Grifols Procleix UltrioPlex E and Procleix Babesia assays receive CE mark

- *Procleix UltrioPlex E Assay enhances blood safety by detecting the presence of HIV-1, HIV-2, HBV, HCV, and HEV in a single, simultaneous test, improving overall laboratory efficiencies*

- *Procleix Babesia Assay detects the Babesia pathogen responsible for one of the most frequent causes of non-viral transfusion-transmitted infections (TTI)*

- *The CE mark for these two assays is an important step forward for the Grifols Procleix portfolio and is another example of the company's commitment to transfusion safety*

Barcelona, Spain, March 25, 2021 - Grifols (MCE: GRF, MCE: GRF.P, NASDAQ: GRFS), a global leader in the development of plasma-derived therapies and in the development of innovative diagnostic solutions, today announced it has obtained the CE mark for its Procleix UltrioPlex E and Procleix Babesia assays.

The Procleix UltrioPlex E Assay is a nucleic acid test (NAT) designed to improve blood safety by detecting the presence of human immunodeficiency virus type 1 (HIV-1), HIV type 2 (HIV-2), hepatitis B virus (HBV), hepatitis C virus (HCV), and hepatitis E virus (HEV) in a single, simultaneous test from human serum or plasma. It was first commercially launched in August 2020 in Japan and represents a significant advance in streamlining a laboratory's NAT testing operations by allowing for an increased screening of viruses from a single-donor specimen without the need for any additional equipment. The Procleix UltrioPlex E Assay also helps produce less waste with higher results throughput and greater walk-away time for laboratory staff when compared with running current screening solutions separately.

The Procleix Babesia Assay detects Babesia, a tick-borne parasite that infects the host's red blood cells and is responsible for one of the most frequent causes of non-viral TTI. It is the first Procleix assay to use a whole blood specimen and, most importantly, target a parasite instead of a virus. The detection of ribosomal RNA, which is present in thousands of copies per parasite, allows equivalent sensitivity in individual samples and pooled lysates. Screening of donated whole blood to detect the presence of the four most common Babesia species is currently mandated in certain parts of the United States where the pathogen represents a serious threat to the safety of the blood supply.

"We are excited to announce the CE mark of two additional assays, as part of our Procleix portfolio for screening blood and plasma, demonstrating Grifols' continued commitment to transfusion safety," said David Dew, President, Grifols Diagnostic Commercial Division. "Certification of the Procleix UltrioPlex E and Procleix Babesia assays enhances the competitiveness of our Procleix portfolio and enables blood banks in Europe to increase transfusion safety."

The Procleix UltrioPlex E and Procleix Babesia assays will be available in all markets accepting the CE mark after completion of any additional registration and notification requirement.

About Procleix UltrioPlex E Assay

The Procleix UltrioPlex E Assay is a nucleic acid test (NAT) that uses Transcription-Mediated Amplification (TMA) to detect the presence of specific nucleic acid sequences for HIV-1, HIV-2, HBV, HCV, and HEV in serum or plasma of donated blood. Because of the high sensitivity and specificity of the amplification technology, detection of the targeted pathogens can be achieved within the early stages of infection, thereby helping in preventing infected blood or blood components to be transfused 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 Procleix Panther System, a fully automated NAT instrument launched by Grifols in the EU market in 2012, and currently widely adopted in laboratories globally.

About Procleix Babesia Assay

The Procleix Babesia Assay is a nucleic acid test (NAT) that uses Transcription-Mediated Amplification (TMA) to detect the presence of specific ribosomal RNA sequences of at least four clinically relevant species of Babesia parasites (B. microti, B. duncani, B. divergens, and B. venatorum) in whole blood specimens from blood donors. Because of the high sensitivity and specificity of the amplification technology, detection of the pathogen can be achieved within the early stages of infection, thereby helping in preventing infected blood or blood components to be transfused 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 Procleix Panther System, a fully automated NAT instrument launched by Grifols in the EU market in 2012, and currently widely adopted in laboratories globally.

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 100 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 nearly 24,000 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 2020, Grifols' economic impact in its core countries of operation was EUR 7.5 billion. The company also generated 140,000 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

Media Contact:

Media Press Office
media@grifols.com
Tel. +34 571 00 02