Health Technology Review	
Technology Ref.:	HTA23015
Technology Name:	Bio-Rad QXDx AutoDG ddPCR System
Approvals by International Bodies:	US FDA, EU, Malaysia, Indonesia and Thailand
Company name:	Al Nawras Medi-Lab Supplies
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Short Description of the Technology:	The QXDx ddPCR System is Bio-Rad's Droplet Digital PCR System approved for use in a regulatory environment. The system, which includes the QXDx Droplet Generator and QXDx Droplet Reader, provides precise and absolute quantification of target DNA or RNA molecules in a wide variety of in vitro diagnostics (IVD). Bio-Rad QXDx ddPCR & QXDx AutoDG ddPCR systems for In Vitro Diagnostics (IVD) is tool for sensitive determination and absolute quantitation of nucleic acid for Identification & detection of Harmful Pathogen (Viral & Microbial) , Detection of rare Genetic Disorders , Oncology & Chimerism Monitoring.

Health Technology Assessment Team Recommendation:	**Approve**

Summary of Review:

The QXDx AutoDG ddPCR System is an automated platform that streamlines the droplet generation process for high-throughput digital PCR analysis. This system integrates the QXDx ddPCR technology with automation, offering increased efficiency and reproducibility. The AutoDG instrument automates the droplet generation step, allowing for the processing of up to 96 samples simultaneously. It reduces hands-on time, minimizes user-to-user variability, and enhances workflow integration, making it an ideal solution for high-volume testing in clinical laboratories.

Advantages	Disadvantages
US FDA , EU, Malaysia, Indonesia and Thailand	Cost associated with ddPCR systems can be higher compared to traditional PCR methods
The ddPCR technology enables absolute quantification of target nucleic acids, providing precise and reliable results without the need for a standard curve.	The QXDx ddPCR system processes samples individually, which can be time-consuming when analyzing large sample numbers
The systems offer high sensitivity for detecting rare targets, low-abundance mutations, or targets with a wide dynamic range	It is more complex to operate than the current real-time PCR system
ddPCR ensures high precision by partitioning the	Multiplexing capability of ddPCR is more limited

sample into thousands of individual reactions, reducing the impact of PCR inhibitors or sample variations	compared to some other PCR methods
The QXDx AutoDG system automates the droplet generation process, improving efficiency and reducing hands-on time	
Both systems come with user-friendly software for data acquisition and analysis, facilitating result interpretation and reporting	
The platforms support a variety of applications, including oncology, infectious diseases, genetic disorders, and personalized medicine.	

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

1. The System should be used and operate by healthcare professionals.
2. Establishing a proper quality monitoring process and reporting of any adverse events or unwarranted consequences including safety issues of employees.
3. 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 "Bio-Rad QXDx AutoDG ddPCR System"

- **Population/ Intended User**;
  - Oncology, infectious disease, genetic disorders, personalized medicine and transplantation patients.
- **To be performed by**:
  - be used by healthcare professionals.
- **By Clinical Setting:**
  - Hospitals and specialized clinics.
- **Condition of use:**
  - Patients who are suspected or diagnosed with a specific disease or condition that can be detected or monitored using the targeted assays on the ddPCR systems.
- **Inclusion criteria:**
  - Patients with specific genetic mutations, biomarkers, or genetic variations of interest that are known to be associated with the disease or condition being diagnosed or monitored. These targets should have clinical relevance and established evidence supporting their use for diagnostic or prognostic purposes.

- **Exclusion criteria:**
  - Patients for whom there is insufficient sample material available for testing may be excluded.
  - Patients for whom the diagnostic context or the intended use of ddPCR is not clinically relevant or appropriate.
  - Patients who do not have the specific genetic mutations, biomarkers, or genetic variations targeted by the ddPCR assays.
  - Patients for whom the use of ddPCR does not offer clinically significant benefits or contribute to decision-making in their specific diagnostic or treatment context.