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| ORGANISATION Details | |
| Organisation Name *(i.e. name of the body taking legal responsibility for the activities of the medical laboratory)* |  |
| UKAS Ref No. **(Existing Customers Only)** |  |

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| Standard |  |  |  |  |
| ISO 15189 |  |  |

Scope(s) Requested:

| No | MEDICAL LABORATORY FIELDS(Activities) | MATERIALS OR PRODUCTS TESTED (Please list all validated/verified sample types) | TYPES OF EXAMINATION/TECHNICAL FIELDS/ACTIVITIES(Please provide general header and listing of all analytes/activities etc.) | **DESCRIPTION OF KEY EQUIPMENT USED, MEASUREMENT PRINCIPLE AND MAIN SOP REFERENCE** | LOCATION1 |
| --- | --- | --- | --- | --- | --- |
| Example 1 | Microbiology | Serum/heparin plasma | Therapeutic drug monitoring – antibiotics  - Gentamicin | Manufacturer’s Analyser using Enzyme-multiplied immunoassay  SOP ABC | Remote ‘spoke’ at Medtown |
| Example 2 | Blood Sciences | EDTA whole blood | POCT Haemoglobin | Manufacturer’s Analyser using photometry  SOP DEF | GP (two sites) and Theatres at main hospital |
| Example 3 | Virology | Nasal swab | Sampling for the purposes of COVID testing | In house method based on manufacturer’s guidance  SOP GHI | Pharmacies (2 sites) and mobile van |
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***1*** *Please indicate [with a ‘\*’] on the details above any tests / examinations / 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)

| **ACCREDITED CUSTOMERS ONLY: PLEASE SPECIFY ANY PART(S) OF YOUR CURRENTLY ACCREDITED SCOPE THAT YOU WISH TO BE WITHDRAWN (INCLUDING METHODS BEING REPLACED BY ANY extension to SCOPE REQUESTED ABOVE)** |
| --- |
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| EXTENSIONS TO SCOPE ONLY: PLEASE PROVIDE CONTEXT TO CHANGE(S) (e.g. method change(s), additional automated platform(s), new test(s), contractual requirement etc.) |
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| PLEASE IDENTIFY ANY EXTERNAL OR SUBCONTRACTED ACTIVITIES WHICH SUPPORT THE FUNCTIONING OF THE SERVICE  (e.g. facilities management, procurement, HR, advisory services, etc. together with their location) | |
| Activity | Location |
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| Further information (COMPLETE FOR NEW APPLICATIONS, AND WHERE RELEVANT TO AN EXTENSION TO SCOPE) | YES | NO |
| --- | --- | --- |
| DOES YOUR LABORATORY MANAGE ANY BLOOD FRIDGES, PHLEBOTOMY SERVICES, BODY STORES OR MORTUARIES?  (If yes please provide details below including the location)  Click here to enter text. |  |  |
| DO YOU PROVIDE A SERVICE FOR ANTENATAL AND NEWBORN SCREENING PROGRAMMES (SCT, IDPS, FASP, NBS)?  (If yes please provide details below)  Click here to enter text. |  |  |
| 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)  Click here to enter text. |  |  |
| DO STAFF PERFORM ANY EXAMINATION OR PRE-EXAMINATION ACTIVITIES OUTSIDE OF A LABORATORY SETTING (e.g. FNA ADEQUACY CHECK, MOHS SLIDE PREPARATION/EXAMINATION, SAMPLE PREPARATION AT SEXUAL HEALTH CLINIC)?  (If yes please provide details below)  Click here to enter text. |  |  |
| INVOLVEMENT WITH RELEVANT REGULATION/INSPECTION BODIES e.g. HTA/MHRA/HSE etc?  (If yes please provide details below)  Click here to enter text. |  |  |
| DO YOU 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)  Click here to enter text. |  |  |

IN-HOUSE CALIBRATION:

Are there any in-house calibration(s) of equipment performed (in order to establish metrological traceability) to support any measurement activities included in your scope of application above? (Note - information on in-house performance checks not required).

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| **Yes** |  |  | **No** |  |

*If ‘Yes’ please provide details below (refer to UKAS publication* [***TPS 41***](https://www.ukas.com/resources/publications/laboratory-accreditation/) *for information)*

| No. | MEASURED QUANTITY / INSTRUMENT | reference standard used | PROCEDURE | PURPOSE(Details of measurement activities that this supports) |
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**MULTI-SITE APPLICATIONS:**

If your application covers activities performed at more than one site, details must be provided below. If this is an *extension to scope* application, please indicate if the application affects the current listing as identified on the first page of your schedule of accreditation.

| **Site No.** | **site location** | activities performed at this site2 | contact details |
| --- | --- | --- | --- |
| Example | ATOWN, ASHIRE | MICROBIOLOGY  PHLEBOTOMY  NASAL SWAB SAMPLING | DR A,  ATOWN SITE,  PHONE XXXXXX |
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**2***Please use the same terms as referred to in the first two columns of the first table used in this form*

**EXTENSIONS TO SCOPE ONLY:**

Please note the following:

* Please complete previous tables as relevant to the scope of the extension
* To enable an effective review of this application, further evidence may be requested by the Assessment Manager

**Desired target grant date:** Click or tap to enter a date.

**Desired assessment arrangements:**

(Please note standard *minimum* UKAS timeframe for the assessment of extensions to scope *is 3 months from receipt of application*, and your Assessment Manager will discuss if your chosen option doesn’t fit in with your desired grant date or if your desired grant date isn’t possible)

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

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 assessment.

*(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 |  |  |
| Method verification / validation data and summary |  |  |
| Estimation of measurement uncertainty |  |  |
| Detail of the measurement traceability chain |  |  |
| Evidence of management of the change / application of ISO 15189 requirements (e.g. change control record) |  |  |
| Other (please state) | Click here to enter text. |  |

*For an extension to scope to be considered for* ***desktop*** *review assessment the following documentation, in addition to that listed above, must be supplied where 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 performance |  |  |
| EQA performance summary |  |  |
| Completed training/competence records of relevant staff |  |  |
| Records of equipment and reagents/consumables batch acceptance testing |  |  |
| Information for users |  |  |
| Example redacted reports |  |  |
| Other (please state) | Click here to enter text. |  |

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.
* By submitting this application I acknowledge that I have read, understood and accepted the UKAS [**Standard Terms of Business**](https://ukasonline.sharepoint.com/:w:/r/sites/ManagementSystem/Shared%20Documents/FIN%201001%20UKAS%20Standard%20Terms%20of%20Business.docx?d=wadf17ab825b6423a82e739dbd4b75cc1&csf=1&web=1&e=1cxh2y).
* If this application relates to an extension to scope, I understand and accept that:
  + An initial charge of 0.5 days at the standard day rate will apply to cover scoping of effort required
    - *This will not result in any additional charge to customers who proceed within 12 months of application. If a customer takes no action to progress an extension to scope application over a period of a year with no mitigating circumstances, UKAS reserves the right to withdraw the application. The initial charge is not refundable as it covers work already undertaken. Once an application is withdrawn, if the customer subsequently wishes to progress the extension to scope, they will need to reapply.*
  + It may be necessary to revise our annual fees upon grant of the extension to scope

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

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