

EN

E-000634/2026

Answer given by Mr Várhelyi
on behalf of the European Commission
(17.4.2026)

1. The proposals put forward by the Honourable Members mentioned were assessed and replied to by the Commission¹, referring to the work of the European Centre for Disease Prevention and Control (ECDC) with the Member States through the Emerging and Vector-borne Diseases Network (EVD-Net)² and the newly designated EU Reference Laboratory (EURL) for public health on high risk, emerging and zoonotic bacterial pathogens³, which covers Lyme borreliosis. There are no current plans to set up a European patient testing registry, but the Commission noted the suggestion.

2. *Borrelia* tests would typically fall into risk class C under Regulation (EU) 2017/746⁴. They are subject to assessment by notified bodies, which certify the quality management system of the manufacturer and assess technical documentation on a sampling basis or, for self-tests, of every device prior to its placement on the market. There are also post-market surveillance, market surveillance and vigilance requirements applicable when the device is on the market. Therefore, Regulation (EU) 2017/746 provides a framework for independent oversight of these tests.

3. Under the existing EU legislative framework, EU institutions do not have a mandate to perform an evaluation of medical devices. The work of the ECDC and the relevant EURL designated by the Commission is described in point 1. Moreover, as part of demonstrating conformity with Regulation (EU) 2017/746 the manufacturer must ensure that the device is state-of-the-art. An assessment of medical technologies is also performed by health technology assessment bodies at national level. The joint clinical assessment under Regulation (EU) 2021/2282⁵ is limited to certain class D devices and therefore would not cover *Borrelia* tests.

¹ Further reply from the Commission, received by the European Parliament on 3 November 2025:

https://www.europarl.europa.eu/doceo/document/PETI-CM-760964_EN.pdf.

² <https://www.ecdc.europa.eu/en/about-ecdc/what-we-do/partners-and-networks/disease-and-laboratory-networks/european-emerging-and>.

³ <https://www.rki.de/EN/Institute/International-activities/eu-reference-laboratory/EURL-PH-HEZB/eurl-public-health-high-risk-bacterial-pathogens-node.html>.

⁴ MDCG guidance on IVD classification: https://health.ec.europa.eu/document/download/12f9756a-1e0d-4aed-9783-d948553f1705_en.

⁵ <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32021R2282>.