CLINICAL DIAGNOSTICS

Clinical Diagnostics Laboratory

May 2021

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Agenda

- Testing Services
- Customized Services
- License & accreditations
- Facilities

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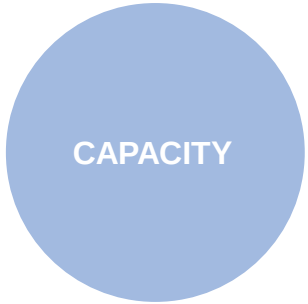
Testing Services

Quality and Experience

KNOW HOW
Tests developed by Progenika Grifols

CE MARK
Certified Quality in all tests



VOLUME
Flexible & scalable capacity for high sample volumes and throughput

+20 YEARS
Providing Clinical Diagnostics Services worldwide, implementing innovative technologies (NextGen seq, DNA chips)

SOFTWARE
Reporting and traceability assurance in compliance with European confidentiality regulations

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Testing Services

Specialized testing services in the following areas:

- AUTOIMMUNITY
- IMMUNOHEMATOLOGY
- CARDIOVASCULAR
- PULMONARY
- COVID19

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Testing Services: AUTOIMMUNITY

Testing for monitoring treatment with biologic drugs

- Quantitative determination of drug plasma levels.
- Quantitative determination of antibodies produced against biological drugs.

The analysis of these parameters provides a high predictive power on the development and clinical response of the patient.

TESTING PORTFOLIO:

- Promonitor GLM (levels of Golimumab)
- Promonitor IFX (levels of Infliximab)
- Promonitor ADL (levels of Adalimumab)
- Promonitor ETN (levels of Etanercept)
- Promonitor RTX (levels of Rituximab)
- Promonitor VDZ (levels of Vedolizumab)
- Promonitor UTK (Levels of Ustekinumab)

- Promonitor Anti - GLM (Anti-Golimumab antibodies)
- Promonitor Anti - IFX (Anti-Infliximab antibodies)
- Promonitor Anti - ADL (Anti-Adalimumab antibodies)
- Promonitor Anti - ETN (Anti-Etanercept antibodies)
- Promonitor Anti - RTX (Anti-Rituximab antibodies)
- Promonitor Anti - VDZ (Anti-Vedolizumab antibodies)
- Promonitor Anti – UTK (Anti-Ustekinumab antibodies)

Testing Services: IMMUNOHEMATOLOGY

Blood Group Genotyping

The genetic testing is an effective and innovative solution for the identification of clinically relevant antigens and platelets. Provides detailed information to ensure maximum compatibility between donor and patient, in order to offer the safest possible transfusion therapy for each individual.

TESTING PORTFOLIO:

- **ID CORE XT:** Blood Group Genotyping Test, from human genomic DNA, which permits simultaneous identification of multiple allelic variants of the most important red cell antigens (RBC) of Rh, Kell, Kidd, Duffy, MNS, Diego, Dom Brock, Colton, Cartwright and Lutheran systems.
- **ID HPA XT**: Blood Group Genotyping Test, from human genomic DNA, allowing simultaneous identification of multiple allelic variants from the major platelet antigens (HPA) from HPA 1 to HPA11 and HPA 15 systems.
- **ID RHD XT**: Blood Group Genotyping Test, from human genomic DNA, allowing simultaneous identification of the most relevant human erythrocyte antigens (antigen D), detecting polymorphisms that determine 6 RHD and HPA-1 variants.

Testing Services: CARDIOVASCULAR

Genetic Diagnosis of Familial Hypercholesterolemia

The Autosomal Dominant Hypercholesterolemia (ADH) is caused by mutations in LDLR, APOB, PCSK9, APOE, STAP1 and LIPA genes, while Autosomal Recessive Familial Hypercholesterolemia (ARH) is caused by mutations in the LDLRAP1 gene. Progenika' s genetic testing detects them all for an accurate diagnosis.

- Simultaneous detection of all possible FH mutations.
- 7 FH related genes analyzed: LDLR, APOB, PCSK9, APOE, STAP1, LIPA (ADH) and LDLRAP1 (ARH).
- 12 SNPs score to detect Polygenic FH.
- SLCO1B1*5: Allele associated with statin-induced myopathy.
- Simplicity & latest Technology: analysis of DNA from Blood or saliva samples using NextGen technology.

Awarded Public Tender for FH screening by the Health Department of Castilla y León Region in Spain. Ongoing.

Junta de Castilla y León
Consejería de Sanidad

Sacyl

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Testing Services: PULMONARY & HEPATIC

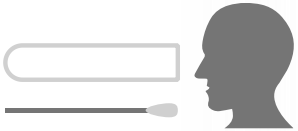
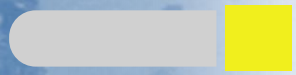
Genetic Diagnosis of Alpha 1 Antitrypsin deficiency.

The A1AT Genotyping Test is a last generation genetic test that analyzes simultaneously the most prevalent mutations in the world associated with the disease in DNA extracted from a blood (whole and DBS) or saliva sample. New mutations causing the disease are also identified by Nextgen sequencing.

