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Diagnostic digital pathology system improving the landscape of cancer diagnosis

In an Australian first, the Federal Government has granted TGA approval for a diagnostic digital pathology system set to radically improve the outlook for cancer patients through rapid and accurate diagnosis.

MetaGene has received TGA class III Medical Device certification for GenASIs – a groundbreaking diagnostic platform offering quantitative, accurate and validated analysis of patient samples in a clinical setting.

MetaGene Managing Director Richard Holder and Dr Eugen Petcu today unveiled the only fully operational GenASIs system currently in Australia, which is located at the Menzies Health Institute.

Mr Holder says the TGA class III certification demonstrates the system's robust design and extensive validation as a clinical device which will alter the landscape of diagnostic technology, leading to a better outcome for patients.

"GenASIs provides higher diagnostic confidence and uncompromising result standardisation, replacing previous indicative diagnosis," he said.

"This highly anticipated system can test thousands of cells in infinitely less time with a more accurate outcome than any other system currently in the market.

"This not only means greater efficiency, quality control and cost savings for laboratories – it means cancer patients will have the chance to receive more personalised treatments plans based on a more accurate diagnosis."

MetaGene is the sole Australian distributor of the GenASIs system, which is now available to hospitals and laboratories across the country.

Global leader in computer-assisted biomedical imaging, Applied Spectral Imaging (ASI), who designed the GenASIs technology, launched an upgraded GenASIs diagnostic system earlier this month at the College of American Pathologists meeting in Orlando FL.

Dr Petcu, associated with Griffith University and the Menzies Health Institute Queensland says GenASIs, which is also approved by the FDA and is currently implemented in clinical settings in the USA, Canada and Europe, is an advanced workflow solution based on revolutionary technology with industry leading applications.

"This is the beginning of an exciting new era in diagnostic technology and I am very grateful to have access to the only fully functioning GenASIs system currently in Australia for my own cancer research," he said.

“Through exceptional image quality and precise computer-assisted analysis, this technology provides uncompromising standardisation of results at the click of a button, providing a quality baseline for consistent accurate analysis of cancer cells.

“This counteracts the inevitable variability that comes with manual analysis.”

The Australian Bureau of Statistics estimates 17,730 new cases of breast cancer will be diagnosed in 2017. In a study of Ki-67 - a cancer aggression marker that indicates how urgently patients require treatment - there was a 6 per cent difference between manual analysis and image analysis on the GenASIs system.

The manual analysis scored lower Ki-67 results. This diagnosis may inadvertently mean those patients could be less likely to receive urgent clinical attention. After comparing the two techniques pathologists reviewed their diagnosis, changing it to reflect the GenASIs system.

Dr Petcu says the GenASIs system functions as an adjunct tool to the microscope allowing the statistical analysis of thousands of cells in relevant tumour regions to be conducted digitally.

“The system is so accurate that it can potentially prevent the need for pathologists to send samples for further testing, significantly improving the turn-around time for results,” he said.

“With a faster, more accurate analysis, the patient can feel confident in their diagnosis and their treatment pathway can be tailored specifically for them.”

For more information visit www.metagene.com.au

About ASI

ASI is a global leader in the development of biomedical imaging solutions, supporting fluorescent, Brightfield and spectral image-acquisition, for the Pathology and Cytogenetics markets.

HiPath Pro™ and PathFusion™, powered by GenASIs™, are automated imaging platforms that provide advanced diagnostic aids for pathologists, with reproducible and standardized results. ASI platforms support manual and automatic scanning for a wide range of workflows and applications, to best suit the needs, size and budget of any laboratory.

ASI’s applications are FDA cleared for BandView, FISHView, CEP XY, UroVysion, ALK, HER2/neu FISH and IHC Family for: HER2, ER, PR and Ki67.

ASI serves clinical laboratories, life science companies and research institutions in over 50 countries.

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