

CASE STUDY
CUSTOM ASSAY PREPARATION SERVICE

From kit discontinuation to an IVDR-ready LDT: securing diagnostic continuity for *Legionella* testing

Background

The *Legionella* NRC, a National Reference Center based in Lyon (France) had been relying on a commercial kit for over a decade to support *Legionella* diagnostic and monitoring activities.

When the kit was abruptly discontinued in July 2022, the lab had to react quickly. They needed an alternative solution that ensured testing continuity while still meeting ISO 15189 requirements and In Vitro Diagnostic Regulation –IVDR– expectations for Lab Developed Tests (LDTs*).

***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

As market availability of commercial PCR assays detecting all *Legionella* species was very limited, the NRC developed its own LDT, based on its strong internal expertise.

But developing an assay was only the start : the NRC still needed to **secure its validation for diagnostic use**.

So they looked for a partner able to provide standardized manufacturing and robust documentation aligned with **ISO 15189** and **IVDR Article 5(5)** requirements for LDTs.

How do we help?

To support the *Legionella* NRC, we prepare custom premix of oligonucleotides based on their specifications, targeting *Legionella* spp. and internal control detection. We provide:

- **Clean room formulation** of custom premix (6 primers + 3 probes)
- **Robotic dispensing** of premixes in 8-wells strips
- **Centralized documentation**
- **Targeted technical advice**

Conclusions

Custom pre-filled strips enabled *Legionella* NRC to secure an easy-to-use, efficient and scalable diagnostic workflow while strengthening traceability, consistency, and regulatory readiness.

Next steps

Encouraged by this initial success, the NRC is extending the approach to a second primer/probe premix that will be dispensed into laser-marked strips to easily distinguish the two assays.

Benefits

To illustrate the impact of Eurogentec's preparation service on their workflow, Dr. Laetitia Béraud shares several concrete benefits observed at the National Reference Center for *Legionella* testing:

Saved mixing & dispensing time

"The main advantage is the technical easiness."

Simplified traceability

"We now change all reagents together with each strip lot, instead of replacing primers and probes separately. This greatly simplifies reagent follow-up and eases traceability"

Focus on more challenging assays

"Routine screening has to be fast and cause no technical issues. The pre-filled strips are easy to use and allow our operators to spend more time on typing or epidemiological techniques, which are more demanding."

Technical guidance

"You provided valuable guidance, notably in selecting the probes. We relied on your expertise, which helped us save time."

Standardized manufacturing

"In-house homogenisation and distribution can lead to initial fluorescence variability between wells. With pre-filled strips, this issue is resolved."

"You were very responsive when we needed support, and your answers were always quick. The technical support provided was invaluable."

Dr Laetitia Béraud, Biologist

National Reference Center for *Legionella* testing
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Contact us



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