Health Technology Review	
Technology Ref.:	**HTA21016**
Technology Name:	**SG Diagnostics Covid-19 Antigen Rapid Test Kit**
Approvals by International Bodies:	**CE-IVD-Marked** **Singapore Health Sciences Authority 1/2021**
Company name:	**SG Diagnostics Pte Ltd**
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Short Description of the Technology:	A rapid antigen diagnostic test suitable for point-of-care testing that directly detects the presence or absence of an SARS-CoV-2 antigen in throat swab or nasal swab. The double antibody sandwich method is adopted in the product, and measurement is conducted in the form of solid-phase immune chromatography.

Health Technology Assessment Team Recommendation:	**Approved with limitation**

Summary of Review:

SG Diagnostics Covid-19 Antigen Rapid Test Kit is used in Singapore, Italy, Germany, Peru, Colombia and Philippines in hospitals, airports, corporations, events, hotels, homes and schools.

Advantages	Disadvantages
Fast and rapid (obtaining result in less than 15 min)	The risk associated with this technology is unknown as the safety has not been determined.
Low cost and for single use only	Local validation study is required
Point of care and non-invasive test which does not require a lab setup	Antigen tests will have more false-negative rate if there is a low or variable viral load in the sample; especially in the early onset of the infection
Portable and easy to use as it does not require any particular skills or devices for the operation	Shall be used by a medical professionals
It is CE-IVD-Marked and has Singapore HAS approval	Samples shall be tested immediately after collection
Used in many countries and different locations such as airports, events, organizations, … etc.	No emergency use approval from international bodies
International validation results shows 97.6% sensitivity and 99.3% specificity	

SEHA Validation Result:

Validation result at SEHA cover around 34 patients at ER shows 100% sensitivity, 95.5% specificity and 4.5% false negative

HTA Recommendation:

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

1. Using the technology as a point of care testing for symptomatic 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