

PROPOSAL TO INTRODUCE POINT OF CARE TESTING (POCT) DEVICE(S)

POCT devices are testing devices/processes located outside the routine Pathology laboratory that are used to perform pathology testing at or near the patient bedside, enabling timely and accurate clinical decisions regarding the patients treatment and or diagnosis.

This proposal form is designed to allow the safe introduction of POCT devices/processes. It will ensure that relevant issues have been covered, that appropriate support is available and that efforts are not duplicated, for example in the preparation of standard operating procedures and in dealing with clinical governance issues including risk management and training.

Introduction of all POCT devices must be approved by the Trust POCT Committee and are subject to financial approval by the appropriate Trust authority.

Use the [TAB] key to progress to the next question/field.

SECTION 1: POCT DEVICE/PROCESS DETAILS

1. What new POCT process/device is proposed?
2. What specialty is proposing this service
3. What is the proposed location(s) of the new POCT process/device?
4. Is the device(s) designed to be static or portable?
5. Who will be named person responsible for introducing the new POCT device? (Name, Contact details, Ward/Clinical site, Directorate)
6. When is the device likely to be used?
M-F, 9-5 <input type="checkbox"/> 24/7 <input type="checkbox"/> Other <input type="checkbox"/> , please state

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7. Who will have the responsibility for necessary training, where will records be held?

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8. Who will actually perform the POCT (what are their roles)?

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9. Will system users be restricted to named (competent) staff? If not, please explain how you will maintain an audit trail

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10. What extra staff time is involved in performing the POCT device/process?

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11. How will results be recorded, including access through EPR or LIS?

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12. Who will be responsible for producing the Standard Operating Procedure (SOP) for the POCT process/device?

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13. What is the rationale and reason for using POCT rather than laboratory analysis?

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14. Has discussion with the relevant laboratory section taken place regarding this particular technique? If so, with whom? *For advice please contact Tracy Miller, POCT Operations Manager.*

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15. Has the relevant pathology laboratory been consulted with regards to units, reference ranges, sample types and, if necessary, correlation with laboratory results (who was involved)?

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16. Are you aware of whether the Method/Instrument is in use within the Trust or within the NHS?
If so please detail wards/departments?

17. If the method/instrument is not being used within the Trust please supply supporting papers/data for the introduction of method/instrument elsewhere?

Is the method/device CE marked?

Is the method/device approved for use within the NHS?

18. What maintenance requirements are required? Has support been discussed with relevant Department? If so, with whom?

19. What will happen if the device/process breaks down and what would the contingency plan be?

20. Who will manage the ordering of consumables and arrange maintenance contracts and emergency call outs?

21. Is the POCT device being used as a rule-in or rule-out test? If so, what is its performance (i.e. sensitivity, specificity etc.) and how will the risk of false positive or false negative results be managed?

22. Has it been established that an external quality assurance (EQA) scheme is available for the device/process? Has this been discussed with the relevant laboratory, if so with whom?

23. Have you read the GSTT Point of Care policy? YES NO

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24. If the new POCT process/device is approved, will it comply with the above policy?

YES NO

If 'NO', please explain:

25. Has funding been granted for the device/procedure?

YES NO

If 'YES' please specify funding source:

26. Have ongoing costs been considered and budgeted for, such as maintenance, quality control, EQA, training, IT requirements and power supplies?

27. Have patients or patient groups been involved in the discussions?

YES NO

Please explain answer:

28. Do the patient facilities meet the requirements for patient safety and dignity, i.e. do they comply with CQC standards for Outcomes 8 and 10?

YES NO - If NO, is there a corrective action plan? Please explain:

29. If this is a pilot trial to introduce a POCT service:

What is the target end date of the pilot?

How far has this process got?

If successful, when would you like to put the device into service?

SECTION TWO: APPLICANT DETAILS

Please give details of person responsible for proposed new POCT device/process

Name:		Tel/Bleep No:	
Position:		E Mail:	
Signed:		Dept/Ward:	
Date:		Directorate:	

This application must be supported by the Directorate General Service Manager and Clinical Director

General Service Manager		Clinical Director	
Name:		Name:	
Signed:		Signed:	
Date:		Date:	

When complete please send or [e-mail](#) to Tracy Miller, POCT Operations Manager, Level 3, Block C, South Wing, St Thomas' Hospital or fax to: 0207 188 8612, STH.
Please contact Tracy if you wish to discuss any part of the application, Ext 80841.

For POCT committee use only:

Pilot trials

Study subjects		Located	
Pilot start date		Pilot end date	
If already started, how far has it got		POCT introduction target date	

Introduction of POCT

Criterion	y/n	Criterion	y/n
SOP available			
EQA available			
Compliance with CQC Outcomes 8 & 10			

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Approval to proceed

Pilot study (y/n/na)		POCT service (y/n)	
Approved by (name)		Position	
Signature		Date	