Health Technology Review	
Technology Ref.:	**HTA22006**
Technology Name:	**GENECHECKER® UF-300 real-time PCR System**
Approvals by International Bodies:	**CE marked, ISO 13485-2016 Certificate and MOHAP**
Company name:	**Cure Plus Medical Center LLC**
Agent in UAE:	**Mohammed Hassan Marei**
Email:	m.marei@cureplus.ae

Short Description of the Technology:	**GENECHECKER® UF-300** is a real-time PCR system based platform using patented chip (SMARTCHEK® Novel Coronavirus (SARS-CoV-2) detection Kit) based reaction provides rapid output- "40 Cycles in 20 Minutes". The proprietary polymer chip enables faster thermal treatment of the sample than the case of using PCR tubes at conventional PCR instrument. The thrermal cycling mechanism of GENECHECKER achieves 8°C/sec ramping rate for both heating and cooling allowing the resut to be ready within 45 min. Unlike conventional RT-PCR, SMARTCHEK® is a method based on microfluidic biochips, which reduces handling by the user, considerably simplifying workflow and reducing the risk of sample contamination, However the preparation of the samples requires 5–10 min and requires manual pipetting, which required to be performed by a trained healthcare professional.

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

Summary of Review:

GENECHECKER®Real-time PCR System is polymer chip based real-time PCR (polymerase chain reaction) detection instrument which is performing rapid amplification of genomic templates and real-time qualitative and quantitative analysis. 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:

A study by G42 of the device using 1128 molecular assays (samples from positive (asymptomatic and symptomatic) and negative patients) found device performance:

- Sensitivity 95.23%
- Specificity 99.2%
- Accuracy 98.05%
- the least percentage of invalid reports.

Advantages	Disadvantages
Method based on microfluidic biochips, which reduces handling by the user, considerably simplifying workflow and reducing the risk of	Preparation of the samples requires 5–10 min and requires manual pipetting, which is recommended to be done in a biosafety cabinet

sample contamination	
Reduce time for determining the sample in an RT-PCR analysis prior to medical intervention. Provides results in 45 minutes.	It required some pipetting technique which cannot be performed in bedside and required to be done by well-trained medical laboratory technologist.
Hight accuracy of result 98.05%	Shortage of kits or suppliers could be a challenge.
GENECHECKER®PCR System has compact and portable design and can be carried to any location conveniently.	
Safe; No harm to patients nor healthcare professionals	
CE marked and ISO 13485-2016 Certificate	

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

1. Using the technology in the authorized laboratories for COVID-19 testing for symptomatic cases only and confirmed case with direct exposure to COVID19.
2. Provide local validation to DoH with large sample size and high Ct value if require screening purpose approval.
3. Establishing a proper quality monitoring process and reporting of any adverse events or unwarranted consequences including safety issues of employees.ion of regular updates and reports about the product to DOH upon request.
4. 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 "GENECHECKER® UF-300 real-time PCR System"

- **Population/ Intended User**;
  - COVID 19 suspected cases (direct contact with COVID19 patients, case findings, Symptomatic cases, etc.)
- **To be ordered by**:
  - By Healthcare Professionals
- **Clinical Setting:**
  - Authorized laboratories for COVID-19 testing
- **Condition of use:**
  - To be used in individuals with symptoms during the first 5-7 days of infection (Symptomatic cases)
- **Exclusion criteria:**
  - It is not indicated for use in screening