

Grifols receives FDA clearance for AlphaID™ At Home, the first free service for U.S. consumers to determine their risk for alpha-1

- AlphaID™ At Home, the company's first FDA clearance for direct-to-consumer use, enables U.S. adults to screen for their genetic risk of alpha₁-antitrypsin deficiency (alpha-1) without prescription from a healthcare professional
- A simple saliva sample collected at home will detect the chances of developing lung and/or liver disease linked to alpha-1, including chronic obstructive pulmonary disease (COPD), a group of respiratory illnesses
- During November, awareness month for both alpha-1 and COPD, Grifols underscores its long-time commitment to the alpha-1 community and identifying more COPD patients with alpha-1

Barcelona, Spain, Nov. 3, 2022 – Grifols (MCE:GRF, MCE:GRF.P, NASDAQ:GRFS), a global leader in plasma-derived medicines and innovative diagnostic solutions, today announced that its AlphaID™ At Home Genetic Health Risk Service, the first-ever free direct-to-consumer program in the U.S. to screen for genetic risk of alpha₁-antitrypsin deficiency (alpha-1), has been cleared by the U.S. Food and Drug Administration (FDA).

The service, also known as AlphaID™ At Home, is the company's first FDA clearance for direct-to-consumer use. It will be available beginning in Q2 2023 for U.S. adults to screen for their genetic risk level of developing lung and/or liver disease related to alpha-1 without a medical prescription.

Alpha-1 is the most common risk factor for chronic obstructive pulmonary disease (COPD), a group of respiratory diseases that includes emphysema and chronic bronchitis. It's estimated that around 16 million Americans have COPD, with millions more yet to be diagnosed.¹ More than 90% of people with alpha-1 are believed to be undiagnosed.²

"Many COPD patients don't know their condition could be caused by alpha-1 because its symptoms are similar to those of COPD or asthma," said Scott Santarella, President & CEO of the Alpha-1 Foundation, pointing out that November is awareness month for both alpha-1 and COPD. "We wholeheartedly support initiatives and innovations that contribute to the diagnosis of alpha-1."

¹ Chronic Obstructive Pulmonary Disease. Centers for Disease Control and Prevention. Accessed October 31, 2022. [Chronic Obstructive Pulmonary Disease \(COPD\) | CDC](#)

² Campos MA, Wanner A, Zhang G, Sandhaus RA. Trends in the diagnosis of symptomatic patients with α 1-antitrypsin deficiency between 1968 and 2003. *Chest*. 2005;128(3):1179-1186.

GRIFOLS

To use the safe saliva collection kit, individuals simply collect their sample and send it to a certified lab for processing. Within a few weeks and through a secure online portal, they will know if they are at risk of developing alpha-1, a condition due to a lack of alpha₁-antitrypsin (AAT). They are encouraged to share the results with their doctor and discuss potential treatment options.

A user comprehension study for AlphaID™ At Home showed that a demographically diverse U.S. population of users (525 participants) could easily comprehend the service reports, with a 90% or greater rate of understanding.

AlphaID™ At Home uses the same accurate test Grifols has made available to physicians globally since 2018 to screen for alpha-1, a focus on diagnosis that has led to more than 1 million patients being screened with Grifols technology over the last 20 years.

The test can screen for the 14 most prevalently reported genetic mutations associated with alpha-1 – the most of any test of its kind – including the S, Z, F, I alleles, as well as rare and null alleles.

“Grifols is very pleased that the FDA cleared the AlphaID™ At Home service, reflecting the robustness and accuracy of the testing platform as well as the value it will provide in helping people detect if they are at risk for alpha-1,” said Antonio Martínez, President of Grifols Diagnostic. “As leaders in alpha-1 testing and treatment, Grifols is redoubling its commitment to the alpha-1 community.”

Only a physician or healthcare provider can make a diagnosis of alpha-1. To learn more about alpha-1, please visit the Alpha-1 Foundation at www.alpha1.org.

For media inquiries:

Caleb Fernandez-Schendt
caleb.fernandezschendt@grifols.com
(919) 316-2128

Grifols Press Office
media@grifols.com
Tel. +34 93 571 00 02

Investor contact:

Investor Relations & Sustainability
inversores@grifols.com - investors@grifols.com
sostenibilidad@grifols.com – sustainability@grifols.com
Tel.: +34 93 571 02 21

GRIFOLS

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 our ever-growing knowledge of many chronic, rare and prevalent conditions, at times life-threatening, drive our innovation in plasma-based therapies 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 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. We provide high-quality biological supplies for life-science research, clinical trials, and for manufacturing pharmaceutical and diagnostic products. 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 27,000 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.

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 [grifols.com](https://www.grifols.com)

LEGAL DISCLAIMER

The facts and figures contained in this report that do not refer to historical data are "future projections and assumptions". Words and expressions such as "believe", "hope", "anticipate", "predict", "expect", "intend", "should", "will seek to achieve", "it is estimated", "future" and similar expressions, in so far as they relate to the Grifols group, are used to identify future projections and assumptions. These expressions reflect the assumptions, hypotheses, expectations and predictions of the management team at the time of writing this report, and these are subject to a number of factors that mean that the actual results may be materially different. The future results of the Grifols group could be affected by events relating to its own activities, such as a shortage of supplies of raw materials for the manufacture of its products, the appearance of competitor products on the market, or changes to the regulatory framework of the markets in which it operates, among others. At the date of compiling this report, the Grifols group has adopted the necessary measures to mitigate the potential impact of these events. Grifols, S.A. does not accept any obligation to publicly report, revise or update future projections or assumptions to adapt them to events or circumstances subsequent to the date of writing this report, except where expressly required by the applicable legislation. This document does not constitute an offer or invitation to buy or subscribe shares in accordance with the provisions of the following Spanish legislation: Royal Legislative Decree 4/2015, of 23 October, approving recast text of Securities Market Law; Royal Decree Law 5/2005, of 11 March and/or Royal Decree 1310/2005, of 4 November, and any regulations developing this legislation. In addition, this document does not constitute an offer of purchase, sale or exchange, or a request for an offer of purchase, sale or exchange of securities, or a request for any vote or approval in any other jurisdiction. The information included in this document has not been verified nor reviewed by the external auditors of the Grifols group.