COVID Nudge

DnaNudge's rapid, lab-free COVID-19 test

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*DnaNudge's COVID Nudge test is a rapid, accurate, portable and lab-free RT-PCR test that delivers results at the point of need and in just over an hour. The test is authorised by the MHRA for clinical use and has subsequently obtained its CE mark. An average sensitivity – compared against numerous NHS lab-based tests – is around 95% and specificity around 100%. These results satisfied the MHRA's performance criteria. The test is now being rolled-out **UK wide** in urgent NHS patient care and elective surgery settings, plus out-of-hospital locations. The IFU for the COVID Nudge test, which includes the initial evaluation data, is publicly available **here**. A paper ("CovidNudge: diagnostic accuracy of a novel lab-free point-of-care diagnostic for SARS-CoV-2"), developed in partnership with academic groups, has been **published by The Lancet Microbe**. Having been deployed in hospitals, further data will be forthcoming on the COVID Nudge test's performance in routine practice.*

Validation

DnaNudge's COVID Nudge test was authorised for use by the Medicines and Healthcare Products Regulatory Agency in April 2020, following an initial MHRA and DHSC evaluation of use cases and a validation involving around 400 patients. The validation was carried out at St Mary's Hospital in Paddington, Chelsea & Westminster Hospital and John Radcliffe Hospital in Oxford. Results of the validation were shared with the Department of Health and Social Care, the MHRA and Public

Health England. The MHRA received all clinical data from the use of COVID Nudge test for review and approval, resulting in the granting of a final authorisation for clinical use at the end of April 2020. The MHRA was actively involved with the evaluation and worked very closely with DnaNudge during the evaluation phase. At the beginning of July 2020, the device obtained a CE Mark for IVD clinical use.

The early trials compared the COVID Nudge test against several NHS PCR laboratory tests through double sampling on 386 patients and led to the MHRA authorisation in April. At that stage, sensitivity varied between 94 to 98 percent, depending on the different NHS laboratory tests, and specificity for all was 100%. This is documented in the COVID Nudge Instruction Manual given to hospitals prior to training. Further tests indicated sensitivity of 94.4% (between 86-98%, with a 95% confidence interval) and specificity of 100% (99-100%, with a 95% confidence interval) over a larger range of PCR machines, including Roche, Abbott, AusDiagnostics, Cepheid and Thermo Fisher Scientific. The clinical trials were conducted by senior clinical virologists at the three trial sites. A paper ("CovidNudge: diagnostic accuracy of a novel lab-free point-of-care diagnostic for SARS-CoV-2") has been published by The Lancet Microbe and is available **here**.

The test is currently being used successfully in eight London hospitals – including cancer wards, A&E and maternity departments at St Mary's Hospital in Paddington, Charing Cross Hospital, West Middlesex University Hospital, Chelsea and Westminster Hospital, Royal Hospital Chelsea (home of the Chelsea Pensioners), Queen Charlotte's and Chelsea Maternity Hospital, the Renal Transplant Centre at Hammersmith Hospital and the Tower Hamlets Centre for Mental Health at Mile End Hospital. The CovidNudge test is now in the process of being deployed across the NHS nationwide, in urgent patient care and elective surgery settings, plus out-of-hospital locations.

For all business enquiries please email business@dnanudge.com

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