September 2025

APPOLON BIOTECK

Appolon Bioteck Presentation

APPOLON
BIOTECK

Agenda

- About Appolon Bioteck
- Mission and Values
- Industrial Hub
- QA/AR department
- Strategic business Areas
- Our offers
- Innovation pipeline
- Our Strength

About Appolon Bioteck

Appolon Bioteck company was founded in 2011 by Dr. Saïd El Mouatassim. The company is specialized in molecular biology applied to diagnostics in medical, veterinary, and environmental laboratories.

Its main clients are private medical laboratories, hospitals, and laboratories involved in agri-food and environmental testing.

Our facilities

Ideally located close to Lyon and Lyon Saint-Exupery Airport/TGV

A 2,400 m² industrial site

+40 employees, including 12 molecular biology researchers

Our history

2011
Company founded

2013
Start of distribution of agri-food kits

2015
Development of genetic kits

2017
Start of distribution of infectious disease kits

Vitro partnership
Master Diagnostica

2020
Distribution of COVID PCR kits and equipment

2021
New headquarters including a production unit

Marketing of our own PCR and MTL kits

2022
ISO13485 certification
"France Relance" award

2023
POC distribution
USTAR partnership

2024
Submission of first IVDR applications

Production of kits for the food industry
Appolon Bioteck

2025
Adaptation of IVDR and development of new kits

Smart GUARD
HLA B27 CE IVDR
Factor IICE IVDR
Factor VCE IVDR

APPOLON
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Values

Expertise

Diversity

Respect

Commitment

Fairness

Mission and culture

Apollon Bioteck designs, develops, produces, distributes, and markets innovative, high-quality molecular biology/IVDR solutions.

Sovereignty and independence

Expertise in products, materials, and skills

Innovation and Quality

Offering certified products of excellence

Responsiveness and flexibility

Organization based on rapid and agile operations

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Strategic business areas

1 MOLECULAR OFFERING

- Appolon Bioteck Solutions
- Partners solutions

2 CDMO

- High production capabilities
- Production on demand

3 SERVICE OFFERING

- IVDR services
- R&D services

APPOLON BIOTECK

Industrial Hub

Industrial Center

"Our Industrial Excellence at the service of our customers"

Our customers

Supplies

A panel of selected and qualified partners and suppliers

Supply-chain

Daily supply chain management: guaranteeing customer service

Manufacturing

Products manufactured with the highest efficiency and to the highest quality standards.

Equipments

Equipment management that ensures continuity, safety and productivity.

Deliveries

Daily deliveries, tailored to our customers' needs and guaranteeing product requirements

APPOLON BIOTECK

Production Hub & Capabilities

A workshop dedicated to quality and performance

Capacity

Up to 2 millions kits per week

Flexibility

Our production hub is built for flexibility, adapting quickly to different volumes and custom requirements. This agility allows us to meet client needs efficiently.

Technology / capability

With a technical expertise and a culture of continuous improvement, we can handle complex projects while guaranteeing flexibility

Teams and knowledge

Our workshop is built on the strength of its team. Made up of skilled and passionate professionals, it brings together many years of experience

Quality

Our workshop is designed with quality at its core. Every step of the process is monitored under strict standards, ensuring consistency, reliability, and compliance with requirements

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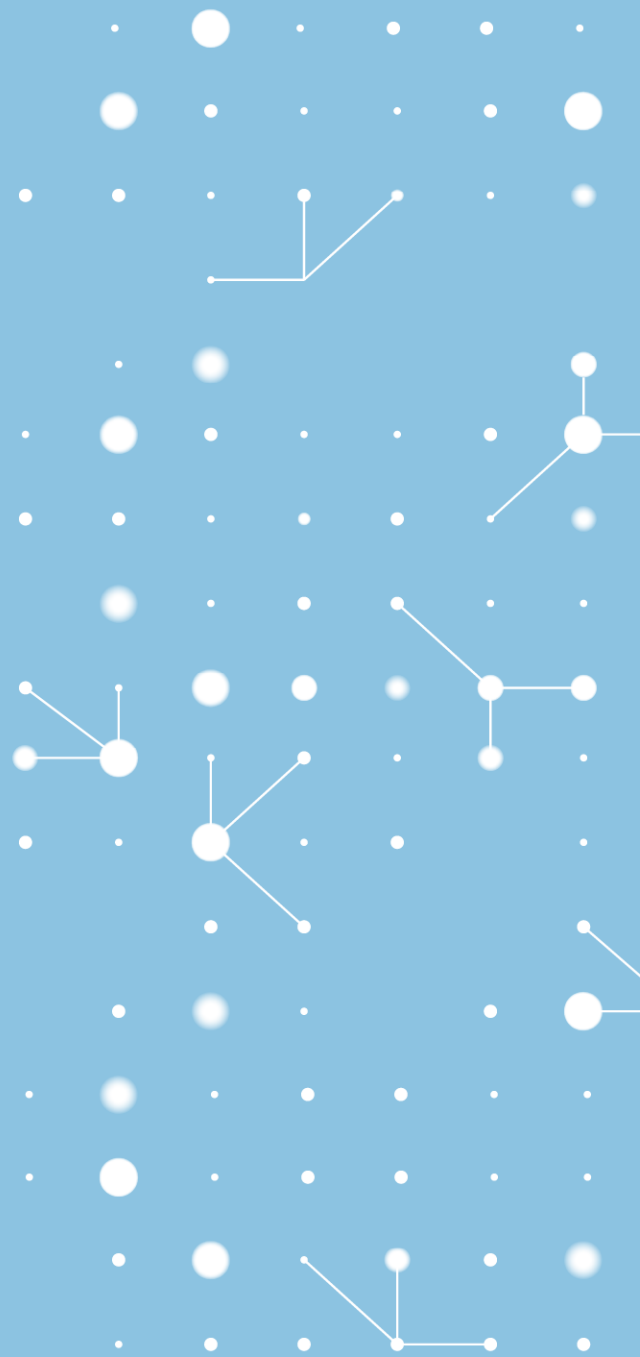
Quality & Regulatory Compliance



Quality Affairs

GMED
GROUPE LNE

CERTIFICAT
CERTIFICATE OF REGISTRATION
N° 40249 rev. 0

GMED certifie que le système de management de la qualité développé par
GMED certifies that the quality management system developed by

APPOLON BIOTECK
205 rue des Frères Lumière
69970 CHAPONNAY FRANCE

pour les activités
for the activities

Conception, développement, fabrication de dispositifs médicaux de diagnostic in vitro de biologie moléculaire destinés au dépistage ou la confirmation de troubles congénitaux ou héréditaires, et des dispositifs destinés à détecter la présence d'un agent infectieux ou l'exposition à un tel agent. Distribution de dispositifs médicaux de diagnostic in vitro.

Design, development, and manufacturing of in vitro diagnostic medical devices for molecular biology intended for the screening or confirmation of congenital or hereditary disorders, as well as devices intended to detect the presence of an infectious agent or exposure to such an agent. Distribution of in vitro diagnostic medical devices.

réalisées sur le(s) site(s) de
performed on the location(s) of

205 rue des Frères Lumière - 69970 CHAPONNAY - FRA

est conforme aux exigences des normes internationales
complies with the requirements of the international standards

ISO 13485 : 2016

Début de validité / *Effective date* : **June 17th, 2025 (included)**
Valable jusqu'au / *Expiry date* : **June 16th, 2028 (included)**
Etabli le / *Issued on* : **June 17th, 2025**

cofrac

On behalf of the President
Béatrice LYS
Technical Director

GMED N° 40249-0
Ce certificat est délivré selon les règles de certification GMED / This certificate is issued according to the rules of GMED certification

GMED • Société par Actions Simplifiée au capital de 300 000 € • Organisme Notifié/Notified Body n° 0459
Siège social : 1, rue Gaston Boissier - 75015 Paris • Tél. : 01 40 43 37 00 • gmed.fr

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+ 10 people's team

- Appolon Bioteck is fully compliant to international standard et European regulation

- **ISO 13485** : The Appolon Bioteck's Quality Management System is in compliance with the ISO 13485 requirements since 2022. This is a perfect recognition of Appolon Bioteck's investment in safety, traceability and regulatory compliance.

- **IVDR (UE) 2017/746** : The company designs and manufactures IVD Medical Devices in full compliance with the IVDR (UE) 2017/746 regulation.

EU-IVDR

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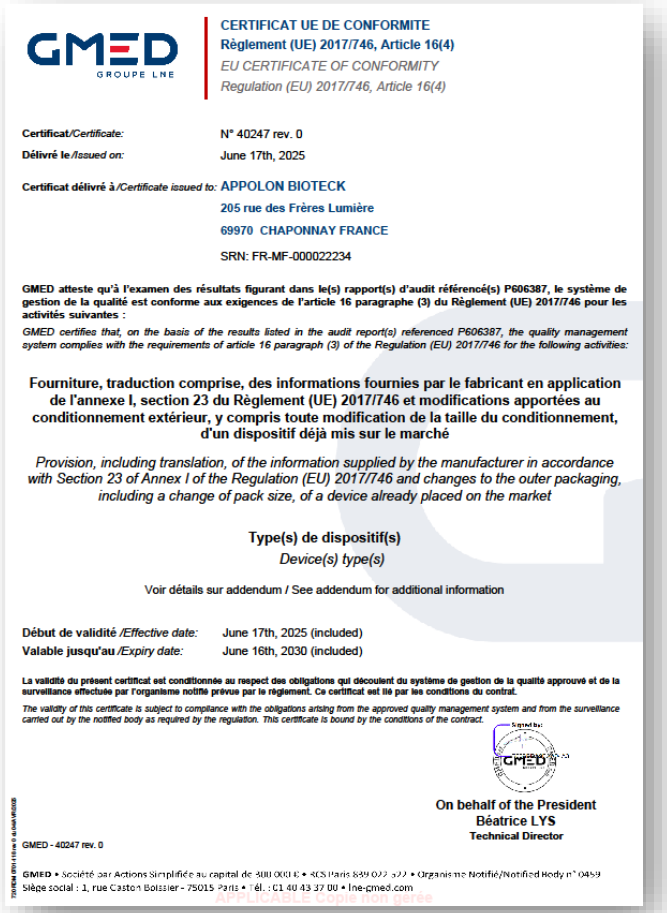
Regulatory Affairs



GMED
GROUPE LNE

CERTIFICAT UE DE CONFORMITE
Règlement (UE) 2017/746, Article 16(4)
EU CERTIFICATE OF CONFORMITY
Regulation (EU) 2017/746, Article 16(4)

Certificat/*Certificate:* N° 40247 rev. 0
Délivré le/*Issued on:* June 17th, 2025

Certificat délivré à/*Certificate issued to:* APPOLON BIOTECK
205 rue des Frères Lumière
69970 CHAPONNAY FRANCE
SRN: FR-MF-000022234

GMED atteste qu'à l'examen des résultats figurant dans le(s) rapport(s) d'audit référencé(s) P606387, le système de gestion de la qualité est conforme aux exigences de l'article 16 paragraphe (3) du Règlement (UE) 2017/746 pour les activités suivantes :
GMED certifies that, on the basis of the results listed in the audit report(s) referenced P606387, the quality management system complies with the requirements of article 16 paragraph (3) of the Regulation (EU) 2017/746 for the following activities:

Fourniture, traduction comprise, des informations fournies par le fabricant en application de l'annexe I, section 23 du Règlement (UE) 2017/746 et modifications apportées au conditionnement extérieur, y compris toute modification de la taille du conditionnement, d'un dispositif déjà mis sur le marché

Provision, including translation, of the information supplied by the manufacturer in accordance with Section 23 of Annex I of the Regulation (EU) 2017/746 and changes to the outer packaging, including a change of pack size, of a device already placed on the market

Type(s) de dispositif(s)
Device(s) type(s)

Voir détails sur addendum / See addendum for additional information

Début de validité */Effective date:* June 17th, 2025 (included)
Valable jusqu'au */Expiry date:* June 16th, 2030 (included)

La validité du présent certificat est conditionnée au respect des obligations qui découlent du système de gestion de la qualité approuvé et de la surveillance effectuée par l'organisme notifié prévue par le règlement. Ce certificat est lié par les conditions du contrat.
The validity of this certificate is subject to compliance with the obligations arising from the approved quality management system and from the surveillance carried out by the notified body as required by the regulation. This certificate is bound by the conditions of the contract.

On behalf of the President
Béatrice LYS
Technical Director

GMED - 40247 rev. 0

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Siège social : 1, rue Caston Boissier - 75015 Paris • Tél. : 01 40 43 37 00 • lne-gmed.com

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- Competent Autority : Appolon Bioteck's site and its quality system has been successfully inspected by our French Competent Authority ANSM in 2025

- **IVDR (UE) 2017/746 :** Appolon Bioteck's QMS is in compliance with the Article 16 and First French Company to get the certification to adapt/change the packaging and the manage the IFUs translations in relation with the local EU country specificities.

EU-IVDR

APPOLON BIOTECK

Our offers

Automated Solutions and Kits

Smart GUARD

01 Genetic Kits & Industry

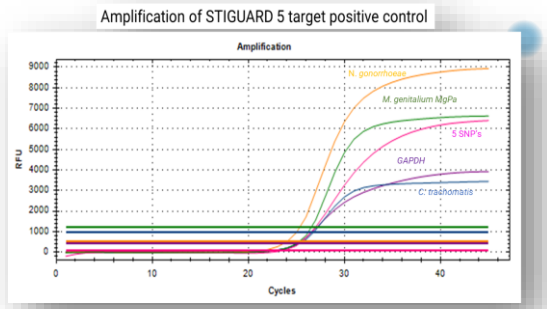
HLA B27
Factor II / Factor V
MEAT

02 Infectious disease kits

CT/NG/MG-MR
MG-MR
RespiGUARD 4Plex

03 Future registration

GI panels: Parasites, Viruses, Bacteria
NGS Panels, Exom, Whole Genome and NIPT



EU-IVDR

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Automated AB Solutions and Kits

Smart GUARD

- Comprehensive solution: Sample management from primary tubes to PCR plate preparation
- Flexible : DNA and RNA Extraction
- Fast: 1 hour for 96 tests (e.g., application for respiratory samples)
- Versatile Automated Range: Adapts to various kits on the market
- Ready for NGS library preparation

High throughput Solution

Universal Extraction kits

- Versatile : Human, viral, and bacterial DNA and RNA extraction kit
- Flexible : for diagnostic applications using qPCR and RT-qPCR
- Fast: 1 hour for 96 tests on Smart GUARD solution (e.g., application for respiratory samples)

EU-IVDR

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EasyNAT System & panels

Emergency solutions

Panel Tuberculosis

MTC
Mycobacterium tuberculosis complex
MTC/NTM
Mycobacterium tuberculosis complex/non-tuberculous mycobacteria

Panel Respiratory

MP
Mycoplasma pneumoniae
MP/CP
Mycoplasma pneumonia (MP) and Chlamydia pneumonia
Novel Coronavirus
Coronavirus 2
Rapid Flu
Influenza A and influenza B
Rapid RSV
Respiratory Syncytial Virus
BP
Bordetella pertussis
BP erythromycin Resistance
Bordetella pertussis erythromycin resistance
.

Panel IST

MG
Mycoplasma genitalium
HSV 1& HSV2
Herpes Simplex Virus 1
Herpes Simplex Virus 2
UU
Ureaplasma Urealyticum
UU/MH
Ureaplasma Urealyticum and Mycoplasma Hominis
GBS
Group B Streptococcus
TP
Treponema Pallidum
TV
Trichomonas Vaginalis
CT/NG
Chlamydia Trachomatis
Neisseria Gonorrhoeae

Panel others kits

Human Parvovirus B19
Malaria
Monkeypox Virus
Vibrio Cholerae

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MultNAT System and panels

Syndromic solution

Panel Tuberculosis

MTB/RIF Assay
(Tuberculosis resistance Rif)
MTB/MDR Assay
(Multi-drug resistant tuberculosis)
MTB/XDR Assay
(Tuberculosis isoniazide, fluoroquinolones, second-line injectable drugs, and ethionamide)
MTB/NTM Assay
(Tuberculous and non-tuberculous mycobacteria
NTM Genotyping Assay*

Panel Respiratory

RSP4-plex
(COVID, influenza, RSV)
RSP24-plex
(extended respiratory panel)
Pneumonia 6-plex
Pneumonia 20-plex*
MRSA*
Norovirus Assay*

Panel IST

STIs Panel*
(extended STI panel)
MG DR Assay *
(M. genitalium + résistances)
HPV Genotyping Panel*

Panel GI

HP Assay
(Helicobacter Pylori)
GI24-plex
(extended gastro panel)
Norovirus Assay*
C. Difficile Assay*

Other

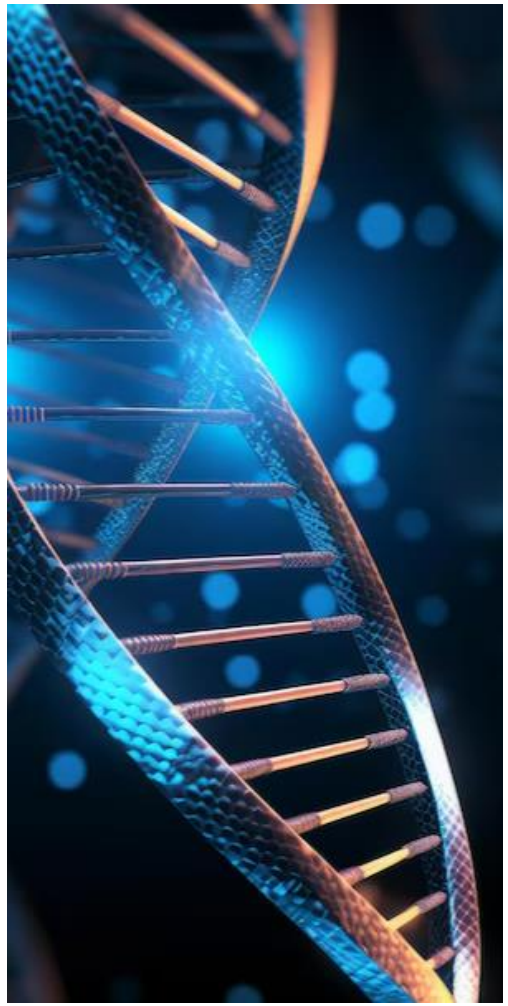
Malaria Assay
Dengue, Zika, and Chikungunya Virus Assay
Carba-R Assay
Meningitis Encephalitis Panel
Meningitis Encephalitis Panel*
Tropical Fever Panel*
Dengue Genotyping Assay*
Mpox Assay*
Ebola Assay*
HIV Viral Load Assay*
HIV/HBV/HCV Assay*
Vancomycin-resistant Enterococci* (VRE)
Human APOE and SLCO1B1 Gene Polymorphism*
Blood Culture Identification Panel*

*White : release in 2026

EU-IVDR

Innovation Pipeline

Innovative & Disruptive technologies



- Appolon patent (PCT demand) for Rapid, Multiplexed PCR at the Point-of-Care
- Sample to Result with real-time Solid-Phase PCR in currently less **than 20 min**
- Declination as a portable device working on battery.

New Results

bioRχiv

Fast and sensitive multiplexed diagnostic system enabled by real-time solid-phase PCR assay

Islam Seder, Rodrigo Coronel Téllez, Jing Zhang, Tao Zheng, Stephen McCleary, Saïd El Mouatassim, Jean-François Brugère, Yi Sun

doi: https://doi.org/10.1101/2025.07.19.665604

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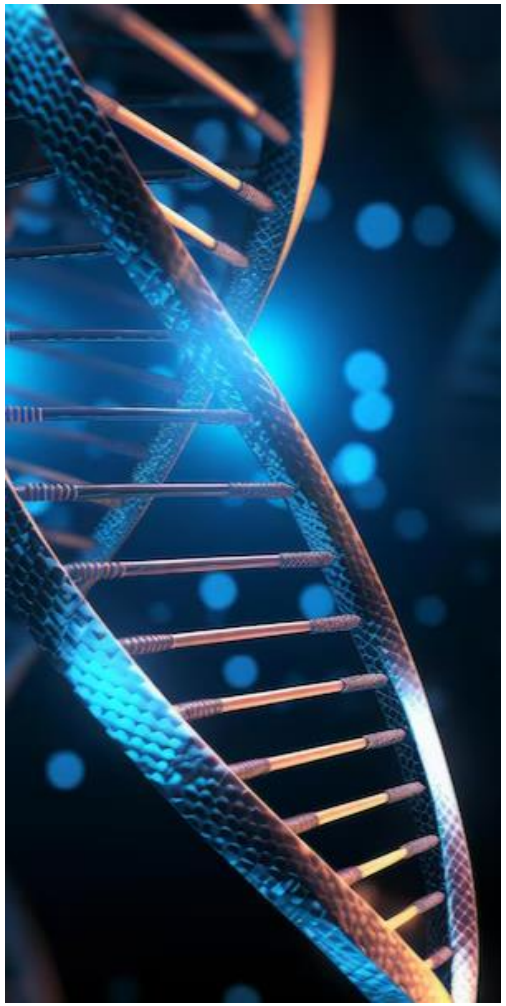

Innovative approach in NGS

- Developing new NGS solutions to adress Customer needs and making NGS affordable
- New panels designed by customers for customers
- Bringing homebrew test to IVDR solution
- Fast time to market
- Competitive pricing to ease NGS adoption

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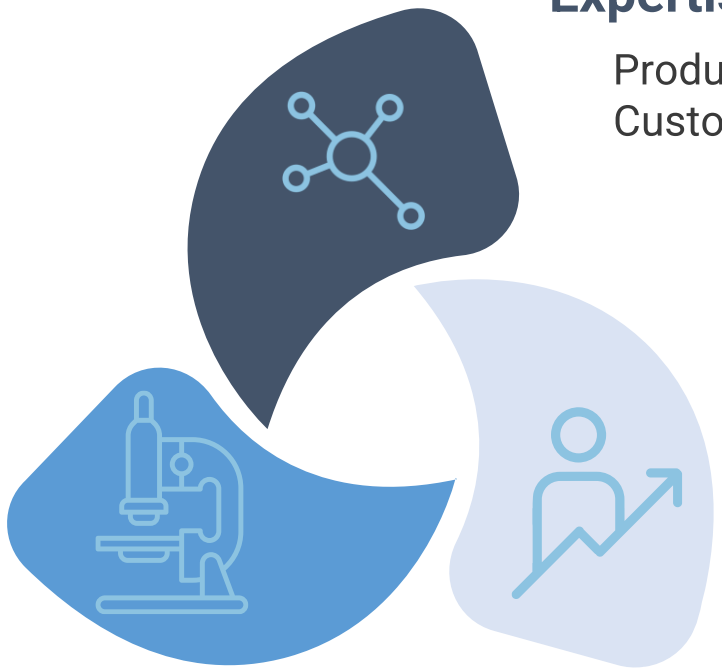
Appolon Bioteck’s strengths

Expertise

Product selection
Customer service



Innovation

Responsiveness
Proximity
Support

Sales network

Extensive presence in
France and Europe

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