Media & Investor Release

Roche receives FDA approval for the first molecular test to screen for malaria in blood donors

- **The cobas Malaria test is the first FDA-approved molecular test to screen U.S. blood donors for malaria.**
- **Malaria is a serious and potentially fatal parasitic infection most commonly transmitted by mosquitoes that can also be spread through blood transfusion.**
- **Roche is dedicated to saving patients' lives through diagnostic solutions that aid in the protection of the global blood supply from infectious diseases.**

BASEL, March 26, 2024 – Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today the U.S. Food and Drug Administration (FDA) approval of the **cobas**® Malaria test for use on the **cobas**® 6800/8800 Systems. This approved test can aid healthcare professionals in reducing potential risks of patient infection from transfused blood products. The **cobas** Malaria test provides a highly sensitive and specific solution to help ensure that infected blood units are removed from the blood supply.

The **cobas** Malaria molecular test screens whole blood samples for the five main species of Plasmodium parasites that are known to cause human infection. The potential value of a molecular donor screening test for malaria is to improve both blood safety and availability. The test is intended for use in screening blood, organ and tissue donors.

"As the first FDA-approved blood screening test for malaria, this represents an important step forward in safeguarding the global supply of donated blood," said Matt Sause, CEO of Roche Diagnostics. "The approval of **cobas** Malaria represents a significant advancement in malaria detection, offering healthcare professionals a reliable tool for donor screening and improving the safety of patients worldwide."

Globally, a large number of possible donors are excluded from giving blood because of travel to or from residences in malaria-endemic areas. Existing microscopy and serological tests are not sensitive enough to reliably mitigate malaria transfusion risk.

The Roche Blood Safety Solutions offering provides the most comprehensive molecular, serological testing and automation options for donor screening in the U.S. market.

In 2022, nearly half of the world's population was at risk of malaria. While sub-Saharan Africa carries a disproportionately high share of the global malaria burden, the World Health

Organization regions of Southeast Asia, the Eastern Mediterranean, the Western Pacific and the Americas also report significant numbers of cases and deaths. There were an estimated 249 million cases of malaria in 2022, and the estimated number of malaria deaths stood at 608,000. In 2022, the African Region was home to 94% and 95% of malaria cases and deaths, respectively.[2]

The test will be available in the U.S. at the end of the second quarter of 2024.

About the cobas Malaria test

The **cobas** Malaria test, a qualitative in-vitro nucleic acid screening test, allows for direct detection of Plasmodium RNA and DNA in whole blood samples from individual human donors. The test, which can be performed with other routine, blood donor–screening tests, is designed for use on the **cobas** 6800/8800 Systems in the U.S. The test is not intended for use to diagnose Plasmodium infection, for use on cord blood samples or for use on cadaveric blood specimens. The test utilizes the Roche Whole Blood Collection Tube, which allows for direct draw from the donor and is loaded directly onto the **cobas** 6800/8800 Systems for increased workflow efficiency.

About the cobas 6800 and cobas 8800 Systems

Since 2014, the **cobas** 6800 and **cobas** 8800 Systems have established the new standard for routine molecular testing by delivering fully integrated, automated solutions that serve the areas of donor screening, infectious disease, sexual health, transplant, respiratory and antimicrobial stewardship. The current molecular donor screening assay menu includes cobas® MPX, cobas® DPX, cobas® WNV, cobas® Zika and cobas® Babesia.

About malaria

Malaria is a serious and sometimes fatal disease caused by a parasite that commonly infects a certain type of mosquito which feeds on humans. People who get malaria typically experience high fever, shaking chills and flu-like symptoms. The disease can also be transmitted through blood transfusion, organ transplant or the shared use of needles or syringes contaminated with blood.[1]

Malaria is preventable and curable. There are five parasite species that cause malaria in humans, and two of these species – Plasmodium falciparum and Plasmodium vivax – pose the greatest threat.

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 personalized 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.

In recognizing 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 fifteenth 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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References

1. CDC.gov. "What is malaria? Frequently asked questions." Last accessed March 21, 2024.
2. World Health Organization. "Malaria". Last accessed March 21, 2024.

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