Media Release

Roche receives CE mark for novel automated high-throughput Elecsys Dengue Ag test to diagnose dengue

- **New dengue antigen test delivers high clinical sensitivity and specificity, as well as inclusivity for all four dengue virus serotypes, helps clinicians confidently distinguish dengue from other acute fever-causing illnesses.**
- **Full automation facilitates medium to high throughput and enables improvement of lab efficiency and test traceability, while reducing the risk of human error.**
- **Test delivers results in just 18 minutes, enabling faster laboratory workflows and patient management during outbreaks.[1]**

Basel, 29 October 2025 - Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that it has received CE mark for its Elecsys® Dengue Ag test – a high-throughput, fully automated immunoassay to be used as an aid in the diagnosis of an acute dengue virus infection. This milestone promises to set a new standard for efficiency and reliability in tackling the growing global challenge of dengue fever.

Dengue fever is the most common mosquito-borne viral illness in the world. In 2024, more cases of dengue were recorded than ever before in a 12-month period, affecting over 100 countries on all continents. During 2024, ongoing transmission, combined with an unexpected spike in dengue cases, resulted in a historic high of over 14.6 million cases and more than 12,000 dengue-related deaths. Over the past 50 years, the spread of the disease has accelerated, posing a significant global health threat as half of the world's population now lives in areas at risk of infection.[2]

The symptoms of dengue aren't unique, so doctors often struggle to distinguish it from other fever-causing illnesses, such as chikungunya or yellow fever. This is why early and accurate diagnosis is critical so that patients can be managed in a timely manner to prevent severe complications.

“Dengue’s rapid worldwide spread has elevated it to a serious global burden, placing a significant strain on healthcare resources,” said Matt Sause, CEO of Roche Diagnostics. “Roche is committed to supporting the global response to the rise of infectious diseases such as dengue. With our novel Elecsys Dengue antigen test, we enable healthcare systems to diagnose dengue more reliably and efficiently.”

Recognising the value of diagnostics, the World Health Organization (WHO) has developed an “Essential Diagnostics List” which includes in-vitro diagnostic solutions that should be

accessible to all countries to increase timely and life-saving diagnoses. Dengue virus NS1 antigen, along with other biomarkers, is included in the WHO essential IVD list.[3]

About the Elecsys Dengue virus antigen immunoassay

The Elecsys Dengue Ag is an in-vitro diagnostic immunoassay for the qualitative detection of the NS1 antigen of the dengue virus in human serum and plasma, a key marker of acute infection during the first days of illness. It is intended for use on Roche's fully automated cobas® e immunoassay analysers: cobas e 801 systems and cobas e 402 platforms – a widely used platform with an extensive installed base in laboratories worldwide.

The test has been shown to reliably detect NS1 antigen for all four dengue virus serotypes – DENV-1, DENV-2, DENV-3, and DENV-4.[4] In clinical studies, it demonstrated 94.90% (CI: 91.44–97.26%) sensitivity in PCR-confirmed positive samples and 99.96% (CI: 99.79–100%) relative specificity in a large cohort of healthy blood donors.

Key benefits of the Elecsys Dengue Ag test include:

Reliable and Fast Results: The Elecsys Dengue Ag test has a turnaround time of 18 minutes. It is designed for use on Roche's automated cobas e immunoassay analyzers with a throughput from 120 to up to 300 tests/hour. This ensures reliable results for effective patient management during outbreaks and supports surveillance efforts in both endemic and non-endemic settings.

Enhanced Efficiency and Traceability: The automated nature of the Elecsys and cobas instruments improves laboratory consolidation, workflow, and traceability, reducing manual activities and the potential for human error.

Comprehensive response across the entire patient journey: The Elecsys Dengue Panel, which includes the Elecsys Dengue Ag test, alongside the Elecsys Dengue IgM test and Elecsys Dengue IgG test that will be subsequently launched, is designed to cover all key serological biomarkers for dengue diagnosis. By addressing NS1 for acute infection, IgM for recent exposure, and IgG for long-term immunity, the panel equips clinicians with the tools to diagnose dengue accurately at every stage of the disease.

About Dengue

Dengue is a mosquito-borne disease transmitted to humans through the bite of infected female mosquitoes, primarily of the *Aedes aegypti* species. While most people have no symptoms or only mild, self-limiting ones (fever, body aches, headache), a small percentage of cases can progress to severe dengue, which is life-threatening and involves complications like bleeding and organ impairment.

The global incidence of dengue is rising sharply due to climate change expanding the mosquito's range, putting nearly half the world's population at risk.[5] Children, the elderly, individuals with weakened immune systems, and those with underlying conditions are at higher risk of developing severe dengue. Close monitoring and fluid management are crucial to prevent severe complications.

About Roche

Founded in 1896 in Basel, Switzerland, as one of the first industrial manufacturers of branded medicines, Roche has grown into the world's largest biotechnology company and the global leader in in-vitro diagnostics. The company pursues scientific excellence to discover and develop medicines and diagnostics for improving and saving the lives of people around the world. We are a pioneer in personalised healthcare and want to further transform how healthcare is delivered to have an even greater impact. To provide the best care for each person we partner with many stakeholders and combine our strengths in Diagnostics and Pharma with data insights from the clinical practice.

For over 125 years, sustainability has been an integral part of Roche's business. As a science-driven company, our greatest contribution to society is developing innovative medicines and diagnostics that help people live healthier lives. Roche is committed to the Science Based Targets initiative and the Sustainable Markets Initiative to achieve net zero by 2045.

Genentech, in the United States, is a wholly owned member of the Roche Group. Roche is the majority shareholder in Chugai Pharmaceutical, Japan.

For more information, please visit www.roche.com.

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