Health Technology Review	
Technology Name:	**SARS-CoV-2 Antigen Rapid Test Kit (colloidal gold immunochromatography)**
Approvals by International Bodies:	**CE Marked for professionals use only** CE– IVD NL-CA002-2020-53290
Company name:	**BEIJING LEPU MEDICAL TECHNOLOGY CO. LTD,CHINA**
Agent in UAE:	**Hyper Health - Dr Bobby Ahmed**
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Short Description of the Technology:	It is a rapid antigen test for the qualitative detection of COVID-19 antigens (N protein) using chromatographic immunoassay in nasopharynx using nasal swab only. It identifies a current COVID-19 infection. The display of the result can be shown through a mobile app CovidPass Application

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

Summary of Review:

SARS-CoV-2 Antigen Rapid Test Kit (colloidal gold immunochromatography) is a point of care test that can be used in hospitals, workplaces, schools and airports showing the result in 15 minutes or less.

Local Validation Result:

Validation result at Union71 covers 50 samples from inpatients and outpatients shows 83.9% sensitivity and 100% specificity. If considering the higher viral load only (ct<30), it shows improvement in the sensitivity (96%)

Advantages	Disadvantages
Fast and rapid (obtaining result in 10-15 min)	MOHAP classification letter restricted to use by professionals only
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
Stable and high accurate	
Local validation shows 83.9% sensitivity and 100% specificity, while with higher viral load the performance is excellent	
Sensitivity (96.6%) and specificity (99.62%) are high as a validation study done at Beijing	
Portable and easy to use as it does not require any particular skills or devices for the operation	

It has CE mark and MOHAP classification letter	

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. Further validation is recommended to be done for asymptomatic and screening settings.
3. Establishing a proper quality monitoring process and reporting of any adverse events or unwarranted consequences including safety issues of employees.
4. Use of the product is initially limited under the supervision of authorized COVID-19 laboratory.
5. Provision of regular updates and reports about the product to DOH upon request.
6. 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.