

CASE STUDY
CUSTOM ASSAY PREPARATION SERVICE

Standardizing qPCR-based LDT production for high-volume diagnostics at AP-HM: a 12-year partnership

Background

As one of France's largest diagnostic hospital groups, Assistance Publique-Hôpitaux Universitaires de Marseille (AP-HM) manages a broad portfolio of more than 400 pathogenic targets. At this scale, relying exclusively on CE-IVD kits is neither economical nor practical, particularly given the limited market availability of several specialized qPCR assays.

Lab Developed Tests (LDTs*) therefore play a central role in sustaining AP-HM's testing capacity, leveraging strong internal expertise in assay design. However, preparing large numbers of LDTs entirely in-house can be demanding, requiring consistent reagent preparation, robust traceability, and documentation that remains aligned with IVDR expectations.



***What is a LDT?** A Laboratory-Developed Test (LDT) is an in-house diagnostic assay developed, validated, and used within a medical laboratory. Under the IVDR (Art. 5.(5)), LDTs have to meet specific quality, documentation, and performance requirements.

The Challenge

At AP-HM, **Laboratory-Developed Tests (LDTs)** are essential to support part of their large and complex qPCR diagnostic portfolio. However, preparing and managing LDTs fully in-house is not sustainable. AP-HM needed a solution to **save hands-on time** while ensuring **safe, reproducible** manufacturing and robust **traceability**, key elements to **support IVDR expectations for LDTs** in routine clinical diagnostic use.

How do we help?

To support the AP-HM, we prepare **35 ready-to-use assays**, where **primers, probes, and Master Mix** are premixed and dispensed into assay-specific qPCR 8-tube strips. We provide:

- **Cleanroom formulation** of 35 custom premixes
- **Robotic dispensing** of premixes in 8-wells strips
- **Assay identification** on strips through distinct trigrams for each target
- **Lot-specific documentation** for each assay
- **Partial deliveries**

Conclusions

Through more than 12 years of partnership, AP-HM relies on **35 ready-to-use qPCR premixes** to streamline LDT production. This approach **provides flexibility** in assay content, formats and delivery planning, while remaining **aligned with budget** constraints. Moreover, **standardized clean-room manufacturing** and accompanying **documentation** support **ISO 15189**-compliant validation for routine clinical diagnostics and **IVDR expectations** for LDTs.

Next steps

AP-HM hopes to **continue outsourcing** their in-house assays preparation, leveraging a **solution** that helps maintain alignment with **evolving IVDR expectations for LDTs**.

Benefits

To illustrate the impact of Eurogentec's preparation service on their workflow, **Elsa Prudent**, Chief Hospital Engineer in molecular biology, highlighted several key benefits she experiences at AP-HM:

Save hands on time

"Even with CE-IVD kits, there is still a manual preparation step involved. With the pre-filled strips, the assay is truly ready-to-use, which is essential for us, given our limited staffing resources."

Traceability & Cleanroom

"We don't have an equivalent service internally, and even if we did, working with you provides a higher level of traceability. Your cleanroom production and traceability fully meet the standards we expect from an outsourced partner."

Plastic-platform flexibility

"Having flexibility with plastics regarding compatibility across different platforms is important, especially since equipment can change with public tenders."

Cost effectiveness

"Price is an important consideration for us, given our tight budget. With your service, price per point is typically five to ten times lower than that of commercial kits."

Partial deliveries

"We appreciate staggered deliveries, usually in two batches, because our -20°C storage space is limited."

"Communication with your team has always been easy and pleasant. We're very happy to work with you, and we hope this collaboration will continue."



Elsa Prudent
Chief Hospital Engineer,
Molecular Biology



Contact us



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SUPPORT YOUR LDT
PRODUCTION



WRITE TO US
dispensing@eurogentec.com