Health Technology Review	
Technology Ref.:	**HTA21024**
Technology Name:	**MD-Bio BCC19 Test Kit**
Approvals by International Bodies:	**CDC, FDA EU & CE IVD**
Company name:	**MobileDetect Bio Inc.**
Agent in UAE:	**Eng. Abdullah Bajjash-Smart Health Tech**
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Short Description of the Technology:	The Mobile Detect Bio BCC19 Test Kit is a reverse transcriptase loop-mediated isothermal amplification (RT-LAMP) test intended for the qualitative detection of RNA from the SARS-CoV-2 in nasopharyngeal (NP), oropharyngeal (OP), mid-turbinate (MT) and anterior nares (nasal) swab specimens from individuals suspected of COVID-19 by their healthcare provider.

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

Summary of Review:

The Mobile Detect Bio BCC19 Test Kit is used in USA in hospitals, government entities & military basis, it could be used in urgent diagnosis on spot like Borderlines, Airports, Seaport, Remote areas, Labour camps, Public Area, Corporates & Schools.

Advantages	Disadvantages
Fast and rapid (obtaining result in 30 min)	Additional RNA extraction step for nasopharyngeal samples received in UTM is required.
Mobile portable Test Kit and its easy to use as it does not require extensive training as traditional PCR	Due care is needed during sample processing
Point of care and non-invasive test which does not require a lab setup	Comparative sensitivity was enhanced when thorough vertexing of the mixture was done prior to initiating the LAMP step. Since (12.2%) of the samples in saline were affected by this problem, it is recommended that the company informs their future customers about this potential error source.
Internationally approved for emergency use (FDA- CE-IVD)	Samples shall be tested immediately after collection.
Passed local validation (SEHA) with results accuracy shows 95% (100% sensitivity and 85.7% specificity)	Shall be used by a medical professional
Cost effectiveness – each test cost around 55.10	Detection of SARS-CoV-2 RNA may be affected

AED	by sample collection methods, patient factors (e.g., presence of symptoms), and/or stage of infection.
No harm to patients nor healthcare professionals	

SEHA Validation Result:

Validation result at SEHA cover around 49 patients for samples collected in saline shows 100% sensitivity, 85.7% specificity and 95.9% accuracy

HTA Recommendation:

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

1. Approval to use the device with RNA extraction step and UTM
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