

## Grifols receives FDA approval for its malaria blood screening assay

- *Procleix Plasmodium Assay is a nucleic acid test (NAT) that detects the presence of Plasmodium, a protozoan parasite that causes malaria worldwide and creates a significant risk for both donor safety and availability*
- *Screening blood donors with the assay can help reduce the risk of transfusion-transmitted malaria and enhance blood availability by reducing the number of donors deferred due to malaria risk*
- *FDA approval for the Procleix Plasmodium Assay further strengthens the Grifols Procleix portfolio for blood donor screening and is another example of the company's commitment to safe blood transfusions globally*

**Barcelona, Spain, April 16, 2026** - Grifols (MCE: GRF, MCE: GRF.P NASDAQ: GRFS), a global healthcare company and leading producer of plasma-derived medicines and innovative diagnostic solutions, today announced that its Procleix Plasmodium Assay, used in conjunction with the Procleix Panther System, has obtained approval from the U.S. Food and Drug Administration (FDA) for screening blood donors for malaria.

The Procleix Plasmodium Assay received a CE mark in 2022 as the first automated nucleic acid test (NAT) specifically validated for screening blood donors for malaria. Its approval in the United States expands its use to support growing global demand and anticipated updates to regulatory requirements for donor screening.

The Procleix Plasmodium Assay aims to improve blood safety by detecting *Plasmodium*, a mosquito-borne parasite that causes malaria and is responsible for an estimated 282 million infections and 610,000 global deaths annually.<sup>1</sup>

The assay uses a whole-blood sample and detects ribosomal RNA, which is present in thousands of copies per parasite. Currently, the risk of malaria infection in blood donors is assessed by blood banks using a questionnaire in which donors who report travel to, or prior residence in, malaria-endemic areas are temporarily deferred.

"We are excited to announce the FDA approval of an additional Procleix blood screening assay, demonstrating Grifols' continued commitment to transfusion safety," said Antonio Martínez, president Grifols Diagnostic. "The Procleix Plasmodium Assay enhances the ability of blood banks in the United States to provide safer blood transfusions."

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<sup>1</sup> World Health Organization. Malaria Fact Sheet. <https://www.who.int/news-room/fact-sheets/detail/malaria> (Accessed February 26, 2026)

## About the Procleix Plasmodium Assay

The Procleix Plasmodium Assay is a nucleic acid test (NAT) that uses magnetic-based target capture, Transcription-Mediated Amplification and chemiluminescence to detect the presence of specific ribosomal RNA sequences of five species of *Plasmodium* parasites that cause malaria in humans (*P. falciparum*, *P. knowlesi*, *P. malariae*, *P. ovale*, and *P. vivax*) in whole blood specimens from blood donors.

The high sensitivity and specificity of the Procleix technology enables pathogen detection to reduce the risk of transfusing infected blood or blood components, even when the donor does not exhibit symptoms and traditional screening techniques are not able to detect the presence of the pathogen, or the antibodies against it. The assay runs on the widely adopted Procleix Panther System, an automated NAT instrument.

## About Procleix Panther System

The Procleix Panther System automates all aspects of NAT-based blood screening on a single, integrated platform, and is capable of delivering the highest result throughput per square meter. It eliminates the need for batch processing and combines walk-away freedom with intuitive design for ease of use.

For more information, please visit [www.diagnostic.grifols.com](http://www.diagnostic.grifols.com).

## About Grifols

Grifols is a global healthcare company founded in Barcelona in 1909 committed to improving the health and well-being of people around the world. A leader in essential plasma-derived medicines and transfusion medicine, the company develops, produces and provides innovative healthcare services and solutions in more than 110 countries.

Patient needs and Grifols' ever-growing knowledge of many chronic, rare and prevalent conditions, at times life-threatening, drive the company's innovation in both plasma and other biopharmaceuticals to enhance quality of life. Grifols focuses on treating conditions centered on six core therapeutic areas: immunology, neurology, pulmonology, hematology, hepatology and intensive care.

A pioneer in the plasma industry, Grifols continues to grow its network of donation centers, the world's most diversified with more than 400 across North America, Europe, Africa and the Middle East, and China.

As a recognized leader in transfusion medicine, Grifols offers a comprehensive portfolio of solutions designed to enhance safety from donation to transfusion, in addition to clinical diagnostic technologies. It provides high-quality biological supplies for life-science research, clinical trials and for manufacturing pharmaceutical and diagnostic products. The company also supplies tools, information and services that enable hospitals, pharmacies and healthcare professionals to efficiently deliver expert medical care.

Grifols, with more than 25,000 employees in more than 30 countries and regions, is committed to a sustainable business model that sets the standard for continuous innovation, quality, safety and ethical leadership.

The company's class A shares are listed on the Spanish Stock Exchange, where they are part of the IBEX-35 (MCE:GRF). Grifols non-voting class B shares are listed on the Mercado Continuo (MCE:GRF.P) and on the U.S. NASDAQ through ADRs (NASDAQ:GRFS).

For more information about Grifols, please visit [www.grifols.com](http://www.grifols.com)

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