Health Technology Review	
Technology Ref.	HTA22011
Technology Name:	Allplex™ SARS-CoV-2 fast PCR Assay
Approvals by International Bodies:	CE Marked
Company name:	Seegene Medical Equipment Trading L.L.C
Agent in UAE:	Lubna Bdour
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Short Description of the Technology:	It is a COVID 19 test that uses the Polymerase chain reaction (PCR) technique and can detect three of Sars Cov 2 target genes {RdRP gene, E gene & N gene), the test Covers all the variants including those classified by VOi, VOU & voe and Provide Results in 1.5 hours, it uses a new enzyme and an innovative extraction-free method which accelerate and optimize the process.

Health Technology Assessment Team Recommendation:	**Approve**

Summary of Review:

Allplex™ SARS-CoV-2 fast PCR Assay is a CE marked test for COVID 19, it detects up to 3 genes of the virus, the test innovative extraction free method helps in large-scale COVID-19 testing & increase the testing capacity, it has been tested in Al Ain Hospital U71 Laboratory and achieved 100% accuracy results.

Advantages	Disadvantages
Fast test results with no extraction step, the Results within 1.5 hours	Restricted to use by a medical professional only
Excellent Specificity and sensitivity result up to 100% as per local validation report in Al Ain Hospital U71 Laboratory	Requires a Laboratory set up
Can detect and identify the variants of SARS COV 2 by using Real Time PCR	
CE Marked	
Safe for Patients & healthcare professionals	
Optimized Assay for mass testing by reducing total turnaround time	

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 at the authorized laboratories for COVID-19 testing.
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

Population, setting and intended user for Technology "Allplex™ SARS-CoV-2 fast PCR Assay"

- **Population/ Intended User**;
  - For Symptomatic and Asymptomatic cases of COVID19
- **To be performed/ ordered by**:
  - By physicians
- **Clinical Setting:**
  - Point of care
- **Condition of use:**
  - For Mass screening & COVID 19 suspected cases
- **Exclusion criteria:**
  - Other conflicting medical issues