Health Technology Review	
Technology Ref.:	**HTA21051**
Technology Name	**Panbio Covid-19 Ag Rapid Test Device (Nasal)**
Approvals by International Bodies:	**WHO and the European Commission Directorate-General for Health and Food Safety**
Company name:	**GULF BMG SUPPLEMENTS TRADING L.L.C.**
Agent in UAE:	**Mohamed Elshamy**
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Short Description of the Technology:	Panbio™ COVID-19 Ag Rapid Test Device is an in vitro diagnostic rapid test for the qualitative detection of SARS-CoV-2 antigen (Ag) in human nasal swab specimens from individuals who meet COVID-19 clinical and / or epidemiological criteria. Panbio™ COVID-19 Ag Rapid Test Device is for professional use only and is intended to be used as an aid in the diagnosis of SARS-CoV-2 infection. The product may be used in any laboratory and non-laboratory environment that meets the requirements specified in the Instructions for Use and local regulation. The test provides preliminary test results. Negative results don't preclude SARS-CoV-2 infection and they cannot be used as the sole basis for treatment or other management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information. The test is not intended to be used as a donor screening test for SARS-CoV-2.

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

Summary of Review:

Panibio test is antigen COVID 19 test is an in vitro diagnostic rapid test for the qualitative detection of SARS-CoV-2 antigen (Ag) in human nasal swab specimens from individuals who meet COVID-19 clinical and / or epidemiological criteria.

Local Validation Result:

Validation result at Union 71 cover 32 nasopharyngeal samples shows 65.2% % sensitivity and 100% specificity. However, in high viral load (ct <30), the validation result shows 83% sensitivity.

Advantages	Disadvantages
Very Fast in producing the results (15 minutes)	Decreased performance with low viral loads samples are observed, the sensitivity decreases to (65.2%).
Performance in the samples with a high viral load is satisfactory; the sensitivity reach (83.3%) and specificity (100%) as per the validation result at Union71	Antigen test must display a high sensitivity for samples with low viral loads to fit the requirement of mass screening.
Portable and easy to use as it does not require	Antigen test is intended to have negative results

any particular skills or devices for the operation; Does Not require a lab setting	when viral load is low. thus, a confirming RT-PCR test is required.
The test is listed in WHO EUL	
No special/additional instruments required	

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

1. The approval on using the mentioned technology in Abu Dhabi and limited to the authorized laboratories for rapid COVID-19 testing.
2. As per the DoH standards and approval process of COVID-19 Antigen Testing, using the technology as a point of care testing for symptomatic cases within 7 days of the symptom onset or only with high viral loads (ct≤25/30).
3. It is recommended to perform validation for asymptomatic cases and screening setting.

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: