Health Technology Review	
Technology Ref.:	HTA22058
Technology Name:	CFX Opus 96 Dx System with CFX Maestro Dx SE Software
Approvals by International Bodies:	US FDA, EU, Malaysia, Indonesia, Thailand- CE Marked device
Company name:	Al Nawras Medi-Lab Supplies
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Short Description of the Technology:	CFX Opus 96 Dx System with CFX Maestro Dx SE Software are intended to perform fluorescence-based PCR to detect and quantitate nucleic acid sequences. The systems and software are intended for in vitro diagnostic use by trained laboratory technicians. The systems are intended to be used with third-party diagnostic nucleic acid tests which have been manufactured and labelled for diagnostic purposes.

Health Technology Assessment Team Recommendation:	**Approve**

Summary of Review:

CFX Opus is a Real-time PCR System that can be setup to cover varies PCR spectrum based on user need by using CFX Maestro Software. The PCR system in a closed system which is good in terms of safety. CFX Maestro Software streamlines the process of plate setup, data collection, data analysis, and data visualization of real-time PCR data the systems and software are intended for in vitro diagnostic use by trained laboratory technicians. It has been used in Canada, USA and Singapore.

Advantages	Disadvantages
Multiplex up to 5 targets per sample	To be used by a well-trained professional only
Analyse and generate traceable, audit-ready reports with electronic signature functionality.	The risk for patient data leak
The device is US FDA approved & CE Marked device	
The manufacturer has the ISO 13485	
CFX Maestro Software streamlines the process of plate setup, data collection, data analysis, and data visualization of real-time PCR data	
The device can cover 96 sample to be analysis at the same time.	

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

1. Ensure data residency and confidentiality as per Department of Health regulation.
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 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 "CFX Opus 96 Dx System with CFX Maestro Dx SE Software"

- **Population/ Intended User**;
  - For In vitro diagnostic test
- **To be performed by**:
  - By Lab technicians
- **Clinical Setting:**
  - clinical laboratory.
- **Condition of use:**
  - As per the manufacturer guidance manual
- **Exclusion criteria:**
  - As per the manufacturer guidance manual