Health Technology Review	
Technology Ref.:	HTA21046
Technology Name:	AllPLEX SARS- COV- 2 Variants I Assay
Approvals by International Bodies:	CE Marked - MOHAP
Company name:	Seegene Medical Equipment Trading L.L.C
Agent in UAE:	Lubna Bdour
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Short Description of the Technology:	Multiplex real time PCR test, it Identifies SARS COV 2 Variants through Detection of RDRP Gene, N501Y, HV69/70 deletion & E484K The test can be conducted using the Specimens from Nasopharyngeal swab, Nasopharyngeal aspirate Oropharyngeal swab, bronchoalveolar lavage, sputum & Saliva.

Health Technology Assessment Team Recommendation:	**Approve**

Summary of Review:

AllPLEX SARS- COV- 2 Variants I Assay is a CE marked test for COVID 19, it detects up to 4 genes of the virus, and it's the upgraded version of product Allplex™ 2019-nCoV Assay which already has US FDA. It has been tested in National Reference Laboratory and achieved 100% accuracy results

Advantages	Disadvantages
Fast test results - Results within 2 hours after extraction	Restricted to us by a medical professional only
Excellent Specificity and sensitivity results up to 100% as per local validation report in NRL	Requires a lab set up
Can detect and identify the variants of SARS COV 2 by using Real Time PCR	
CE Marked and MOHAP registered	
Safe for Patients & healthcare professionals	

We recommend an **approval of using this technology** with the following conditions:

1. Using the technology as a point of care testing for both symptomatic cases and Asymptomatic cases.
2. Establishing a proper quality monitoring process and reporting of any adverse events or unwarranted consequences including safety issues of employees.
3. Use of the product is initially limited under the supervision of authorized COVID-19 laboratory.
4. Provision of regular updates and reports about the product to DOH upon request.
5. Any other documents or information requested regarding the product and cost to finalize the

approval process.

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: