Health Technology Review	
Technology Ref.:	HTA22017
Technology Name:	LabGun™ COVID-19 ExoFast RT-PCR Kit
Approvals by International Bodies:	FDA and CEIVD
Company name:	labgenomic
Agent in UAE:	Al Bahar Al Azraq drug store
Email:	Mujeeb@ivision.com.co

Short Description of the Technology:	**The LabGunTM COVID-19 ExoFast RT-PCR Kit** contains a specific ready-to-use system for the detection of the SARS-CoV-2 using RT-PCR (Reverse Transcription Polymerase Chain Reaction) in the real-time PCR system. The targets (RdRp and N genes) and Internal Control are amplified in a manner of multiplex real-time RT-PCR in one tube. The first step is a reverse transcription (RT), during which the SARS-CoV-2 RNA is transcribed into cDNA. Afterwards, a thermostable DNA polymerase is used to amplify the specific gene fragments by PCR. Fluorescence is emitted and measured in real-time by the optical unit of a real-time PCR instrument during the PCR step. In addition, the kit contains a system to identify RNA extraction effectiveness and possible PCR inhibition by amplifying the internal control in the same reaction.

Health Technology Assessment Team Recommendation:	**Approve**

Summary of Review:

LabGunTM COVID-19 RT-PCR Kit is a real-time reverse transcription polymerase chain reaction (rRT-PCR) test intended for the qualitative detection of nucleic acid from the SARS-CoV-2 in nasopharyngeal, or oropharyngeal, anterior nasal and mid-turbinate nasal swabs, as well as nasopharyngeal wash/aspirate or nasal aspirate specimens and sputum, from individuals who are suspected of COVID-19 by their healthcare provider.

Local Validation Result:

A study by G42 of the device using 75 molecular assays (samples from positive (asymptomatic and symptomatic) and negative patients) found device performance:

- Sensitivity 100%
- Specificity 96.55%
- Accuracy 98.05%

Advantages	Disadvantages
Safe; No harm to patients nor healthcare professionals	Restricted to use by a medical professional only

Fast RT PCR Solution with high specificity ≥95% and sensitivity ≥95%	Requires a Laboratory set up
High quality reporting and traceability of having very low level of infection in an individual	
RT-PCR, are considered the Gold Standard for diagnosing SARS-CoV-2 virus	
LabGun kit showed 98.75% concordance for positive samples and 100% concordance for negative samples	
FDA and CE marked	

We recommend an **approval** with the following conditions:

1. Using the technology as Realtime PCR testing for both symptomatic cases and Asymptomatic cases at the authorized laboratories for COVID-19 testing.
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.

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 "The LabGunTM COVID-19 ExoFast RT-PCR Kit"

- **Population/ Intended User**;
  - COVID 19 suspected cases (direct contact with COVID19 patients, case findings, Asymptomatic and symptomatic, etc.)
- **To be ordered by**:
  - By Healthcare Professionals
- **Clinical Setting:**
  - Authorized laboratories for COVID-19 testing
- **Condition of use:**
  - COVID 19 suspected cases
- **Exclusion criteria:**
  - Other conflicting medical issues