Health Technology Review	
Technology Ref.:	HTA21043
Technology Name:	Cell ID Quiz Biochip PCR
Approvals by International Bodies:	ISO 13485 certified/ CE Approval 98/79/EC
Company name:	CELL ID PTE LTD
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Short Description of the Technology:	Quiz Biochip is a single-use molecular diagnostic test (NAT) that can detect COVID-19 infected patients. This innovative technology uses extracted RNA from Nasopharyngeal Swabs on biochips providing fast results via Laptop display. The test requires a tiny amount of specimen to be applied to the biochip, which when plugged into a laptop, runs a real-time reverse transcription loop-mediated isothermal amplification (RT-LAMP) assay for the qualitative detection of SARS-CoV-2 RNA. Positive results can be confirmed as fast as 15 minutes.

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

Summary of Review:

Quiz Biochip PCR is a palm-sized portable genetic test kit that uses an app on a laptop to detect, anywhere, at any time, if a person has COVID-19. Test has been validated in Union 71 lab using Nasopharyngeal swabs were collected from 122 patients – fresh sample in Abu Dhabi for its accuracy, sensitivity and specificity by comparing it against the Cobas 6800 SARS PCR showing the overall agreements acceptance of 85.3%

Advantages	Disadvantages
Very Good sensitivity (94.4%) and specificity (93.8 %) as per the validation result at Union 71. (P.S. for samples with high viral loads (CT <30),)	The sensitivity rate reduced to 82.2% when the results equal or above a ct-value of 30 (i.e., samples with low viral load) is considered.
Affordable Cost	Required a medical professional
Fast Results (15 minutes)	The test Limited for the screening setting if the expected viral load is not high (ct<30).
Safe to use; No risk to healthcare professional	
Portable & easy to use	
Digital result in short time	

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

1. Using the technology as a point of care testing for the screening setting if the expected viral load is high (ct<30) in symptomatic cases.

2. Cconfirmation with RT-PCR is required when the viral load is low in symptomatic cases
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.

Health Technology image