Health Technology Review	
Technology Ref.:	**HTA22004**
Technology Name	**Roche Elecsys SARS-2 Antigen Test**
Approvals by International Bodies:	**CE Marked- FDA Approved for Emergency Use Authorisation (EUA)**
Company name:	**Yas Cinic groups -ADSSC**
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Short Description of the Technology:	Elecsys Anti-SARS-CoV-2 Antigen assay uses monoclonal antibodies directed against the SARS-CoV-2 N protein in a double-antibody sandwich assay format for the qualitative detection of SARS-CoV-2 in upper respiratory tract specimen the test is performed by healthcare professionals and uses nasopharyngeal or oropharyngeal swab samples from patients with symptoms suggestive of COVID-19, or people with either known or suspected exposure to SARS-CoV-2

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

Summary of Review:

Elecsys Anti-SARS-CoV-2 is an antigen test, its intended use as an aid in the diagnosis of active SARS-CoV-2 infection , the test would be beneficial in support high-volume testing of suspected COVID-19 patients and help in increasing the testing capacity as a supplement to PCR testing . it could be used in the Symptomatic (signs or symptoms of COVID-19) patients or cases with confirmed exposure.

Local Validation Result:

Validation result at Union71 Lab cover 70 nasopharyngeal samples shows sensitivity 91.7% and specificity 100% in samples with ct values ≤ 29.

Advantages	Disadvantages
Very Fast in producing the results(can provide test results in 18 minutes for a single test)	Not to be used for asymptomatic cases; 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; the test decrease sensitivity to 82.5% if all CT values considered
Automated laboratory assay; A laboratory-based automated antigen assay allows for cost and error reduction due to removal of manual handling	This test should not be used to diagnose or exclude acute SARS-CoV-2 infection; A negative result may require to be confirmed with a PCR test or repeated (antigen test) after one to two days
The test has reliable sensitivity rate and high	Due to possible evaporation effects, samples,

specificity; the Local Validation showed a 91.7% sensitivity & 100% in samples with ct values ≤ 29	calibrators and controls on the analyzers should be analyzed/measured within 2 hours
Needs fewer steps to produce the results which means shorter protocols; One-step double antibody sandwich assay	
Safe; No harm to patients nor healthcare professionals	

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

1. Using the technology in the authorized laboratories for COVID-19 testing for symptomatic cases only and confirmed case with direct exposure to COVID19 and a negative result may require to be confirmed with a PCR.
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 "Roche Elecsys SARS-2 Antigen Test"

- **Population/ Intended User**;
  - COVID 19 suspected cases (direct contact with COVID19 patients, case findings, Symptomatic cases, etc.)
- **To be ordered by**:

  - By Healthcare Professionals
- **Clinical Setting:**
  - Authorized laboratories for COVID-19 testing
- **Condition of use:**
  - To be used in individuals with symptoms during the first 5 days of infection (Symptomatic cases)
- **Exclusion criteria:**
  - It is not indicated for use in screening