

(English version)

**Question for written answer E-003360/25
to the Commission
Lynn Boylan (The Left), Kathleen Funchion (The Left)
(2 September 2025)**

Subject: Evolved and new blood tests for Lyme disease

The European Parliament's 2018 resolution on Lyme disease ⁽¹⁾ mentions the absence of appropriate diagnostic tests. Since 2018, Lyme disease blood tests have evolved and new tests have been developed. These newer blood tests, which show the end of an active infection, require further attention.

1. How does the Commission assess the evolved and new blood tests?
2. Which blood tests does the Commission intend to use for counting Lyme disease cases?

Submitted: 2.9.2025

**Answer given by Mr Várhelyi on behalf of the European Commission
(20 October 2025)**

According to Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices, before a manufacturer can place tests such as the Lyme disease blood tests on the EU market, they have to fulfil a set of detailed requirements and apply for certification by a notified body.

Once the device is on the market, it can be subject to market surveillance by national competent authorities. The Commission is not involved in the assessment of individual devices.

The European Centre for Disease Prevention and Control (ECDC) collects surveillance data from Member States on Lyme neuroborreliosis, a severe form of Lyme borreliosis.

Lyme neuroborreliosis testing methods relevant for reporting at Union level are described in the EU case definition ⁽¹⁾. They include serological methods (Lyme borreliosis antibodies in cerebrospinal fluid and blood), presence of an increased number of white blood cells in the cerebrospinal fluid (pleocytosis) and direct pathogen detection methods (isolation of *Borrelia* bacteria, or detection of its DNA in cerebrospinal fluid); however, each country decides which specific methods to use based on their own (public) health system.

The EU has contributed to advancing research on Lyme disease diagnostics through various funding programmes, primarily under the research and innovation frameworks (7th Framework Programme and Horizon) as well as the POCTEFA cross-border cooperation programme ⁽²⁾.

Funded projects focused on improving diagnostic accuracy and addressing limitations of testing methods for Lyme disease, contributing to the development of more effective diagnostic tools, with an estimated investment of approximately EUR 15 million.

¹ European Parliament resolution of 15 November 2018 on Lyme disease, OJ C 363, 28.10.2020, p. 94.

⁽¹⁾ <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32018D0945&from=EN>.

⁽²⁾ <https://interreg.eu/programmes/spain-france-andorra-poctefa/>.