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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 evidence  Click 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 evidence  Click 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 available  Click 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 evidence  Click 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 evidence  Click 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](mailto:apps@ukas.com)