Name Redacted
MHRA Director of Devices

MHRA IVD EAG
8th July 2021

Dear Name Redacted

Re: Authorisation of special use of DHSC COVID-19 (Innova) Self-Test Kit

At the IVDEAG meeting of 29th June 2021, the Exceptional Use Authorisation for the DHSC COVID-19 (Innova) self-test kit was discussed. We have concerns about the extended use scenarios that MHRA have approved; we would like to highlight these concerns and to support the MHRA in clarifying the evidence required for the extension.

Background:

1. On the 10th June 2021 the FDA issued a Safety Notice and Class 1 recall warning the (American) public to immediately stop using the Innova Medical Group SARS-CoV-2 Antigen Rapid Qualitative Test, and a warning letter was issued by the FDA to Innova.

https://www.fda.gov/medical-devices/safety-communications/stop-using-innova-medical-group-sars-cov-2-antigen-rapid-qualitative-test-fda-safety-communication

https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/innova-medical-group-inc-614819-06102021

2. Shortly afterwards the DHSC issued "*Incident and corrective and preventative action report MHRA incident reference: 2021/006/011/601/004, Jacques du Preez, June 2021*", which was an internal review by the DHSC to determine if the FDA's claim represent a risk to patient safety and public health in the UK market. We note that the DHSC is the manufacturer of the DHSC (Innova) Lateral Flow Device (LFD) as a Self-Test, the distributor of Innova LFD and policy maker on the clinical use of the test. Their internal review concluded "*In summary our review of DHSC quality and assurance processes and supporting evidence show that the situation Innova finds themselves in the US has not put the Public in the United Kingdom at any increased risk or introduced any new risks. We are confident that DHSC Innova LFD antigen tests are performing as expected and play a key role in the national testing strategy*".

3. On the 17th June MHRA wrote to the DHSC granting an extension to the special authorisation for the above non-UKCA/CE marker medical device. As part of that extension, MHRA gave authorisation for: "*That this authorisation is solely for the use for repeat testing to detect positive cases amongst asymptomatic people, **one-off testing prior to an activity to reduce risks**, outbreak testing and asymptomatic testing. Daily testing of contacts is not covered by this authorisation*".

4. In response to question by Lord Scriven in the House of Lords on the 28th June about the safety and effectiveness of the DHSC/Innova test, Baroness Penn replied that "*My Lords, the Innova test has gone through the rigorous Porton Down assessment process that the UK uses for coronavirus testing approved by the MHRA, the independent regulator for medicines and medical devices in the UK. I reassure the noble Lord that there is rigorous assurance work in the lab and in the field to ensure that Innova tests consistently perform to the required standard.*"

In summary, the FDA has ruled that the Innova LFD should not be used, with immediate effect, and to *"Destroy the tests by placing them in the trash"*. The DHSC has concluded that the FDA patient safety concerns do not apply to the UK and the MHRA has approved the test for repeat and one-off testing. MHRA "approval" is quoted by the government as evidence to support the continued use of this test in the UK.

As members of the MHRA IVD EAG, we feel duty bound to inform the MHRA of our concerns about the use of this test for certain use cases.

The *specificity* of the test is quoted as between 99.7% and 99.97% and as such it is being used as a "red light" test; i.e. if a person is positive using this kit then the person should be considered as presumptive positive (but verification with PCR is encouraged to identify false positives). We would be happy to discuss this in detail but as a matter of priority we need to raise our concerns about the claims on the *sensitivity* of the Innova self test kit and the inappropriateness of using this test for one off testing - "green light" test. We would advise that the evidence would suggest that performance characteristics of the Innova self test LFD is such that it is not suitable as a green light test, and that none of the "risk mitigation" measures mentioned by DHSC appear likely to be effective.

1. It is our understanding that the DHSC is the legal manufacturer of the Innova LFT. As such claims regarding the performance of the test, and the review of the FDA Class 1 recall should be seen as "manufacturer" comments that have not been independently validated. **We would advise that prior to any further extension of the Authorisation of Specialist Use, the MHRA should seek independent evidence and not just rely on the evidence submitted by the manufacturer.**
2. We note that the manufacturer has used this test for about six months and to our knowledge has not applied for CE Marking to use this test as a self-test. This is surprising. Neither does it appear that the sensitivity of the test as a self-test or for use in children (for school testing) has been evaluated. **We would advise that the MHRA consider whether continual extensions are appropriate and that the manufacturer should be asked to go through the CE marking process, as it is our understanding that the UK will continue to recognise CE marking until June 2023.**
3. The incident report in response to the FDA was written by the DHSC, about a product where the legal manufacturer is the DHSC and is being used by the DHSC under a Special Use Authorisation granted by the MHRA by the DHSC. This review should not be considered as independent. **We would advise the MHRA that the "manufacturer's" narrative on the FDA's Class 1 Recall should have independent scrutiny.**
4. The IFU for the DHSC/Innova LFD states that *"Negative Result: If you get a negative result, you were likely not infectious at the time you took the test. A* ***negative test result, however, is not a guarantee that you do not have COVID-19.***" We would agree that a negative Innova LFD is not a guarantee that you do not have COVID-19. However the MHRA Authorisation grants authorisation to use the Innova LFD as a "green test", i.e. if the result is negative then the interpretation is that the person does not have COVID-19. **We would advise that the MHRA should re-consider the Authorisation of Special use, and to exclude its use as a "*one-off testing prior to an activity to reduce risks*" as the manufacturer is using the test without CE marking and outside it's own IFU.**
5. Sensitivity studies on the Innova Self test were undertaken by PHE and Oxford University. In the Phase 4 studies they found that sensitivity was optimal when the LFD was used by laboratory scientists 79.2%, (95% CI: 72.8-84.6%) versus trained healthcare-workers -73.0%, (95% CI: 64.3-80.5%). However test-and-trace centre staff given a protocol showed a sensitivity of 57.5%, (95% CI:52.3-62.6%). DHSC have excluded other less favourable estimates from reports: sensitivity in their Naval Barracks study, sensitivity in Durham