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| ORGANISATION Details |
| Organisation Name*(i.e. name of the body taking legal responsibility for the activities of the laboratory)* | Click here to enter text. |
| UKAS Ref No. | Click here to enter text. |

  Scope requested:

* Standard ISO 15189 [ ]  ISO/IEC 17025 [ ]

| SAMPLE TYPE | TYPES OF EXAMINATION (e.g. COVID-19 antigen or antibody; COVID-19 RNA) | **platform, description of key equipment used, measurement principle and main sop reference** | if delivered at multiple locations, indicate which – if legal entity differs, please highlight this |
| --- | --- | --- | --- |
| Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. |
| Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. |

**For non-NHS laboratories:**

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| Please confirm and provide evidence that there has been contact with NHS England Improvement and/or Department of Health and Social Care to demonstrate acceptance into the COVID-19 testing programme | Click here to enter text. |

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| question | response |
| 1. Is the platform used for any other virology testing? If yes, please detail
 | Yes / No |
| 1. Is the other testing performed on this platform accredited?
 | Yes / No / N/A |
| 1. Reference the validation used to demonstrate fitness for purpose of the assay selected (e.g. a specific PHE publication)
 | Click here to enter text. |
| 1. Why was the method selected and how was this verified?
 | Note: Please provide verification as evidenceClick here to enter text. |
| 1. Please detail the mechanisms of on-going quality control (including the materials being used) and any reference materials included
 | Note: Please provide QC procedure and IQC control charts as evidenceClick here to enter text. |
| 1. Please detail the method of acceptance testing of new reagent batches and controls
 | Click here to enter text. |
| 1. Please detail any interlaboratory comparisons that have or will be performed
 | Note: Please provide ILC/EQA performance summary where availableClick here to enter text. |
| 1. Please describe how the competence of staff has been confirmed for this testing
 | Note: Please provide an example competence record as evidenceClick here to enter text. |
| 1. Has a separate positive/negative decision-making tool needed to be built into the platform? Please describe how results are reported and interpreted and who performs this
 | Note: Please provide an example report as evidenceClick here to enter text. |
| 1. Do the laboratory staff perform any examination or pre-examination activities outside of the laboratory setting? If yes, please detail
 | Click here to enter text. |

**SUPPORTING DOCUMENTATION/EVIDENCE REQUIRED:**

| **Documentation** | **‘Check’ if supplied** | **Justification for non-submission** |
| --- | --- | --- |
| Documented technical procedure | [ ]  |   |
| Method verification | [ ]  |   |
| Details of Internal Quality Control including control charts | [ ]  |   |
| EQA/ILC performance summary | [ ]  |   |
| Example training and competence record | [ ]  |   |
| Example report | [ ]  |   |
| Confidentiality waiver (F542) | [ ]  |   |

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.
* I understand and accept that an assessment fee will normally be charged for the extension to scope.
* By submitting this application I acknowledge that I have read, understood and accepted the UKAS **Standard Terms of Business**.

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| --- | --- |
| **Name:** | Click here to enter text. |
| **Position:** | Click here to enter text. |
| **Date:** | Click or tap to enter a date. |

Applications to be Submitted To: apps@ukas.com