The deficit of alpha-1 is a genetic inherited disorder that can cause the development of the disease chronic obstructive **pulmonary disease (COPD),** mainly emphysema, **and various types of liver diseases**. It is characterized by very low levels, or nonexistent, of the alpha-1 antitrypsin protein in blood. The main function of this protein is to protect the lung tissue from inflammation caused by infections and irritants inhaled, such as tobacco smoke.

A1AT Genetic Testing Program currently ongoing in Spain, LATAM countries, and Turkey.

Testing Services: COVID19 DIAGNOSTIC

	Grifols TMA test	Fast test	ELISA test
Detection	SARS CoV-2 virus	**Antibodies** Anti-SARS-CoV-2 IgG, IgM	**Antibodies** Anti-SARS-CoV-2 IgG, IgM, IgA
Sample	 Nasal	 Capillary blood	 Serum
TAT	**24-48 h** (in lab)	**15 min** (PoC)	**24-48 h** (in lab)
Technology	**TMA** (transcription-mediated amplification)	Lateral flow chromatographic immunoassay	**ELISA** (Enzyme-Linked ImmunoSorbent Assay)

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Testing Services

Instructions for collecting and sending samples:

EU

1 2 3 4

Collecting the sample

- Extract the patient sample
- Label the Tubes

Prepare the sample to be sent

- Complete the analysis request
- Prepare the tubes to be sent
- Sample storage conditions
  - Store at 4ºC for up to 48h max
  - For longer periods, keep at -20ºC

Contact Grifols Customer Service

- Contact Grifols Customers Service, which organizes the collection of samples
- (+34) 800 098 161
- Contact Grifols distributor in your country

Receive the results report for your patient's samples

- The test report is sent by encrypted email to the address provided in the requisition form.

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Customized Services for Third Parties & Pharma Industry

Progenika Grifols Clinical Diagnostics Lab has participated in projects for third parties in different areas:

CARDIOVASCULAR

Genetic Diagnosis of Familial Hypercholesterolemia in Next Generation Sequencing.
6 FH related genes analyzed: LDLR, APOB, PCSK9, APOE, STAP1 (ADH) and LDLRAP1 (ARH).

Participation in several projects with Pharma companies such as: SANOFI, REGENERON, GENZYME
Other institutions: UNIVERSITY OF PENNSYLVANIA, MEDPACE LAB.

SANOFI REGENERON GENZYME Penn MEDPACE

NUTRITION

Genetic testing for a healthy diet in Luminex Technology for: Pharma company CINFA, and the UNIVERSITY OF NAVARRA.

Cinfa Universidad de Navarra

VETERINARY

Genetic testing for hip dysplasia disease diagnostics in Golden Retriever dogs for Pharma company BIOIBERICA.

Bioiberica

FUNCTIONAL GENOMICS

Customized genomic services for:

- LOREAL
- FUTBOL CLUB BARCELONA
- EUROPEAN UNIVERSITY
- UNIVERSITY OF SANTIAGO DE COMPOSTELA
- UNIVERSITY OF GRANADA

L´ORÉAL FCBARCELONA Universidad Europea

UNIVERSIDAD DE SANTIAGO DE COMPOSTELA SERVIZO GALEGO de SAUDE UNIVERSIDAD DE GRANADA

License and Accreditations

CLINICAL DIAGNOSTICS LABORATORY LICENSE

- Progenika-Grifols is an official authorized laboratory in compliance with European legislation.
- Holds Registered Clinical Diagnostics License number 48C25635476, granted by the Basque regional government under the authorization of the Spanish Ministry of Health.

EUSKO JAURLARITZA
GOBIERNO VASCO

OSASUN SAILA
DEPARTAMENTO DE SALUD

GOBIERNO DE ESPAÑA
MINISTERIO DE SANIDAD, CONSUMO Y BIENESTAR SOCIAL

QUALITY CERTIFICATES:

- **EMQN:** The European Molecular Genetics Quality Network (EMQN) is a provider of External Quality Assessment (EQA) services which are essential for any laboratory seeking to maintain and provide a quality service.
- **CTCB:** Centre Toulousain pour le Contrôle de qualité en Biologie clinique.

CTCB
Centre Toulousain pour le Controle de qualité en Biologie clinique

EMQN
The European Molecular Genetics Quality Network

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Facilities, location

Our Clinical Diagnostics Lab is located in Derio, north of Spain, at the Bizkaia Technologic Park, only 5 minutes drive from Bilbao International Airport that enables perfect communications and expedite logistics for sample handling.

Facilities, location

Facilities in buildings 502 and 504.
State of the art facilities with the latest equipment for innovative diagnostics solutions

Facilities

CAPACITY:

Progenika Grifols is currently testing approximately 5,000* samples per week for a variety of tests and technologies.
*Additional 3,500 samples could be easily accommodated into the operations with pooling strategies in TMA services.

TECHNOLOGIES:

- Next Generation Sequencing by ILLUMINA.
- SANGER Sequencing by Applied Biosystems
- Genetic Testing in xMAP (BEADS) by LUMINEX
- Transcription-Mediated Amplification (TMA) by PROCLEIX Panther Grifols.
- ELISA Enzyme-Linked ImmunoSorbent Assays.
- RTPCR Polymerase Chain Reaction
- Others

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Product registration and availability vary by country. Please ask the Grifols representative for more information

GNL-SDX9-2100001