Prototype

Automated multiplex diagnostics system*

Country of origin | China

Primary use | Diagnosis/measurement/monitoring

Category | Medical device (including in vitro diagnostics)

Commercial information

List price (USD): 32 000

Expected year of commercialization: 2023

Number of existing prototypes in use/trials/tests: 10

Currently used in: China

Model: MPA-G01R06

Product description

The system fully automates conventional laboratory-based PCR processes in an all-in-one system with three elements: an analytical machine, a microfluidic reagent cartridge, and software. Pre-handling is minimal as it automatically runs extraction, reagent dispensing, nucleic acid amplification, signal detection, and analysis. The design is a combination of engineering, biochemistry, and production know-how, delivering a high-quality diagnostic system at an affordable cost. Innovative amplification methods and proprietary primer design enable simultaneous 42-plex multiplex detection while maintaining superior sensitivity and specificity.

Product details

Accessories: Control PC, barcode scanner (optional), keyboard and mouse set (optional)

Consumables: Reagent cartridge

Warranty duration: One year warranty and thereafter maintenance and service package available

Lifetime: 8 years

Energy requirements: 200-240V, 50/60 Hz, 700 W (maximum), 10A fuse; 100V or other values are available depending on the targeted countries/regions

Facility requirements: Operating temperature of ~18-28 °C; Operating humidity between 10 and 90% RH; maximum altitude of 2000 meters. Suitable for point-of-care settings.

Contact: Prof. Terence Lau; Ms Bianca Ko | Phone: (852) 2389 6899 | Web: https://bit.ly/45Ryo6l

*** Information reported by manufacturer, October 2023**

WHO assessment**

Clinical

Clinical — Recommended with caution

The technology is a system composed of an automated multiplex analyser (instrument) machine, a microfluid reagent cartridge with a panel of assays and interpretive software. The manipulation steps are few, given the design of the instrument and cartridge. The current test cartridge targets 42 respiratory pathogens (28 viruses, 11 bacteria and 3 fungi). This is a fully automated point-of-care diagnostics system. It can provide results in less than 1.5 h without a resource-intensive laboratory, multiple equipment, or trained technicians. As it is a point-of-care system, it performs the test one sample at a time.

Overall, this technology would add value by allowing a comprehensive and relatively fast diagnosis of the targeted panel of respiratory pathogens with a very high level of performance.

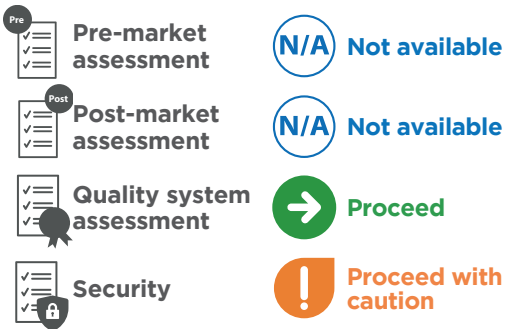
** This assessment was initiated November 2023

Comparison with WHO technical specifications

Cannot be verified.

The manufacturer provides detailed technical specifications, and their declarations are well supported by technical documentation (that is, instructions and a user manual). At the time of this report's creation, WHO technical specifications related to an automated PCR analyser were not available to compare the proposed technology.

Regulatory



Pre-market: The manufacturer has shared the design verification and validation test reports. The submitted documentation does not adequately demonstrate the clinical sensitivity and specificity of the product, or its clinical performance. The manufacturer has not conducted a clinical evaluation of the product yet.

Post-market: The manufacturer has briefly described customer complaints and field safety corrective action procedures.

Quality management system (QMS): The manufacturer has submitted a ISO13485:2016 which is valid until 8 June 2025. Based on the certification and standards, the manufacturing of the product conforms to ISO13485:2016. The product is safe and effective, and its performance is in accordance with the intended use.

Security: This technology could introduce a risk for biosecurity.

The manufacturer must submit complete risk management documentation based on ISO14971:2019, the risk analysis, risk management plan, risk control, post-production information, and other hazard reports.

The manufacturer must declare conformance to IEC62304 software validation for the lifecycle of the device and to address the cybersecurity risk.

Health technology assessment

The innovator has published a study that suggests that the system offers superior performance for bacteria identification, while the overall performance is comparable to standard single-tube single-target PCR. The system is better in terms of costs, turnaround time, and higher multiplexing than the standard of care.

The technology is safe, and risk procedures have been set according to ISO 13485; however, there is no clear information on any risk assessment performed. Only basic training appears to be required. User and instruction manuals have been included. There is no specific evidence on legal aspects, but, in principle, the technology should not require additional legislation. While there is no evidence on social aspects, the innovator states that the Innovation and Technology Commission of the Hong Kong SAR (China) Government, users at the Queen Mary Hospital and the Queen Elizabeth Hospital, and frontline clinics in Hong Kong and Macau SAR (China) provided substantial support. There is no substantiating evidence regarding any aspect of the green environment. According to the innovator, the system reduces carbon emissions by eliminating the need for transport to a laboratory and minimizing reagent use and energy consumption. The cartridges are disposed of as clinical waste per EU laws on waste from electrical and electronic equipment. The system is reusable, but recyclability is limited due to the nature of medical diagnostic end products.

As confirmed by further evidence, the product is innovative in terms of multiplexing functionalities, large sample intake, better sample volume extraction and cleaning, and lower costs.

Technology readiness level 8

Technology evidence assessment Recommend with caution

Health technology management

- Durability
- Ease of Use
- Ease of maintenance
- Environmental conditions
- Affordability
- Local access to technical support
- Ease of cleaning
- Infrastructure requirements

Health-care delivery platform

The Avalon Automated Multiplex System is an IVD device that uses a reagent-prefilled cartridge system, intended for running multiplex PCR. After the sample has been inserted into the cartridge, it is placed in the system tray for measurement. The result is printed after the screening of multiple respiratory target pathogens. The sample can be discarded after its use as biological material. In the future, the platform offers the possibility of adding more tests. A refrigerator is necessary, as part of the infrastructure requires storing the cartridge at 2-8°C when not in use. Integrated into one single unit, this device substitutes for the usual laboratory devices required for PCR tests. Its limitation to testing one sample at a time, taking 1.5 h for testing, and use of manufacturer-supplied consumables may prove to be an inconvenience in some situations. The evaluation of durability in low-resource settings is not feasible due to the absence of supporting evidence. The fact that replacement parts are currently available only in China may make it more difficult for people in other countries to access local support.

Intellectual property and local production

- Technology transferability
- Open source/ access
- Local production

Intellectual property: This technology is protected by copyrights, trade secrets, and patents. The software is proprietary. The use of all intellectual property will require clearance. Caution is advised due to pending patent applications and the likely dependence on third-party intellectual property for manufacturing critical parts.

Local production: The technology has a compliant manufacturing process; however, the device is in the early phase of commercialization and hence might evolve further. The technology has a weak business case for end-to-end manufacturing, as it is highly import-dependent and needs a comparatively high level of technical and quality control expertise, the availability of a robust, consistent, highly flexible supply chain in the region, and related in-house manufacturing infrastructure.