

AC 6 Medical Testing Laboratory Accreditation

ORGANISATION DETAILS	
Organisation Name <i>(i.e. name of the body taking legal responsibility for the activities of the medical laboratory)</i>	
CQC or CPA Ref No. (Existing Customers Only)	

STANDARD

ISO 15189

ISO 22870 (POCT)

Scope(s) Requested:

No	MEDICAL LABORATORY FIELDS (activities)	TYPES OF EXAMINATION/TECHNICAL FIELDS/ACTIVITIES (please provide general header and listing of all analytes etc.)	MATERIALS OR PRODUCTS TESTED	DESCRIPTION OF KEY EQUIPMENT USED, MEASUREMENT PRINCIPLE AND MAIN SOP REFERENCE	LOCATION ¹
Example 1	Microbiology	Therapeutic drug monitoring - antibiotics - Gentamicin	Blood	Manufacturer's Analyser using Enzyme-multiplied immunoassay SOP ABC	Remote 'spoke' at Medtown
Example 2	Blood Sciences	POCT Haemoglobin	Blood	Manufacturer's Analyser using photometry SOP DEF	GP (two sites) and Theatres at main hospital
1					
2					
3					
4					
5					
6					

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7					
8					
9					
10					
11					
12					
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25					

¹ Please indicate [with a '**'] on the details above any tests/activities that you carry out at remote sites including POCT activities undertaken in other areas of the hospital, or in temporary or mobile facilities. Please also indicate the type of site (e.g. mobile facility) and locations.

(To facilitate completion, the list of scopes requested can be documented on an accompanying spreadsheet or table)

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PLEASE IDENTIFY ANY SPECIFIC ACTIVITIES WHICH SUPPORT THE FUNCTIONING OF THE MEDICAL LABORATORY (E.g. facilities management, procurement, HR, advisory services, etc. together with their location)	
ACTIVITY	LOCATION

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FURTHER INFORMATION	YES	NO
<p>DOES YOUR LABORATORY MANAGE ANY BLOOD FRIDGES, PHLEBOTOMY SERVICES, BODY STORES OR MORTUARIES? (if yes please provide details below including the location)</p> <p>Click here to enter text.</p>	<input type="checkbox"/>	<input type="checkbox"/>
<p>DO YOU PROVIDE A SERVICE FOR ANY SCREENING PROGRAMMES (e.g. ANTENATAL, NEW BORN, CANCER)? (if yes please provide details below)</p> <p>Click here to enter text.</p>	<input type="checkbox"/>	<input type="checkbox"/>
<p>DO YOU OFFER /PROVIDE ACTIVITIES OR EXAMINATION PROCEDURES THE RESULTS OF WHICH COULD BE USED AS EVIDENCE IN THE CRIMINAL JUSTICE SYSTEM? (if yes please provide details below)</p> <p>Click here to enter text.</p>	<input type="checkbox"/>	<input type="checkbox"/>
<p>DO THE LABORATORY STAFF PERFORM ANY EXAMINATION OR PRE-EXAMINATION ACTIVITIES OUTSIDE OF THE LABORATORY SETTING? (if yes please provide details below)</p> <p>Click here to enter text.</p>	<input type="checkbox"/>	<input type="checkbox"/>

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DOES YOUR LABORATORY CONDUCT ANY MEDICAL TESTING ACTIVITIES THAT YOU DO NOT WISH TO HAVE INCLUDED WITHIN THE SCOPE OF YOUR ACCREDITATION? (if yes please provide details below)

IN-HOUSE CALIBRATION:

Are there any in-house calibration(s) of equipment used for any measurement activities included in your scope of application?

Yes No

*If 'Yes' please provide details below (refer to CQC publication **TPS 41** for information)*

No.	MEASURED QUANTITY / INSTRUMENT	REFERENCE STANDARD USED	PROCEDURE	PURPOSE <small>(details of measurement activities that this supports)</small>
1				
2				
3				
4				
5				
6				

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MULTI-SITE APPLICATIONS:

If your application covers activities performed at more than one site, details must be provided below.

SITE NO.	SITE LOCATION	ACTIVITIES PERFORMED AT THIS SITE ²	CONTACT DETAILS
Example	ATOWN, ASHIRE	MICROBIOLOGY PHLEBOTOMY	DR A, ATOWN SITE, PHONE XXXXXX
1			
2			
3			
4			
5			

² Please use the same terms as referred to in the first two columns of the first table used in this form

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EXTENSIONS TO SCOPE ONLY:

1. I wish this extension to scope application to be processed now (and understand this may require an extra visit by CQC).

Desired Timeframe for Assessment: Select from drop-down list

Please note standard CQC timeframe for the assessment of extensions to scope is 3 months from receipt of application

2. I wish this extension to scope application to be processed with my next surveillance/re-assessment visit.
3. I would like to propose that this extension to scope application is considered for desktop review
(Please note that the decision on the applicability of this proposal will be made by CQC based on a number of factors including existing scope of accreditation and competences demonstrated)

SUPPORTING DOCUMENTATION:

For an extension to scope to be progressed by CQC the following documentation must, as a minimum, be supplied where it is applicable. Applications submitted with no supporting documentation will not be accepted.

Documentation	‘Check’ if supplied	Justification for non-submission
Documented Technical Procedure	<input type="checkbox"/>	
Method Verification / Validation Data and Summary	<input type="checkbox"/>	
Estimation of Uncertainty of Measurement	<input type="checkbox"/>	
Detail of the Measurement Traceability Chain	<input type="checkbox"/>	
Other (please state)	Click here to enter text.	

*For an extension to scope to be considered for **desktop** review the following documentation, in addition to that listed above, must be supplied, where it is applicable. Applications submitted with no supporting documentation will not be accepted.*

Documentation	‘Check’ if supplied	Justification for non-submission
Details of Internal Quality Control including control charts	<input type="checkbox"/>	
EQA Performance Summary	<input type="checkbox"/>	
Training and Competence Records of Relevant Staff	<input type="checkbox"/>	
System Suitability Checks	<input type="checkbox"/>	
Other (please state)	Click here to enter text.	

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DECLARATION:

- I declare that I am authorised, on behalf of the organisation, to submit this application, and that the information contained herein is both correct and accurate to the best of my knowledge and belief.
- If this application relates to an extension to scope, I understand and accept that an assessment fee will normally be charged for the extension to scope, and it may be necessary to revise our annual fees upon grant of the extension to scope.

For medical laboratories transferring from CPA accreditation:

- By submitting this application I acknowledge that I have read, understood and accepted the CPA Terms and Conditions which shall remain in force until the laboratory is granted ISO 15189 accreditation under CQC, and agree to pay the associated transition fee.

For new medical laboratories applying directly for CQC accreditation:

- By submitting this application I acknowledge that I have read, understood and accepted the CQC Standard Terms of Business.

Name: [Click here to enter text.](#)

Position: [Click here to enter text.](#)

Date: [Click here to enter a date.](#)

APPLICATIONS TO BE SUBMITTED TO:

EMAIL: manager@cqcert.co.uk