**Capturing info from manufacturers of COVID-19 test kits**

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| **Name of Manufacturer:** |  |
| **Name of supplier/distributor/Authorised Representative:** |  |
| **Name of kit / catalogue number:** |  |

Criteria Details Acceptable? Y/N

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| **BASIC Performance and test info** | | | |
| 1 | Intended use  Self-test or professional user tst |  |  |
| 2 | ***Performance evidence:***  *Details of all validation work completed, incl. numbers of samples, range etc.* |  |  |
| 2.1 | Ideal time to take test for most accurate result (days post symptoms?) |  |  |
| 2.2 | Analytical specificity |  |  |
| 2.3 | Clinical sensitivity |  |  |
| 2.4 | Antibody being detected  IgM, IgG, IgA |  |  |
| 2.5 | Sample type:  Blood via finger prick (also whole blood, serum)  Plasma  Nasopharyngeal swab  Other swab |  |  |
| .6 | What other equipment or consumables are needed to perform the test and analyse the specimen |  |  |
| 2.7 | How to store and transport the test the sample and or test |  |  |
| 2.8 | Consumable availability (lancet/swab)  Supplied with test kit?  Alternative supply required? |  |  |
| **TAKING THE TEST** | | | |
| 3.1 | Number of steps for the test to be taken |  |  |
| 3.2 | Evidence of successful test i.e. control line |  |  |
| 3.3 | Time to take test  Time to get result |  |  |
| 3.4 | How to interpret the test |  |  |
| 3.5 | Disposal of test kit advice |  |  |
| **COMMERCIALISATION** | | | |
| 4.1 | CE marked? Y/N  *If Y then details of the Registration in an EU Member State and, if self-test, a copy of the CE certification from an NB.* |  |  |
| 4.2 | Other regulatory authority approval granted |  |  |
| 4.3 | How many tests can you supply and by when |  |  |
| 4.4 | What are the costs per test?  Any other costs? |  |  |
| 4.5 | What other forward commitments can you make |  |  |
| 4.6 | Have you any plans or capability for gathering the test results and recording them for epidemiology and PMS purposes |  |  |
| 4.7 | PROVIDE THE IFU |  |  |
| 4.8 | Website or link to other documents |  |  |
| **ANY OTHER IMPORTANT AND RELEVANT INFO WITH LINKS, ATTACHMENTS ETC.**  **Please refer to our webpage on** [**exceptional use**](https://www.gov.uk/guidance/exceptional-use-of-non-ce-marked-medical-devices)**.** | | | |
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