Health Technology Review	
Technology Name:	Foundation Medicine (FoundationOne CDx®, FoundationOne Liquid CDx®, and FoundationOne Heme®)
Approvals by International Bodies:	**FDA (Foundation Medicine Laboratory is CLIA, CAP, NYSDOH & ISO 13485:2016)**
Company name:	**Roche Pharmaceuticals Middle East FZCO**
Agent in UAE:	Roche Pharmaceuticals Middle East FZCO – Dubai Branch (represented by City Pharmacy Co LLC)
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Short Description of the Technology:	FoundationOne CDx®, FoundationOne Liquid CDx®, and FoundationOne Heme® are NGS (next-generation sequencing) based comprehensive genomic profiling services that work alongside the public healthcare system and the treating physicians to fill the gaps of available conventional testing to enable precision medicine in cancer patient care. Foundation Medicine testing portfolio empowers the physician and patient to make tailored treatment decisions specific to the patients' cancer genomic/molecular profile using comprehensive, up-to-date and evidence-based analyses. It uses hybrid-capture next generation sequencing technology to identify all four classes of genomic alterations across cancer-related genes. Additionally, they interrogate genomic signatures (TMB, MSI, LOH, and PD-L1), hence providing patients and treating physicians with a comprehensive overview of cancer related aberrations. Test results are provided within a user-friendly report that states the identified genomic/molecular aberration(s) to generate a comprehensive genomic profile (CGP) and potential targeted therapy options and clinical trial options.

Health Technology Assessment Team Recommendation:	**Approve**

Summary of Review:

Although this technology is expensive and not cost effective, there is a high need to have such gene therapy in the health sector due to its effectiveness and cheaper than chemotherapy. Foundation Medicine is already in the market. No gene therapies including Foundation Medicine is covered by insurance yet in Abu Dhabi.

Advantages	Disadvantages
One of the few gene profiling that is FDA approved	Expensive approach compared to other types of gene profiling
Foundation Medicine Laboratory has External Quality Certification and accreditation from CLIA, CAP, NYSDOH & ISO 13485:2016	Foundation Medicine Laboratory does not have ISO 15189:2012 quality accreditation
Personalized gene therapy (targeted therapy)	Not sufficient cost effectiveness studies provided by the applicant

It is one of gene profiling therapies that are recommened by NCCN guidelines	Local cost effectiveness study was not provided by the applicant
Cheaper than the current practice (cytotoxic chemotherapy)	Did not submit studies exactly as what was requested such as comparison between Foundation Medicine and other gene therapy techniques although it is available in the public
Showing Life-year gained (but not clear about QALY)	Clinical utility is lower than other gene profiling
Delivers comprehensive diagnostics within days	It does not show cost effectiveness and not value of money in international publication. The cost effectiveness ratio is high compared to some countries' thresholds.

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

1. Utilize the use for only patients who are within the inclusion criteria.
2. For Emarati population in Abu Dhabi in alignment with Emirati Genome Project.
3. To be as a self pay
4. The applicant (Roche and foundation medicine) create forms and collect data on all the patients who are being tested and treated and analyse the data after 1 year or longer to decide the value.

Due to the launch of the Emirati Genome Project we do not recommend to cover the cost for FoundationOne CDx®, FoundationOne Liquid CDx®, and FoundationOne Heme® for Thiqa card holders, but encourage all UAE Nationals to go for whole genome sequencing in one of the Emirati Genome Project partner healthcare facilities.

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.

Foundation Medicine Use Criteria

Question	Answer	Comments
Which case?	Patients with advanced cancer	
Which doctors?	Oncologists	
Which hospital?	Hospitals that have oncology department such as Tawam, SKMC, SSMC, CCAD, Burjel Medical City, Gulf Cancer Center, … etc.	
Inclusion criteria	Recurrent, relapsed, refractory, metastatic, or advanced stages III or IV cancers	
	All advanced solid tumours upon diagnosis , only one test per patient	
	In all newly diagnosed non-small cell lung cancer (stage IV)	
	All unknown primary cancers after thorough work up including biopsy and tumour markers and PET scan and upper and lower endoscopy.	
	All patients with suspected cancer and unable to obtain a biopsy due to technical challenges (tumor near critical blood vessel , deep in liver , small lung nodules that cannot be biopsied , should be also consider cases by case when requested as difficult to have clear indication when it is not feasible to do the biopsy and depend on the skills of the interventional radiology and also the tumour location).	
	Blood cancer if unable to reach a definitive diagnosis post clear biopsy , flow cytometry , bone marrow biopsy : Acute Myeloid Leukemia , Myelodysplastic leukemia , Non-Hodgkin lymphoma , Multiple myeloma	
Exclusion criteria	All early stages and not advanced stages of cancers	
	Patients who responded well to other therapies	