EU4H-2025-HERA-PJ-2

Call for proposals for the Development of new diagnostic tests for vector-borne diseases

Info session - Open Call for Proposal on crisis preparedness

DG HERA

Call ID EU4H-2025-HERA-PJ-2

15 Sep 2025

European Commission

Agenda

Call for proposals for the development of new diagnostic tests for vector-borne diseases

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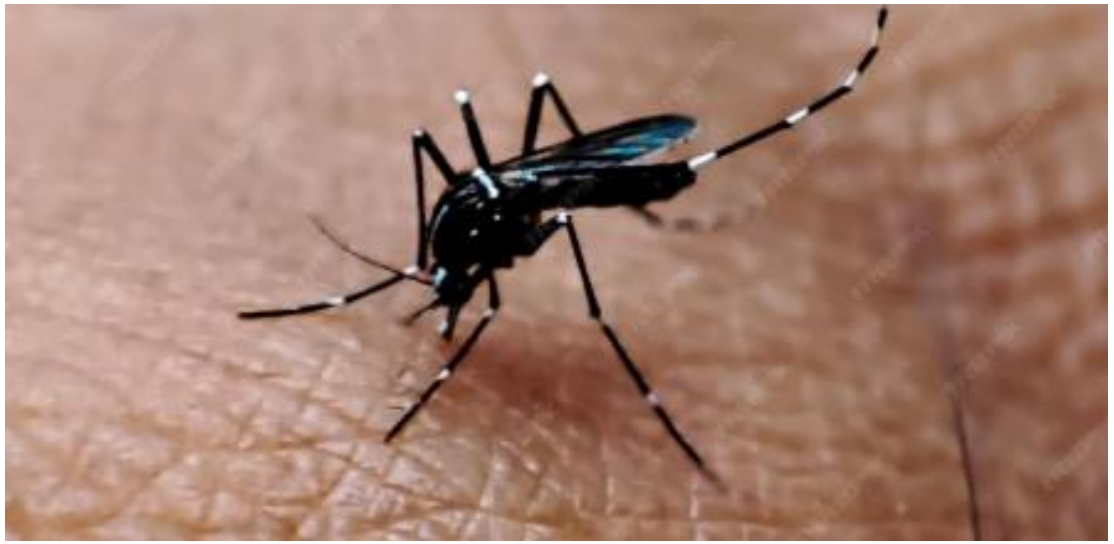
2. Objectives of the call
3. Scope
4. Specific action-level indicators for reporting purposes
5. Expected impact and results
6. Key Parameters
7. Timetable and deadlines
8. Deliverables & Milestones

1.Policy context: Vector-borne diseases (VBDs)

ECDC has warned that record breaking outbreaks of West Nile virus (WNV) infection and chikungunya virus disease point to a 'new normal' in Europe prompting the need for a robust and coordinated response to protect public health across Europe.

