement (SLA),** covering the range of service, operational details and responsibilities of the laboratory and the POCT users. |  |
| **6** | **Who will be POCT service co-ordinator for day-to-day running of this service** (including maintaining quality standards, review of IQC and EQA performance and undertake regular review of this service)**?** |  |
| **7** | **Who will be responsible & accountable for this POCT service from a Governance point of view?** This will usually be the Clinical Lead. What is the mechanism for reporting adverse incidents? Has an appropriate Risk Assessment of the POCT Service been undertaken with satisfactory results? |  |

**Section 2 - DESCRIPTION OF THIS POCT SERVICE**

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| **1** | **Parameter(s) being measured** |  |
| **2** | **Detail categories of patients being tested.**List location of POCT services.Have these POCT premises been evaluated for suitability from a H&S perspective? |  |
| **3** | **Specify POCT device(s)** |  |
| **3a** | **How does the POCT device record patient ID information** |  |
| **3b** | **How does the POCT device report test result data** |  |
| **3c** | **Can the POCT device be electronically linked to facilitate the electronic transfer of patient ID and result test data to NHSGGC IT Systems (i.e. SCI, Clinical Portal, TrackCare, LIMS)** |  |
| **4** | **Number & Location of devices and their date of installation**(each device should have a unique identifier) | ID Location Date Installed |
| **5** | **Category of staff who will operate POCT device** |  |
| **6** | **Specimen requirements** |  |
| **7** | **Specify consumables (reagents)** |  |
| **8** | **Specify IQC and EQA** |  |
| **9** | **Who is responsible for monitoring and ordering supplies?** |  |

**Section 3 - MANAGEMENT AND ORGANISATION OF THIS POCT SERVICE**

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| **1** | **There is a training policy & manual, which will include:*** Name of designated trainer(s)
* Details of training programme, including
* The context and clinical utility of the POCT service
* The analytical principles of the POCT system
* Sample collection and handling
* Reagent storage
* Quality Control
* Infection Control
* Limitations of the Measuring Systems
* Response to results outside predetermined limits
* Documentation and reporting of results
* Details of competency assessment
* List of trained staff
* Details of frequency and extent of training updates for staff
 |  |
| **2** | **There is a comprehensive Standard Operating Procedure (SOP), which will detail:*** Instructions for use of device (as per manufacturers guidance)
* Summary of analytical principle of the device
* Guidance on which patients should be tested and when
* Specimen requirements
* Limitations of device / analysis
* Simple guidance on results acceptance, interpretation & action
* Instructions for results documentation
* Guidance on health & safety issues for the operator, to include details of COSHH (Control of Substances Hazardous to Health) and arrangements for disposal of waste reagent and clinical material
* There is a documented procedure for decontamination / cleaning of equipment
* All Infection Control risks & issues are addressed
* Simple guidance on troubleshooting and contact details for advice
* Details of agreed maintenance schedule
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| **3** | **There is a QA policy, which will include:*** Details of IQC requirements and actions required when IQC lies out-with designated limits
* Details of EQA arrangements
* Details of regular QA audit, and the individual(s) responsible for monitoring against the QA policy
* Advice on the reporting of adverse incidents through the routine hospital system and to the Medicines & Healthcare products Regulatory Agency (MHRA) where a device shortcoming has been identified
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| **4** | **Record keeping.****a) Each device has a log detailing*** Date of equipment acquisition
* Appropriate safety checks (e.g. PAT testing)
* Results of any pre-installation, or subsequent, validation exercise
* Any relevant service/maintenance contract
* Results of calibration procedures
* Equipment failure & service/repair details

**b) There is complete and confidential documentation of all analyses, to include:*** Date of test
* Identity of device
* Batch number of reagent (if applicable)
* Result obtained
* Identity of operator (for patient & QC samples)
* Identity of patient

 (not all the above information need be stored in the same format/file/location)**c) Patient results are recorded in their medical record** (i.e. secure hard copy medical case sheet or recognised electronic equivalent) **and are distinguishable from results of the same analyte reported by the laboratory** (i.e. by non-POCT methods).**Where applicable, Patient ID and Test Result Data have been demonstrated to meet with NHSGGC IT Policy, for the electronic transfer (upload) to NHSGGC IT Systems (i.e. SCI, Clinical Portal, TrackCare, LIMS – define).****d) IQC and EQA data are recorded and reviewed regularly** |  |