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Grifols Procleix ArboPlex Assay® receives CE mark, the first and only 4-in-1 NAT for arbovirus screening

- ***Grifols' in vitro nucleic acid test detects four types of arboviruses, helping mitigate the risk of transfusion-transmitted infections***
- ***Arboviruses are a growing emerging threat, with changes in climate and increasing global connectivity making the geographic spread more prevalent***
- ***CE mark for Grifols' Procleix ArboPlex Assay reinforces the company's leadership in transfusion medicine and commitment to ensuring the safety of the world's blood supply***

Barcelona, Spain, April 4, 2024 – Grifols (MCE: GRF, MCE: GRF.P NASDAQ: GRFS), one of the world's leading producers of plasma-derived medicines and innovative diagnostic solutions, today announced that its new Procleix ArboPlex Assay has obtained the CE mark under the In Vitro Diagnostic Regulation (IVDR), the first for an automated nucleic acid test (NAT) specifically validated for screening blood donors to detect four major arboviruses: chikungunya, dengue, West Nile and Zika viruses.

These are the four most significant arboviruses of concern, all spread through mosquito vectors. Changes in climate and increasing global connectivity have made the geographic spread of – and growing exposure to – arboviruses a major public health concern. With the dengue virus alone, there were more than 5 million cases and 5,000 deaths reported globally in 2023.[1]

Further strengthening the Grifols Procleix portfolio for blood donor screening, the Procleix ArboPlex Assay uses plasma or serum samples to detect arboviral RNA. Currently, risk for arboviruses in blood donors is evaluated either with a monoplex test, duplex test or through a questionnaire in which donors who declare having traveled to or prior residence in arbovirus-endemic areas are temporarily deferred. Blood banks and collection centers could decide that deferrals are unnecessary if donors were tested and found negative using the Procleix ArboPlex Assay.

"With its 4-in-1 arbovirus test feature, the Grifols Procleix ArboPlex Assay has the ability to speed up and overall improve donor screening laboratory efficiency," said Antonio Martínez, president of Grifols Diagnostic Business Unit. "Certification of this new assay provides a reliable and efficient solution to ensure accurate and consistent results, demonstrating Grifols' continued commitment to innovating blood screening safety."

[1] https://www.who.int/emergencies/disease-outbreak-news/item/2023-DON498 accessed March 2024

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

About Procleix ArboPlex Assay®

The Procleix ArboPlex Assay is a nucleic acid test (NAT) that uses magnetic-based target capture, Transcription-Mediated Amplification (TMA) and chemiluminescence to detect the presence of RNA sequences of four arboviruses (chikungunya virus, dengue virus RNA, West Nile virus RNA, and Zika virus) in plasma and serum from human 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. 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.

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 is focused on treating conditions across a broad range of therapeutic areas: immunology, hepatology and intensive care, pulmonology, hematology, neurology and infectious diseases.

A pioneer in the plasma industry, Grifols continues to grow its network of donation centers, the world's largest with over 390 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 23,000 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, please visit www.grifols.com

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