Health Technology Review	
Technology Ref.:	**HTA21038**
Technology Name:	**Seegene Allplex SARS-CoV-2**
Approvals by International Bodies:	**CE-IVD MARKED**
Company name:	**Seegene Middle East**
Agent in UAE:	**Lubna Bdour**
Email:	**Lubna.bdour@seegene.com**

Short Description of the Technology:	Test Kit Assay that provide the Detection and identification of 4 target genes for SARS-CoV-2 using multiplex real-time PCR N gene / S gene / RdRP gene / E gene

Health Technology Assessment Team Recommendation:	**Approved**

Summary of Review:

Seegene has applied for a request to approve on adding the Seegene Allplex SARS-CoV-2 to the approval list for COVID testing, the test is a multiplex real-time PCR assay to detect 4 target genes of SARS-CoV-2, causing COVID-19 in a single tube, Seegene kits are used in different laboratories in UAE like in Latifa Hospital in Dubai.

Local Validation Result:

Validation result at Tawam Regional Blood Bank cover 20 samples shows 100% sensitivity and specificity

Advantages	Disadvantages
Real time PCR - Fast test results (Results within 2 hours)	Shall be used by a medical professional
The kit is efficient and reliable for confirmation and screening	Requires a lab set up
Excellent sensitivity and specificity as per the local validation(100%)	
It is CE-IVD-Marked	
High Accuracy; The kit is able to detect 4 genes, i.e. E, RdRP, S and N compared to other kits which only detect 2 – 3 genes	
Reducing the cost as no need to repeat the results	

We recommend an **approval of using this technology** only 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.

Health Technology image