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## Additional QA information on antigen testing

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The Randox testing method for 2019-nCoV Coronavirus Covid-19 is a molecular assay based on the detection of the nucleic material (RNA) within the virus. Whereas other testing methods are based on the detection of antibodies which are only produced as a response to the infection, detection of viral RNA allows for the identification of an infection at a much earlier stage since initial exposure.

### Accuracy

1. Randox are a MDSAP (Medical Device Single Audit Programme) and ISO13485: 2016 certified manufacturer of in vitro diagnostic medical devices. As such the Company is subjected to rigorous external inspections by Regulatory Authorities worldwide, including to date, six inspections by the USA Food and Drug Administration. None of these inspections has resulted in regulatory action.
2. Given the recent nature of this outbreak we are not aware of any tests for the Covid-19 virus that have achieved laboratory accreditation within the UK.
3. Randox have significant experience in developing tests for viruses that are both CE marked and accredited.
4. Randox have previously achieved CE marking for 22 respiratory viruses and bacteria. Seven of the previously CE marked viruses are on this panel. The two Covid-19 assays and MERS assay have been developed using the same procedures and processes.
5. Randox Extended Coronavirus Multiplex Array tests are conducted within a Randox laboratory that holds ISO17025:2017 accreditation, have significant experience of ISO17025:2017 operations and complies fully with Randox Quality Processes that are comprehensively audited within the ISO17025:2017 assessments.

### Analytical sensitivity

The analytical sensitivity for the Extended Coronavirus Multiplex Array 2019-Novel Coronavirus (SARS-CoV-2) target was established using dilutions of quantified nucleic acid extracts derived from clinical specimens, as no quantified virus isolates are currently available (see Table 1).

Table 1 – Limits of Detection

|    | Pathogen                                   | Strain                       | Source | Concentration  |
|----|--|------------------------------|--------|----------------|
| 1. | SARS-CoV-2                                 | BetaCoV/Germany/BavPat1/2020 | EVAg   | 50 copies/test |
| 2. | Sarbecovirus (SARS, SARS like, SARS-CoV-2) | SARS-CoV Frankfurt 1         | EVAg   | 50 copies/test |

The specificity of the Extended Coronavirus Multiplex Array for 2019-Novel Coronavirus (SARS-CoV-2) was primarily ensured by selection of the primers and probes. An alignment was performed with the oligonucleotide primer and probe sequences of the Randox Extended Coronavirus Multiplex Array Panel with all publicly available nucleic acid sequences for SARS-CoV-2 in GenBank as of 1st March 2020 to demonstrate the predicted inclusivity of the Randox Extended Coronavirus Multiplex Array test for SARS-CoV-2. All the alignments show 100% identity of the Randox Extended Coronavirus Multiplex Array SARS-CoV-2 and Sarbecovirus targets to the available SARS-CoV-2 / 2019-nCoV sequences with the exception of one nucleotide mismatch with the Sarbecovirus probe in one deposited sequence (MT039890.1), bringing the homology to 97.8%.

The Extended Coronavirus Multiplex Array was also challenged using QCMD 2019 Coronavirus RNA and MERS Coronavirus EQA Programmes, which include seasonal Coronavirus such NL63, OC43, 229E and HKU as well as MERS samples, which are derived from clinical isolates. The Extended Coronavirus Multiplex Array detected all 'Core' samples correctly. The SARS-CoV-2 / Sarbecovirus did not show any cross-reactivity with these panels.