Health Technology Review	
Technology Ref.:	HTA20009
Technology Name:	Oxford Nanopore's LamPORE SARS-CoV-2
Company name:	G42
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Short Description of the Technology:	LamPORE is a combination of loop-mediated isothermal amplification (LAMP) and nanopore sequencing. By placing barcodes in the LAMP reaction and coupling these with Oxford Nanopore's rapid barcoding technology, a dual indexing approach is achieved, enabling a large number of barcode combinations to be generated and sequenced. Loop-mediated Isothermal Amplification (LAMP) is a single-tube technique for the amplification of DNA and a low-cost alternative to detect infectious diseases. Reverse Transcription LAMP (RT-LAMP) combines LAMP with a reverse transcription step to allow the detection of RNA targets

Health Technology Assessment Team Recommendation:	**Approval with Limitation**

Summary of Review:

Oxford Nanopore's LamPORE SARS-CoV-2 is more sensitive than using real-time PCR testing.
It seems to be a viable alternative to Real-time PCR. Since DoH currently does not have all required details of validation tests done with SEHA and in UK, HealthTech team suggest to give conditional pre-approval subject to submission of these data and initially limit the use of the new technology to be used with G42 and SEHA only

Advantages	Disadvantages
Scalable, users can run many tests by using a simple machine using a single flow cell, i.e. significant increase of Abu Dhabi testing capacity	Availability of validation data is limited, in meeting with DoH HealthTech team, G42 mentioned that a validation series with SEHA has been done as well as a bigger data set in the UK (already submitted for UK) approval. Both data need to be provided for DoH as soon as ready
Testing cycle takes less than two hours, so that time to availability of test results can be shortened significantly	Sequencing assay can sometimes prove "too sensitive" in the sense that false positive reads are observed in the sequencing data
On demand processing which gives flexibility rather than a requirement for a batch	
In addition, the "LamPORE Respiratory Panel",	

currently in development, is designed to detect multiple viruses in a single sample including the most common winter respiratory viruses including Influenza A and B and RSV.	

We recommend **an approval of using this device under the proof of concept principles** of DoH HealthTech with the following conditions

1. Establishing a proper quality monitoring process and reporting of any adverse events or unwarranted consequences including safety issues of laboratory employees
2. Submission of validity data acquired in the UAE or internationally
3. Use of the product is initially limited to laboratories under the supervision of Group 42 and SEHA until the final approval is given
4. Provision of regular updates and reports about the product to DOH upon request.
5. Any other documents or information requested regarding the product.

Moreover, DOH has the right to stop the product at any stage if deemed necessary, initial Conditions and any subsequent conditions must be satisfied before obtaining final approval. Failure to do so will reflect in provoking the approval.

Technology Image