Health Technology Review	
Technology Ref.:	HTA22005
Technology Name:	BinaxNOWTMCOVID-19 Ag CARD
Approvals by International Bodies:	Emergency-use authorization (EUA) from the U.S. Food and Drug Administration (FDA).
Company name:	Rapid Test NYC
Agent in UAE:	Mark Golberg
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Short Description of the Technology:	The BinaxNOWTM COVID-19 Ag Card is a lateral flow immunoassay intended for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 in direct anterior nasal (nares) swabs from individuals suspected of COVID-19 by their healthcare provider within the first seven days of symptom onset.

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

Summary of Review:

The technology used is called a "lateral flow immunoassay." In simple terms, that means it works like a pregnancy test. It's basically a paper card with a test strip. As the sample flows through it, it hits antibodies that stick to the virus protein and then to a coloured marker. If the virus is present, a pink bar appears on the strip. The test could be use at the point of care testing for quick results but not definitive, the local validation conducted at Union 71 Lab shows that The Abbott Binax Now has a very good performance for samples with a higher viral load (CT<30) with a sensitivity of 90.9% and specificity of 100%. The overall agreement was 92.3%.

Advantages	Disadvantages
Rapid Antigen test: can be used as a tool to rapidly detect SARS-CoV- 2 within 15 minutes.	**Low Sensitivity:** if the samples with a low viral load (CT>= 30) considered, the sensitivity drops to 77.42% which is below the recommended threshold of 80%.
Easy to use: does not require a lab setting, it's a point of care test & easy to perform.	**A confirmation PCR test** shall be conducted to confirm the negative results.
it is highly specific: the local validation report at Union 71 shows specificity of 100%.	The test **cannot differentiate between the SARS-CoV and SARS-CoV2**
Improve access to COVID-19 testing and to help limit the spread of SARS-CoV-2.	Inadequate or inappropriate sample collection, kit storage and transport may yield **false or invalid test results**
Inexpensive	Not to be used for asymptomatic cases

We recommend an **approval/approval with limitation of using this technology** 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 seven days of onset of symptoms
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 "BinaxNOWTMCOVID-19 Ag CARD"

- **Population/ Intended User**;
  - COVID 19 suspected cases (Symptomatic Patients, direct contact with COVID19 patients, case findings, etc.)
- **To be performed by**:
  - By physicians
- **Clinical Setting:**
  - Point of care
- **Condition of use:**
  - To be used in individuals with symptoms during the first 7 days of infection (Symptomatic cases)
- **Exclusion criteria:**
  - It is not indicated for use in screening.