Araclon Biotech
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Araclon Biotech obtains CE mark for early-stage Alzheimer's disease diagnostic tests

- ***ABtest-MS and ABtest-IA are the first tests developed by a Spanish company for the measurement of amyloid peptides in blood to assist in assessing the risk of Alzheimer's disease. This certification is applicable in all European Union countries, Iceland, Liechtenstein and Norway***

- ***Through mass spectrometry (ABtest-MS) and ELISA (ABtest-IA), both tests can quantify Aβ40 and Aβ42 proteins – both associated with the risk of getting AD – in biological samples***

- ***Both tests are currently available in a research environment through the ABtestService: for plasma samples in the case of ABtest-MS, and plasma and cerebrospinal fluid (CSF) for ABtest-IA.***

- ***Receiving the CE mark represents another step towards incorporating ABtest-MS and ABtest-IA into routine clinical practices for future Alzheimer's disease diagnosis as they constitute a reliable, minimally invasive, highly agile and cost-effective detection tool using plasma samples.***

Zaragoza, Sept. 20, 2022 - Araclon Biotech, a Grifols Group company dedicated to the research and development of therapies and diagnostic methods applied to Alzheimer's disease (AD), has obtained the CE mark for its two early-stage diagnostic tests, ABtest-MS and ABtest-IA. Both tests are capable of quantifying Aβ40 and Aβ42 proteins, whose accumulation in the brain is considered the first pathological change related to AD[1]. ABtest-IA also allows their quantification in cerebrospinal fluid (CSF).

ABtest-MS and ABtest-IA are the first AD risk-assessment tests developed by a Spanish company to obtain the CE mark, applicable in all European Union countries, Iceland, Liechtenstein and Norway. Certification is a step forward for Araclon Biotech, whose objective is to incorporate the tests into routine clinical practices for future Alzheimer's diagnosis.

When applied to plasma samples, the tests contribute to diagnosis through an agile, reliable and minimally invasive method that is less costly than alternatives. In addition, the use of these plasma tests as pre-screening (triage) tools could considerably accelerate and lower the cost of recruitment for clinical trials of new treatments.

"Obtaining the CE mark for our early Alzheimer's disease diagnostic tests reinforces our commitment to researchers, healthcare professionals and patients, as it advances our roadmap to establish them as Alzheimer's screening standards in the future. These tests have been validated in several studies, involved thousands of clinical samples and can predict the presence of brain amyloid deposits in initial stages of the disease, which could facilitate its early management," explains Jose Terencio, Araclon CEO and vice president of Innovation at Grifols.

[1] Hansson, O. Biomarkers for neurodegenerative diseases. Nat Med 2021, 27, 954–963. https://doi.org/10.1038/s41591-021-01382-x

Both tests are currently available in a research environment, including centers specialized in AD research and experimental researchers who specialize in this neurodegenerative disease, through the ABtestService, which offers both test options in plasma samples, as well as CSF samples (ABtest-IA only).

ABtest-MS and ABtest-IA: two innovative tests which accurately quantify Aβ40 and Aβ42 proteins associated with Alzheimer's disease.

ABtest-MS and ABtest-IA are two innovative methods developed entirely by Araclon and capable of accurately quantifying Aβ40 and Aβ42 proteins in plasma samples. ABtest-MS is based on liquid chromatography coupled to mass spectrometry, while ABtest-IA uses the ELISA immunoassay technique and can also quantify both proteins in CSF.

The results of recent studies, which have been presented at international congresses[2,3], demonstrate the high predictive ability of ABtest-MS to accurately identify subjects with cerebral amyloid load, a sign indicative of early-stage AD. These data support preliminary results of recently published studies in high-impact scientific journals such as *Alzheimer's Research & Therapy*[4], *Nature Aging*[5] and *Alzheimer's & Dementia: The journal of the Alzheimer's Association*[6], confirming that beta-amyloid biomarkers measured with ABtest-MS in plasma are linked to AD.

In turn, ABtest-IA has also evidenced a close association between plasma β-amyloid protein levels and amyloid deposits in the brain[7,8]. Furthermore, ABtest-IA has been able to predict longitudinal changes in the course of Alzheimer's disease, demonstrating that lower levels of the Aβ42/Aβ40 ratio are associated with a greater accumulation of brain amyloid over time[9] and a higher risk of progression to dementia[10].

In addition, the ABTest-MS will be used to analyze samples from a patient cohort at risk of AD as part of a study being led by New York University's Grossman School of Medicine.

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[2] Plasma Aβ42/Aβ40, measured by a novel mass spectrometric method, identifies early amyloid deposition in individuals at risk of Alzheimer's disease (FACEHBI Cohort). Allúe JA et al. Oral presentation, Barcelona, 19/03/2022, AD/PD Congress, 2022.
[3] Accurate discrimination of brain amyloid status in the multi-centric a4 study by plasma Aβ42/Aβ40 measured with a novel HPLC-MS/MS method. Sarasa L et al. Poster presentation.
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[5] Cullen, N.C., Leuzy, A., Palmqvist, S. et al. Individualized prognosis of cognitive decline and dementia in mild cognitive impairment based on plasma biomarker combinations. Nat Aging 1, 114–123 (2021). https://doi.org/10.1038/s43587-020-00003-5
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[7] Pérez-Grijalba V, Arbizu J, Romero J, Prieto E, Pesini P, Sarasa L, Guillen F, Monleón I, San-José I, Martínez-Lage P, Munuera J, Hernández I, Buendía M, Sotolongo-Grau O, Alegret M, Ruiz A, Tárraga L, Boada M, Sarasa M; AB255 Study Group. Plasma Aβ42/40 ratio alone or combined with FDG-PET can accurately predict amyloid-PET positivity: a cross-sectional analysis from the AB255 Study. Alzheimers Res Ther. 2019 Dec 1;11(1):96. doi: 10.1186/s13195-019-0549-1. PMID: 31787105; PMCID: PMC6886187.
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[9] Fandos N, Pérez-Grijalba V, Pesini P, Olmos S, Bossa M, Villemagne VL, Doecke J, Fowler C, Masters CL, Sarasa M; AIBL Research Group. Plasma amyloid β 42/40 ratios as biomarkers for amyloid β cerebral deposition in cognitively normal individuals. Alzheimers Dement (Amst). 2017 Sep 12; 8:179-187. doi: 10.1016/j.dadm.2017.07.004. PMID: 28948206; PMCID: PMC5602863.
[10] Pérez-Grijalba V, Romero J, Pesini P, Sarasa L, Monleón I, San-José I, Arbizu J, Martínez-Lage P, Munuera J, Ruiz A, Tárraga L, Boada M, Sarasa M. Plasma Aβ42/40 Ratio Detects Early Stages of Alzheimer's Disease and Correlates with CSF and Neuroimaging Biomarkers in the AB255 Study. J Prev Alzheimers Dis. 2019;6(1):34-41. doi: 10.14283/jpad.2018.41. PMID: 30569084.

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About Araclon Biotech

Araclon Biotech specializes in researching and developing therapies and diagnostic methods for Alzheimer's disease (AD) and other neurodegenerative diseases. The company, in which Grifols holds a stake of almost 76%, focuses on two research areas: the early diagnosis of AD by means of detecting amyloid-beta peptides in the blood, and the treatment of the disease using immunotherapy (vaccines).

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

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