



Health Technology Review	
Technology Ref.:	HTA23002
Technology Name:	Q-Suite (Pantheon and AI Modules)
Approvals by International Bodies:	<ul style="list-style-type: none"> • Pantheon is HSA Class A registered. • Pantheon is CE IVDD marked • AI Colon module is registered with HSA under Class A.
Company name:	Qritive Pte Ltd.
Agent in UAE:	Bruno Occhipinti
Email:	Bruno.occhipinti@qritive.com

Short Description of the Technology:	<p>Pantheon is a standalone software, which serves as a case management system and an advanced image display for digitized images of microscope slides used in routine clinical diagnosis. This software is designed to allow users to upload, access, browse and manage digital images on a computer as an alternative to viewing glass slides on a light microscope. Pantheon can be used for storage, management, and analysis of pathology images, which are captured and created by imaging devices (whole-slide scanners) approved for clinical use. Pantheon can be used remotely for telepathology and management of cases.</p> <p>- AI Modules:</p> <ul style="list-style-type: none"> ○ Prostate, Colon and Lymph Node AI modules classify biopsy tissues into benign and malignant, and further sub-classify malignant areas as Pattern 3, 4, 5 supporting Gleason Score and ISUP Grading for reporting. This assists pathologists in accurately reporting disease presence and/or progression. ○ IHC AI module classifies cells in the selected ROI (Region of Interest) within a whole slide image as positive or negative for malignancy and calculates the respective number of cells in each of the classified categories for reporting. This assists pathologists in accurately reporting disease presence and/or progression.
--------------------------------------	-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

Health Technology Assessment Team Recommendation:	Conditional Approval
Summary of Review:	
Utilizing the digital pathology which is transferring a microscopic images of tissue samples to a computer, where they are analysed using advanced image processing techniques. Q-Suite is consisting of case management system and an advanced image display for digitized images of microscope slides (Pantheon) leveraging the AI deep learning module to analyse the data for specific cancers types (prostate, colon cancers, quantify IHC markers, and lymph node metastasis). Its intended use to prioritise and grade specific cases while improving the detection of hard-to-diagnose cancers.	
Advantages	Disadvantages



The system has CE marked and the manufacturer Qritive Pte. Ltd. Is ISO certified.	Insufficient clinical validation studies that prove the software and AI module (Q-Suite) accuracy and effectiveness in clinical diagnosis and screening.
Digital pathology help reduce human error as well as producing precise diagnostic results in short turnaround time.	AI module development restriction and challenges including the available & quality of imaging data.
Artificial intelligence brings several benefits to pathology, including offering second opinions for general analysis, training practitioners, and speeding up drug discovery and development.	Challenges to the implementation of AI, including data anonymisation and storage, which can be time-consuming and costly for healthcare institutions.
The technology is a potential screening tool to create initial interpretations and assist pathologists to streamline the workflow, thereby effectively reducing the diagnostic burden on pathologists and Improved Patient Care with Earlier Diagnosis.	AI Model bias & integrity, including the under-reporting of important demographic information such as race and ethnicity, and the implications this can have on generalisability.
Easy to use and adopt. It is a single-window operation with an integrated patient management system that can entirely be accessed remotely in case of emergencies, it has On-premises and cloud deployment options.	The need for a systematic evaluation of these softwares and ongoing calibration and training for composite AI model.
	Required special training for the pathologist & clinicians to utilize.

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

1. Approve to use the Q-Suite (Pantheon and AI Modules) in a clinical trial setting to validate the model's outcome.
2. Approved from Abu Dhabi Healthcare Information Security Program with following conditions:
 - Maintain all infrastructure and data within UAE at all times
 - Continued compliance with applicable Laws, Regulations & Circulars
 - Right to audit by regulatory body (DOH)
3. Establishing a proper quality monitoring process and reporting of any adverse events or unwarranted consequences including safety issues of employees.
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.



Population, setting and intended user for Technology “Q-Suite (Pantheon and AI Modules)”

- **Population/ Intended User;**
 - For the detection of cancer cases (Prostate, Colon and Lymph Node AI & IHC)
- **To be performed by:**
 - In Pantheon users are restricted to four user groups based on different user requirements. These are configurable using role-based access implemented in Pantheon. These user groups are:
 - Pathologists
 - Pathology technicians
 - Pathology lab administrators
 - Other clinicians
- **Clinical Setting:**
 - Healthcare facilities and laboratories, telepathology.
- **Condition of use:**
 - As per manufacturer instructions.
- **Exclusion criteria:**
 - NA.