Media Release

Roche receives U.S. FDA Emergency Use Authorization for its high-throughput test to detect monkeypox virus

- **In May 2022, Roche was one of the first companies to develop a suite of tests to detect the monkeypox virus and aid in the understanding of why and how the disease is spreading.**
- **cobas MPXV for use on cobas 6800/8800 Systems is the first monkeypox virus test granted EUA following evaluation in actual patient samples rather than just samples formulated in the laboratory.**
- **High-throughput solutions enable rapid results, allowing individuals to avoid additional testing or unnecessary isolation, and supporting access to appropriate treatment as soon as possible.**

Basel, 16 November 2022 - Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that the U.S. Food and Drug Administration (FDA) granted Emergency Use Authorization (EUA) for cobas® MPXV for use on the cobas® 6800/8800 Systems. The test is a real time PCR test for the qualitative detection of DNA from monkeypox virus (MPXV) in lesion swabs collected from individuals suspected of monkeypox infection by their healthcare provider.

cobas MPXV targets two different regions of the MPXV genome, which are both less prone to mutations than other parts of the genome. This dual-target approach ensures that cobas MPXV will continue to detect the virus even if a mutation occurs in one of the target regions.

“When multiple clusters of monkeypox virus infection were initially reported in countries where the disease is not endemic, Roche was among the first companies to address virus concerns with test kits,” said Thomas Schinecker, CEO of Roche Diagnostics. "In order to meet the testing needs and workflow demands of laboratories as well as expand access to safe and reliable diagnostic solutions, we developed the cobas MPXV on the fully automated and high-throughput cobas 6800/8800 system."

The high-throughput solution can help individuals get the right results quickly. This is important so that patients are not subjected to unnecessary additional testing or isolation, and will have access to appropriate treatment as soon as possible.

Like many viruses, monkeypox cannot be conclusively diagnosed by symptoms alone. This is because many monkeypox symptoms closely resemble those of other rash-producing illnesses such as chickenpox, measles, bacterial skin infections, and even hives or allergies.

For more information on the test kits launched for researchers that were launched in May 2022 please follow this link: Roche develops unique PCR tests to detect the monkeypox virus.

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About the test

cobas® MPXV is intended for use for the qualitative detection of DNA from monkeypox virus in individuals suspected of monkeypox infection by their healthcare provider. cobas MPXV for use on cobas 6800/8800 Systems is the first monkeypox virus test granted EUA following evaluation in actual patient samples rather than just samples formulated in the laboratory. The assay uses β-globin, a target present in human DNA, as an endogenous control to ensure specimen adequacy. Unlike the previously cleared assay, cobas MPXV detects monkeypox nucleic acids and the endogenous control in the same well, improving laboratory efficiency by effectively doubling the number of clinical samples a laboratory can assess on each plate and halving reagent needs per sample.

cobas MPXV is only for use under the FDA's EUA in laboratories certified under Clinical Laboratory Improvement Amendments that meet requirements to perform high or moderate complexity tests. Laboratories within the United States and its territories are required to report all results to the appropriate public health authorities. cobas MPXV is intended for use by qualified clinical laboratory personnel specifically instructed and trained in the techniques of real-time PCR and on the use of the cobas 6800/8800 Systems.

About the cobas 6800/8800 Systems

The Roche cobas 6800/8800 Systems provide results in three and half hours and offer improved operating efficiency, flexibility and fastest time-to-results with the highest throughput providing up to 96 results in about three hours and a total of 1,440 results for the cobas 6800 System and 4,128 results for the cobas 8800 System in 24 hours.

About monkeypox

Symptoms of monkeypox include fever, chills, headaches, muscle aches, fatigue, swollen lymph nodes and a painful rash that characteristically appears as raised bumps on the skin and tends to be distributed on the face, extremities and genitals. As the disease progresses, these bumps fill with pus and fluid and become umbilicated. They will eventually ulcerate, scab and fall off.

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.

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In recognising our endeavor to pursue a long-term perspective in all we do, Roche has been named one of the most sustainable companies in the pharmaceuticals industry by the Dow Jones Sustainability Indices for the thirteenth consecutive year. This distinction also reflects our efforts to improve access to healthcare together with local partners in every country we work.

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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