AVICENA

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FOR IMMEDIATE RELEASE

New WA-born diagnostic technology achieves regulatory milestone with the TGA

A new Western Australian-developed medical technology has achieved a significant milestone, with the Therapeutic Goods Administration (TGA) authorising its listing on the Australian Register of Therapeutic Goods (ARTG) as a Class 1 In Vitro Diagnostic device (IVD).

The Avicena Sentinel is a fully automated laboratory instrument for running authorised[1] molecular diagnostic assays. The Sentinel processes saliva or nasal samples using Loop-Mediated Isothermal Amplification (LAMP) chemistries, to rapidly and accurately identify respiratory pathogens like COVID or Influenza on a vast scale.

A wide range of LAMP diagnostic chemistries are being increasingly used globally for screening against pathogens given the technology's accuracy, speed, and affordability. LAMP works like PCR but is faster and easier to scale and can be readily adapted to detect a range of highly infectious pathogens such as HIV, Ebola, Zika, Foot and Mouth Disease, and Monkeypox to help control outbreaks.

Avicena's Executive Chairman and Chief Scientific Officer, Dr Paul Watt, said the ARTG listing represented a significant milestone in the continuing success of the Western Australian developed technology.

"The TGA is regarded as one of the most rigorous regulatory agencies in the world, so this is a big step forward for the Sentinel and Avicena," Dr Watt said.

"The Sentinel is one of only two Australian-developed molecular diagnostics analysers currently listed on the ARTG. This achievement is a testament to the innovation, passion, and efficiency of Avicena's team in developing and validating the world's highest throughput LAMP-based diagnostic instrument in less than two years."

Avicena CEO, Tony Fitzgerald highlighted the impact the ARTG listing will have on Avicena’s global aspirations.

"The ARTG listing will facilitate Avicena's ability to market the Sentinel instrument overseas and provide potential customers with yet another level of confidence in the safety and performance of the Sentinel."

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[1] The Avicena Sentinel is an automated high throughput instrument, intended to be used by trained laboratory professionals for IVD workflows involving isothermal amplification methods which have been authorised by the by the relevant regulatory body in each jurisdiction and authorised by Avicena Systems as being compatible with the instrument. In Australia, such IVD reagents would either be listed on the Australian Register of Therapeutic Goods (ARTG) or otherwise authorised by the Therapeutic Goods Administration (TGA).

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"A TGA listing is highly respected by international customers and will prove invaluable in discussions with current and prospective partners and foreign medical regulatory bodies, as we continue to take this WA innovation to global markets."

The listing is timely, as positive outcomes emerging from ongoing trials in the aged care and resources sectors are already supporting the Sentinel's potential as an effective biosecurity solution to manage outbreaks and prepare against future pandemic threats. The Sentinel instrument provides a versatile platform for diverse large-scale health applications, as a range of new diagnostic IVD LAMP reagents are authorised for use.

Developed in WA with Commonwealth and State Government support, the Sentinel System can process up to 100,000 samples daily. Results are available within 30 minutes from loading samples, with national and international clinical trials demonstrating accuracy of more than 94 per cent in detecting infectious levels of the SARS-CoV-2 virus[2].

The Sentinel system combines the best features of PCR and Rapid Antigen Tests (RATs) in a single integrated and scalable system, with the following key advantages:

- Speed: Returns results in approximately 30 minutes from sample loading.
- Cost: Cheaper and easier to scale than PCR testing.
- Early detection: Detects infectious individuals earlier than RATs, even before symptoms appear.
- Convenience: Testing uses saliva samples that can be self-collected anywhere.
- Accuracy: Reported accuracy exceeding 94%[2] – more reliably detecting infectious virus.
- Flexibility: Adaptable to screen for multiple other pathogens, including influenza.

Ends

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[2] *Dewhurst, R.E. et al. Validation of a rapid, saliva-based, and ultra-sensitive SARS-CoV-2 screening system for pandemic-scale infection surveillance. Sci Rep* ***12****, 5936 (2022). DOI.*

About Sentinel LAMP technology

The Avicena Sentinel surveillance system is based on LAMP (Loop Mediated Isothermal Amplification), a sensitive technique like PCR, which is already widely used globally for the high-throughput surveillance screening of pathogens. The system is flexible, designed to adapt its workflow to support the diagnosis of a wide range of pathogens, including COVID-19, Dengue, Hepatitis B, Tuberculosis, and Influenza, using authorised IVD reagents as they become available.

Avicena's Sentinel technology has been independently benchmarked against other COVID-19 diagnostic technologies, including RAT. Multiple studies have shown RATs to be less reliable early in the infection cycle, particularly before symptoms appear.

An independent, peer-reviewed validation study of healthcare workers (from a UK government-appointed COVID screening lab) has confirmed that the Sentinel LAMP technology is greatly superior to both RAT (Surescreen) and the leading UK LAMP technology (Optigene) across a wide range of viral loads, offering comparable sensitivity to RT-PCR in detecting potentially infectious individuals (Ct <33), including those without COVID symptoms[2].

About Avicena Systems

Avicena is an award-winning, Perth-based medical technology company that has developed the ground-breaking Sentinel Biosecurity Platform. The Sentinel System provides an accurate, rapid, and scalable means of detecting diverse pathogens, combining the best features of the PCR and Rapid Antigen Tests (RAT) in a single integrated system.

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