



Health Technology Review	
Technology Ref.:	HTA22037
Technology Name:	COVID-19 (SARS-CoV-2) Nucleic Acid Test Kit (Freeze-dried)
Approvals by International Bodies:	CE Marked Paul-Ehrlich-Institut in Germany National Medical Products Administration of China
Company name:	Bio One Medical Supplies
Agent in UAE:	Ekramy Mohamed Mohamed Yousef
Email:	<a href="mailto:Ekramy@bionemedical.com">Ekramy@bionemedical.com</a>

Short Description of the Technology:	The COVID-19 (SARS-CoV-2) Nucleic Acid Test Kit (Freeze-dried) is a real-time reverse transcription polymerase chain reaction (RT-PCR) test with multiplex PCR-fluorescent probe technology and one-step RT-PCR technology. The oligonucleotide primers and probes for detection of SARS-CoV-2 were selected from the conserved regions of the virus nucleocapsid (N) gene and ORF1ab. After the end of amplification reaction, the results will be determined by analyzing the cycle threshold (Ct) of each channel. In addition, the human housekeeping gene RNaseP, which is used to monitor the sampling, extraction, template addition, amplification and other processes, is designed as the internal control of the kit to effectively prevent the occurrence of false positive and false negative.
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Health Technology Assessment Team Recommendation:	Approve
Summary of Review:	
<p>The COVID-19 (SARS-CoV-2) Nucleic Acid Test Kit(Freeze-dried) developed by EasyDiagnosis is intended for the qualitative detection of nucleic acid from SARS-CoV-2 in oropharyngeal swabs, nasopharyngeal swabs and sputum specimens from individuals suspected of COVID-19. The test kit has been validated in Unioin71 for <b>90 samples</b> and achieved the results with Sensitivity <b>97.62%</b> &amp; Specificity <b>100%</b>.</p>	
Advantages	Disadvantages
Fast; Results Available Within 34 Minutes.	The test results with the kit are for clinical reference only For confirmed cases.
CE Marked	Test kit for professional use only.
The performance of the eDiagnosis CoViD-19 Nucleic Acid Test Kit is very good (sensitivity 97.62% & Specificity100%)	Negative results also cannot rule out SARS-CoV-2 infection. Factors that may lead to false negative results must be excluded.
No risk to healthcare professional	

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

1. Using COVID-19 (SARS-CoV-2) Nucleic Acid Test Kit (Freeze-dried) 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 “COVID-19 (SARS-CoV-2) Nucleic Acid Test Kit (Freeze-dried)”

- **Population/ Intended User;**
  - Using COVID-19 (SARS-CoV-2) Nucleic Acid Test Kit (Freeze-dried) 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