Health Technology Review	
Technology Ref.:	HTA21038
Technology Name	CareStart COVID-19 Antigen test
Approvals by International Bodies:	Emergency use Authorization by FDA
Company name:	AL MIDIAFF INTERNATIONAL CO LLC
Agent in UAE:	Mubarak Hamad Mohammed Marzouq Al Ameri
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Short Description of the Technology:	Diagnostic tests can show if you have an active COVID-19 infection and need to take steps to quarantine or isolate yourself from others. Antigen tests are types of diagnostic tests than can detect if you have an active COVID-19 infection. Samples for diagnostic tests are typically collected with a nasal swab.

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

Summary of Review:

It's a Rapid Diagnostic Test for the Detection of SARS-CoV-2 Antigen. The test is intended to use in point of care settings and operated by healthcare professionals, it performed by collecting nasopharyngeal or anterior nasal swab specimens directly from individuals who are suspected of COVID-19 by their healthcare provider within the first five days of symptom onset.

Local Validation Result:

Validation result at Union 71 cover 105 samples shows 93.3% sensitivity and 88.9% specificity.

Advantages	Disadvantages
Fast and rapid (result obtained in 10 minutes)	Low sensitivity Antigen tests, thus it cannot be used for screening settings .
Portable and easy to use as it does not require any particular skills or devices for the operation	Recommended only for individuals with symptoms during the first 5 days of infection
Point of care and non-invasive test which does not require a lab setup	High false-negative rate: Antigen tests are qualitative, they can be inaccurately interpreted due to reader error. If an antigen test is negative, a confirmatory RT-PCR test is required
Safe; No harm to patients nor healthcare professionals	Not to be used for asymptomatic cases

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

1. Using the technology as a point of care testing at authorized healthcare providers for COVID19 testing for symptomatic cases only within the first five days of onset of symptoms.
2. Use of the product is initially limited under the supervision of authorized COVID-19

laboratory.

3. Provision of regular updates and reports about the product to DOH upon request.
4. 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 "CareStart COVID-19 Antigen test"

- **Population/ Intended User**;
  - COVID 19 suspected cases (direct contact with COVID19 patients, case findings, etc.)
- **To be ordered by**:
  - By physicians
- **Clinical Setting:**
  - Point of care
- **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.