Health Technology Review	
Technology Ref.:	HTA22048
Technology Name:	SARS-CoV-2 Nucleic Acid Rapid Detection Kit- Fluorescence RT-PCR system (consisting Nucleic Acid Release Buffer, SARS-CoV-2 Nucleic Acid Rapid Detection Kit (Fluorescence RT-PCR), LineGene MiniS Fluorescent Quantitative Detection System)
Approvals by International Bodies:	CE_IVDR & China National Medical Products Administration
Company name:	Hangzhou Bioer Technology Co., Ltd.
Agent in UAE:	Hangzhou Bioer Technology Co., Ltd.
Email:	ra_oversea@bioer.com.cn

Short Description of the Technology:	Nucleic Acid Release Buffer is intended for release of the nucleic acid from clinical specimens to be analyzed by nucleic acid-based assays. For in vitro diagnostic use only. For professional use only. Surfactant, tris buffer, guanidinium and RNase inhibitor in the buffer are used to inactive and denature the viral capsids / envelops (or other protection structures) in biological specimens. Affected by lysis and shock, nucleic acids are released in the solution and can be directly used in the PCR amplification-based in vitro diagnostic assays. In addition, the release buffer can keep the nucleic acid from degrading in the transportation. Specimens preserved in Release Buffer (without Dilution Buffer) are allowed to be stored at ambient temperature (about 15~30°C) for up to 72 hours, or at refrigerated temperature (about 2~8°C) for up to 1week, or at -20°C or -80°C for up to 6 months. SARS-CoV-2 Nucleic Acid Rapid Detection Kit (Fluorescence RT-PCR) is a real-time RT-PCR test used for the qualitative detection of the RNA from SARS-CoV-2 in nasopharyngeal, nasal or oropharyngeal swab specimens from suspected cases. The kit is used for the auxiliary diagnosis and epidemiological surveillance of SARS-CoV-2 infection, cannot be used as the basis for the diagnosis or exclusion of cases alone. For in vitro diagnostic use only. For professional use only. This product selects the ORF1ab (FAM) and N gene (HEX) regions of SARS-CoV-2[1-3], and designs two sets of primers and fluorescent probes. The two sets of primers and probes can specifically bind to the target sequences. When the RT-PCR amplification reaction is performed, the fluorescent signal(s) can be detected by a full-automatic fluorescent PCR detector to realize real-time online monitoring of the RT-PCR reaction. In order to control the entire extraction and detection process, human gene was act as a non-competitive internal control during the extraction and detection process. In addition, the nucleic acid release buffer in this kit can denature the protein structure of the cells or virus, lysing the sample to release nucleic acid, which can be directly used for downstream PCR detection.

	For the specimens stored and pretreated with nucleic acid release buffer: The positive reference standard was diluted into 2000 copies/mL, 1000 copies/mL, 750 copies/mL and 500 copies/mL, and the diluted positive standards were tested by 3 lots of kits. Each concentration was tested with 20 replicates. The testing data demonstrated that the kit can detect SARS-CoV-2 with detection rate equal or higher than 95% at the concentration equal or higher than 750 copies/mL. The LineGene MiniS Fluorescent Quantitative Detection System is an automated instrument used for quantitative detection of analytes in the related nucleic acids (DNA/RNA) from human sample using the polymerase chain reaction process. The instrument is for in vitro diagnostic only. The LineGene MiniS Fluorescent Quantitative Detection System is intended for used in medical and biological laboratories by professional user trained in molecular biological techniques and the operation of LineGene MiniS Fluorescent Quantitative Detection System.

Health Technology Assessment Team Recommendation:	**Approve**

Summary of Review:

The Bioer System consist of Nucleic Acid Release Buffer, SARS-CoV-2 Nucleic Acid Rapid Detection Kit (Fluorescence RT-PCR), LineGene MiniS Fluorescent Quantitative Detection System), the Rapid Detection Kit (Fluorescence RT PCR) is a real time RT PCR test used for the qualitative detection of the RNA from SARS CoV 2 in nasopharyngeal, nasal or oropharyngeal swab specimens from suspected cases. The kit is used for the auxiliary diagnosis and epidemiological surveillance of SARS CoV 2 infection, cannot be used as the basis for the diagnosis or exclusion of cases alone. The test kit has been validated in Unioin71 for 90 samples and achieved the results with Sensitivity 97.62% & Specificity 100%.

Advantages	Disadvantages
The Test has CE Marked	With a very low viral load the BioER might give false negative results.
High Performance (Sensitivity 97.62% & Specificity 100%)	For professional use only
Real-time RT-PCR test, Short time consumption: Results interpretation can be completed in 1.5 hours.	The results of the test are just for clinical reference. The test should not be used as sole criteria for diagnosis. Results should be considered in conjunction with the clinical information and other data available to the physician
No risk to healthcare professional	

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

1. Using SARS CoV 2 Nucleic Acid Rapid Detection Kit (Fluorescence RT PCR) for covid 19 testing for symptomatic patients.
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

Population, setting and intended user for Technology "SARS-CoV-2 Nucleic Acid Rapid Detection Kit- Fluorescence RT-PCR system"

- **Population/ Intended User**;
  - Using SARS CoV 2 Nucleic Acid Rapid Detection Kit (Fluorescence RT PCR) for covid 19 testing for symptomatic patients.(suspected cases)
- **To be performed by**:
  - By Healthcare Professionals
- **Clinical Setting:**
  - Point of care
- **Condition of use:**
  - As per the manufacturer instruction
- **Exclusion criteria:**
  - Other conflicting medical issues