Health Technology Review	
Technology Ref.:	HTA22033
Technology Name:	COVID-19 PCR KIT-ASTRAGENE
Approvals by International Bodies:	Device is CE marked
Company name:	ASTRAGENE FZ LLC
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Short Description of the Technology:	AstraGene's COVID-19 -PCR Kit is a multiplex real-time reverse transcription polymerase chain assay for the qualitative detection of nucleic acid from the SARS-CoV-2 in human nasopharyngeal swab extracts from individuals who are suspected of COVID-19. The SARS-CoV-2 primer and probe set(s) are designed to detect specific sequences of E gene and N gene of the SARS-CoV-2 genome and Internal Control primer and probe is designed to detect Human housekeeping gene β2M. Nucleic acids are isolated from the collected swabs using Nucleic acid purification system. The purified nucleic acid is directly amplified using the COVID-19-PCR Kit on the Real-time PCR Instrument system. In the process, the probe anneals to a specific target sequence located between the forward and reverse primers. During the extension phase of the PCR cycle, the 5' nuclease activity of Taq polymerase degrades the probe, causing the reporter dye to separate from the quencher dye, generating a fluorescent signal. With each cycle, additional reporter dye molecules are cleaved from their respective probes, increasing the fluorescence intensity. Fluorescence intensity is monitored at each PCR cycle by the Real-time PCR Instrument system

Health Technology Assessment Team Recommendation:	**Approve**

Summary of Review:

The technology is covid19 PcR test kit to detect specific sequences of E gene and N gene of the SARS-CoV-2 genome from NS samples. The test kit has been validated at Union 71 with total of 42 nasopharyngeal samples, it shows sensitivity 92.59% & 100% specificity for COVID19 testing. It met the WHO requirements for COVID19 testing.

Advantages	Disadvantages
Device is CE marked	To be used by healthcare professionals only
No risk to healthcare professional & patients	The results of the test are just for clinical reference. The test should not be used as sole criteria for diagnosis. Results should be

	considered in conjunction with the clinical information and other data available to the physician
Point of care test	
Easy to use and fast results	
Good Performance (92.59% sensitivity & 100% specificity for COVID19 testing)	

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

1. Using COVID-19 PCR KIT-ASTRAGENE for Covid19 testing on suspected 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

Population, setting and intended user for Technology "COVID-19 PCR KIT-ASTRAGENE"

- **Population/ Intended User**;
  - Using COVID-19 PCR KIT-ASTRAGENE for symptomatic patients.
- **To be performed by**:
  - By Healthcare Professionals
- **Clinical Setting:**
  - Point of care
- **Condition of use:**
  - As per the manufacturer instruction
- **Exclusion criteria:**
  - Other conflicting medical issues