

# GRIFOLS

## Grifols Procleix Plasmodium Assay receives CE mark, a first for malaria blood screening

- *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 blood safety and availability*
- *Screening blood donors with the assay can reduce the risk of transfusion-transmitted malaria (TTM) and enhance blood availability by reducing the number of donors rejected and deferred due to malaria risk*
- *CE mark 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, June 8, 2022** - Grifols (MCE: GRF, MCE: GRF.P, NASDAQ: GRFS), a global leader in the development of plasma-derived therapies and the development of innovative diagnostic solutions, today announced that its Procleix Plasmodium Assay has obtained the CE mark, the first for an automated nucleic acid test (NAT) system specifically validated for screening blood donors for malaria.

The Procleix Plasmodium Assay, designed for NAT, aims to improve blood safety by detecting Plasmodium, a mosquito-borne parasite that causes malaria and is responsible for more than 240 million infections and 620,000 deaths annually<sup>1</sup>.

This assay uses a whole blood sample and detects ribosomal RNA (rRNA), which is present in thousands of copies per parasite, allowing equivalent sensitivity in both individual and pooled samples. Currently, risk for malaria in blood donors is typically evaluated using a questionnaire in which donors who declare having traveled to or prior residence in malaria-endemic areas are temporarily deferred. Blood banks and collection centers could decide that deferrals could be unnecessary if donors were tested and found negative using the Procleix Plasmodium Assay.

“We are excited to announce the CE mark certification of an additional Procleix assay, demonstrating Grifols’ continued commitment to transfusion safety,” said Antonio Martínez, President, Grifols Diagnostic Business Unit. “Certification of the Procleix Plasmodium Assay enhances the ability of blood banks in Europe to provide safer blood transfusions.”

The Procleix Plasmodium Assay will be available in all markets accepting the CE mark certification after completion of any additional registration and notification requirements.

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<sup>1</sup> World Health Organization. Malaria Fact Sheet. <https://www.who.int/news-room/fact-sheets/detail/malaria> (Accessed April 21, 2022)

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## **About Procleix Plasmodium Assay**

The Procleix Plasmodium Assay is a nucleic acid test (NAT) that uses magnetic-based target capture, Transcription-Mediated Amplification (TMA) 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 from Grifols.

## **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. Its four divisions – Bioscience, Diagnostic, Hospital and Bio Supplies – develop, produce and market innovative solutions and services that are sold in more than 110 countries.

Pioneers in the plasma industry, Grifols operates a growing network of donation centers worldwide. It transforms collected plasma into essential medicines to treat chronic, rare and, at times, life-threatening conditions. As a recognized leader in transfusion medicine, Grifols also offers a comprehensive portfolio of solutions designed to enhance safety from donation to transfusion. In addition, the company supplies tools, information and services that enable hospitals, pharmacies and healthcare professionals to efficiently deliver expert medical care.

Grifols, with more than 23,000 employees in 30 countries and regions, is committed to a sustainable business model that sets the standard for continuous innovation, quality, safety and ethical leadership.

In 2021, Grifols' economic impact in its core countries of operation was EUR 7.7 billion. The company also generated 141,500 jobs, including indirect and induced.

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, please visit [www.grifols.com](http://www.grifols.com)

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