

## AC 6 Medical Testing Laboratory Accreditation

ORGANISATION DETAILS	
<b>Organisation Name</b> <i>(i.e. name of the body taking legal responsibility for the activities of the medical laboratory)</i>	North West Anglia NHS Foundation Trust
<b>UKAS or CPA Ref No. (Existing Customers Only)</b>	8055

### 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 <sup>1</sup>
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	Microbiology	Isolation and identification of pathogens and antibiotic sensitivity testing	Swabs, sterile fluids, drains, tissue, fae ceccs, line/catheter tips, spinal fluid, sputum/respirator y	Sensativity by disc diffusion EUCAST B028	PCH

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2	Microbiology	Urine Microscopy and Culture	Urine	Menarini Sedimax for microscopy	PCH
3	Haematology	ESR	Whole Blood:EDTA	Microvette CB200	PCH
4	Histopathology	Examination to identify cell morphology changes/abnormalities, and diagnosis for the purposes of disease identification	Human tissue samples/ organs, cell blocks	Thermo Excelsior Fixation and Processing Tissue Protocols	PCH
5	Histopathology	Examination to identify cell morphology changes/abnormalities, and diagnosis for the purposes of disease identification	Human tissue samples/ organs, cell blocks	Sakura Prisma staining machine and Film coverslipper CP-H-314	PCH
6	Histopathology	Special stains	Human tissue samples/ organs, cell blocks	Remove- Micro organisms and parasites Giemsa	PCH
7	Histopathology	Immunohistochemistry	Human tissue samples/ organs, cell blocks	Additional antibodies please see attached scope.	PCH
8	Immunology	ANA Screen	Serum	Werfen Bioflash CIA IMM-LP-CIA-CTD	PCH
9	Immunology	ENA Screen	Serum	ImmunoCAP 250 EliA technology IMM-LP-EIA-ENAS	PCH
10					

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11					
12					
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23					
24					
25					

<sup>1</sup> 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><b>DOES YOUR LABORATORY MANAGE ANY BLOOD FRIDGES, PHLEBOTOMY SERVICES, BODY STORES OR MORTUARIES?</b> (if yes please provide details below including the location)</p> <p>Click here to enter text.</p>	<input type="checkbox"/>	<input type="checkbox"/>
<p><b>DO YOU PROVIDE A SERVICE FOR ANY SCREENING PROGRAMMES (e.g. ANTENATAL, NEW BORN, CANCER)?</b> (if yes please provide details below)</p> <p>Click here to enter text.</p>	<input type="checkbox"/>	<input type="checkbox"/>
<p><b>DO YOU OFFER /PROVIDE ACTIVITIES OR EXAMINATION PROCEDURES THE RESULTS OF WHICH COULD BE USED AS EVIDENCE IN THE CRIMINAL JUSTICE SYSTEM?</b> (if yes please provide details below)</p> <p>Click here to enter text.</p>	<input type="checkbox"/>	<input type="checkbox"/>
<p><b>DO THE LABORATORY STAFF PERFORM ANY EXAMINATION OR PRE-EXAMINATION ACTIVITIES OUTSIDE OF THE LABORATORY SETTING?</b> (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 UKAS 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 <sup>2</sup>	CONTACT DETAILS
Example	ATOWN, ASHIRE	MICROBIOLOGY PHLEBOTOMY	DR A, ATOWN SITE, PHONE XXXXXX
1			
2			
3			
4			
5			

<sup>2</sup> 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 UKAS).

**Desired Timeframe for Assessment:** Select from drop-down list

*Please note standard UKAS 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 UKAS 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 UKAS 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 checked="" type="checkbox"/>	
Method Verification / Validation Data and Summary	<input checked="" type="checkbox"/>	
Estimation of Uncertainty of Measurement	<input checked="" type="checkbox"/>	
Detail of the Measurement Traceability Chain	<input checked="" 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 checked="" type="checkbox"/>	
EQA Performance Summary	<input checked="" type="checkbox"/>	
Training and Competence Records of Relevant Staff	<input checked="" type="checkbox"/>	
System Suitability Checks	<input checked="" 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 UKAS, and agree to pay the associated transition fee.

### For new medical laboratories applying directly for UKAS accreditation:

- By submitting this application I acknowledge that I have read, understood and accepted the UKAS [Standard Terms of Business](#).

**Name:** Kerry Winham-Whyte

**Position:** Pathology Quality Manager

**Date:** 26/10/2017

### APPLICATIONS TO BE SUBMITTED TO:

**EMAIL:** [apps@ukas.com](mailto:apps@ukas.com)

**POST:** Applications Unit, United Kingdom Accreditation Service, 2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR