

Firalis Molecular Precision: France's First CAP-Accredited Laboratory

Expanding Reach and Reliability Through CAP's Trusted Standards

OVERVIEW

Quality that Opens Doors

Firalis Molecular Precision has long been committed to delivering exceptional bioanalytical services—supporting everything from sample management and assay development to bioinformatics and advanced molecular testing. As the company set its sights on global expansion in neurodegenerative diseases and oncology, one thing became clear: credibility and trust in the accuracy of laboratory results would define their success.

The College of American Pathologists (CAP) accreditation and proficiency testing/external quality assessment (PT/EQA) programs provided that credibility. It aligned Firalis with internationally recognized standards like ISO, CLIA, and IVDR, ensured continuous improvement through inspections and checklists, and strengthened their reputation with regulators, healthcare providers, and patients worldwide. The CAP programs helped Firalis streamline processes and improve operational efficiency that helped open doors to further growth and collaboration.



AREAS OF IMPACT



Business Growth

Credibility obtained through CAP accreditation enabled Firalis to conduct large-scale research, supporting their launch of a clinical study in France to recruit up to 100,000 subjects for Alzheimer's research. Additionally, it provided confidence to clients when Firalis expanded to the US.



Operational Excellence

CAP accreditation provided standardization to align with IVDR and FDA requirements assisting with both internal and client assays. The CAP checklist updates, inspections, and educational resources fostered a culture of continuous improvement to help Firalis meet growing demand.



Diagnostic Confidence

The scientific rigor gained from CAP accreditation allowed Firalis to have robust data for a novel assay they developed, facilitating the assay's approval without needing additional studies to generate more data. Compliance doesn't just check regulatory boxes—it builds trust that enables innovation.



Hüseyin Firat, MD, PhD
Founder and Chief Executive Officer
Firalis S.A.

“CAP accreditation has facilitated our involvement in regulatory studies and has opened doors to collaborations with major suppliers. It has contributed to the success of our business and consequently our expansion plans, including doubling our laboratory space.”

Global Standards Powering Precision Diagnostics

BACKGROUND

A Compliance Mindset with Global Reach

Already ISO-certified and GCP-compliant, Firalis desired to continue their expansion in Europe and abroad to meet growing customer demand. CAP’s programs not only identified areas for improvement but also provided education, resources, and benchmarking data to guide lasting change. **Due to CAP accreditation, global share of revenue from United States went from 10% before accreditation to 25% after.**

“CAP’s accreditation program enhanced our ability to serve a diverse client base across multiple geographies,” explained Dr. Firat. “They gave us confidence that we were meeting the highest expectations worldwide.”

APPROACH

Specialized Testing, Universal Standards

Firalis is known for its focus on clinical trials and pre-clinical programs that demand highly tailored approaches. They provided very custom workflows —revalidating assays for unique samples, carefully defining platforms, and ensuring every validation step is precise as they expand their IVD offerings for neurodegenerative diseases and oncology. With so much riding on accuracy, the CAP’s PT/EQA helped in reinforcing the reliability of their results.

“Many of the assays we are developing—and that our clients request—are next-generation sequencing and PCR-based,” explained Dr. Firat. “CAP proficiency testing validates these capabilities and gives our clients confidence that the results we deliver are benchmarked to the highest international standards.”

This assurance has not only supported Firalis’ scientific credibility but also enabled them to form deeper collaborations with leading hospitals, universities, and pharmaceutical partners worldwide

CONCLUSION

Providing the Framework for Tomorrow’s Diagnostics

The CAP inspection was more than an audit—it became a turning point. By embedding CAP’s rigorous standards into everyday practice, Firalis strengthened its global positioning, improved compliance readiness, and created a stronger platform for collaboration and research. Already one of the first in France to achieve ISO 20387 for biobanking, Firalis embraced CAP’s rigorous standards to further elevate its quality culture and strengthen its position for international growth. This was evident with the FDA clearance of the APO-Easy® Genotyping Kit in the fight against Alzheimer’s disease, helping patients today and tomorrow.

“CAP accreditation brings another level,” Dr. Firat reflected. “It enabled us to operate as a truly global laboratory, capable of meeting the needs of clients across multiple countries.”

For Firalis, the outcome has been clear: a stronger reputation, more efficient operations, and a trusted foundation for tomorrow’s diagnostics.

FACTS AND FIGURES	
Year Founded	2019
Headquarters	Huningue, France
Number of Sites	4 locations—3 in France, 1 in US (Boston)
Scope of Service	CRO/CDMO, specializing in biomarkers
Research Clients	120 worldwide

“To work with biotech companies and academia, we had to prove we were doing high-quality work. They knew CAP very well which helped position us as a credible and quality-assured partner.”



Sébastien Langé, PharmD, MBA
Chief Executive Officer-US Affiliate
Firalis Molecular Precision



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