



## Seegene Launches Allplex<sup>®</sup> MDRO Assay Under IVDR: Expanding AMR Testing Portfolio in Europe

### Descrizione

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SEOUL, South Korea, May 21, 2026 /PRNewswire/ <sup>®</sup> Seegene, a global molecular diagnostics company, announced the European launch of its new antimicrobial resistance (AMR) testing product, Allplex<sup>®</sup> MDRO Assay, which is CE marked under the EU In Vitro Diagnostic Regulation (IVDR). The assay is designed to support the detection of multidrug-resistant organisms (MDROs) associated with healthcare-associated infections (HAIs).

The assay is designed to identify key multidrug-resistant pathogens and associated resistance genes in a single run, enabling rapid simultaneous detection across a broader range of MDRO targets. It also supports rapid first-line screening before the availability of culture-based results, helping enable timely infection prevention and control (IPC) responses in hospital settings. The launch reflects Seegene's strategy to expand its AMR testing capabilities in response to evolving infectious disease trends.

As antimicrobial resistance continues to rise globally, the burden of healthcare-associated infections is increasing, driving demand for faster and more comprehensive diagnostic approaches. Public health agencies, including the U.S. Centers for Disease Control and Prevention (CDC), have continued to emphasize the importance of strengthened infection surveillance and control capabilities in healthcare settings.

The Allplex<sup>®</sup> MDRO Assay complements Seegene's existing Allplex<sup>®</sup> Entero-DR Assay, enabling a combined testing approach that covers both antimicrobial-resistant enteric bacteria and additional high-risk MDRO targets. This combined approach can support broader infection-control efforts against antimicrobial-resistant organisms, while strengthening Seegene's overall AMR testing portfolio.

The assay enables simultaneous detection of multiple resistance genes and can support same-day reporting depending on laboratory workflow. This can provide timely information to support infection-control responses and complement conventional culture-based workflows. It may also help support

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more efficient laboratory workflows in appropriate clinical settings.

“This launch represents more than just the addition of a new product. It marks an important step in expanding our diagnostic portfolio to support broader infection control efforts in hospital settings,” said Daniel Shin, Executive Vice President and Chief Global Sales and Marketing Officer at Seegene. “We will continue to develop diagnostic solutions that can be effectively implemented in real-world clinical environments.”

Seegene plans to further strengthen its diagnostic capabilities for healthcare-associated infections and advance its strategy in line with growing demand for enhanced infection surveillance and control. Product availability may vary by country and is subject to local regulatory requirements.

The company is also developing the Allplex<sup>®</sup> MRSA Assay for detection of methicillin-resistant *Staphylococcus aureus* (MRSA), which is targeted for launch next year as part of its broader AMR testing portfolio expansion strategy.

### About Seegene

Seegene is a global molecular diagnostics company with more than 25 years of expertise in research, development and manufacturing of syndromic real-time PCR technologies. The company is widely recognized for its proprietary multiplex PCR technology, which enables the simultaneous detection of multiple pathogens in a single test.

A core feature of Seegene’s syndromic real-time PCR technology is its ability to detect up to 14 pathogens that cause similar signs and symptoms in a single tube while providing quantitative information to support more efficient clinical decision-making.

Seegene’s technological capabilities were demonstrated during the COVID-19 pandemic, when the company supplied more than 340 million COVID-19 tests to over 100 countries worldwide.

Building on its molecular diagnostics expertise, Seegene is expanding beyond assay-based diagnostics to develop an integrated diagnostic ecosystem. The company is advancing new technologies including STAgora<sup>®</sup>, a real-time diagnostic data analytics platform, and CURECA<sup>®</sup>, a fully automated PCR system designed to streamline the entire molecular testing workflow.

Through its Technology Sharing Initiative and global partnerships, Seegene aims to broaden access to molecular diagnostics technologies and strengthen global preparedness for infectious diseases.

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Photo

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1. ImmediaPress

### Data di creazione

Maggio 21, 2026

### Autore

redazione

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