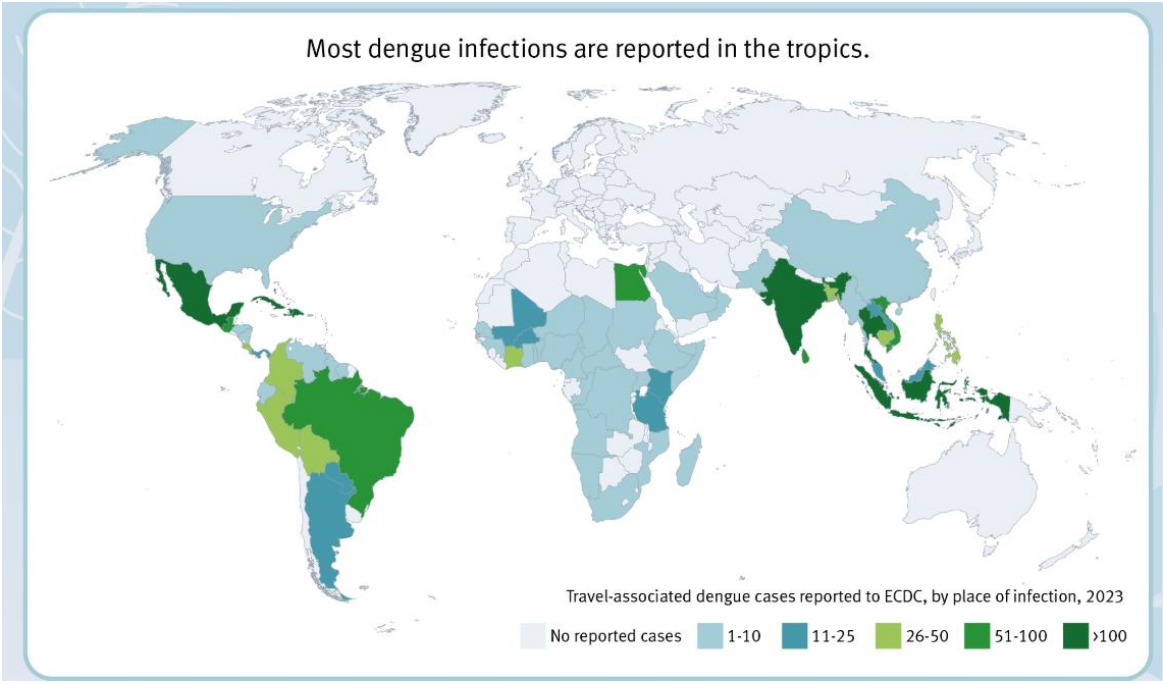


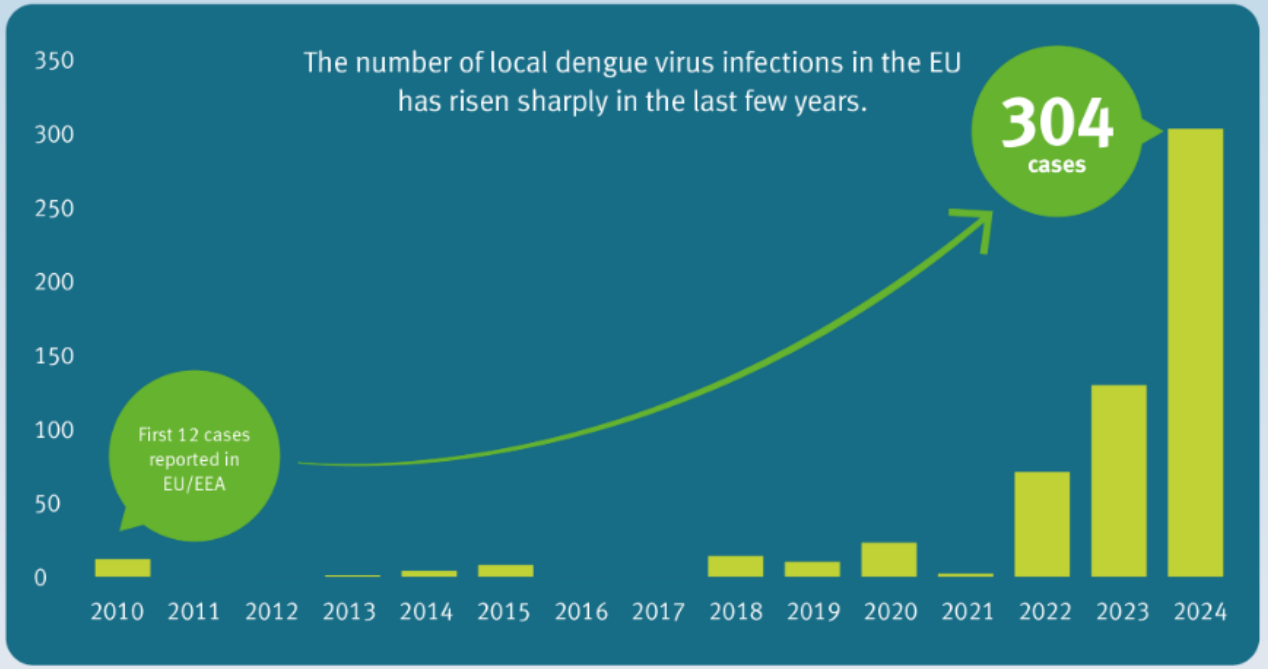
> *'Europe is entering a new phase — where longer, more widespread and more intense transmission of mosquito-borne diseases is becoming the new normal. ECDC is working closely with all Member States to provide tailored support and timely public health guidance to strengthen Europe's response'.*

As vector-borne disease (VBD), specifically mosquito-borne disease landscape evolves, more people in Europe will be at risk in the future.

Vector-borne diseases are increasingly occurring in EU

As vectors expand their geographical, the EU faces increased threat from several VBDs, particularly mosquito-borne diseases such as Dengue, Zika, Chikungunya and West Nile fever.





Limitations of current diagnostic methods

- **Sub-optimal sensitivity** → false negatives
- **Limited availability / uneven coverage** (rural/peripheral areas under-served)
- **Cross-reactivity among flaviviruses**
- **Narrow detection window** (antigen early phase only, IgM later)
- **Require confirmatory testing**
- **Single-target tests** → lack of multiplex options
- **Practical barriers** → cold chain, cost, EU regulatory adaptation, low uptake in routine care

Current Needs for VBD diagnostics

Priority for HERA:

Developing cost-effective diagnostics for resource-limited settings

Critical need to develop:

New point of care diagnostic tests that are:

- ↑ Sensitive
- ↑ Specific
- Affordable
- Multiplex
- Enable **early** detection for timely treatment/control

2. Objectives

- Enhance disease detection, reduce misdiagnoses, and improve patient outcomes by broadening the diagnostic toolkit, with a focus on **rapid tests**.
- Advance **early detection** of vector-borne diseases (VBDs) through the development of **novel** diagnostic tests that identify these diseases at an early stage, enabling timely treatment and control.
- Increasing the **sensitivity and specificity** of existing diagnostic assays to better identify VBD pathogens, thus minimising misdiagnoses.

3. Scope

- Supporting **late-stage development of in-vitro diagnostics** → bring to (**near-)market**
- **Improve existing products**: **accessibility, affordability, sensitivity**
- **Address unmet needs** with innovative solutions
- Supported actions will need to **advance beyond the current R&I status**, build on/complement ongoing EU projects
- **Expand diagnostic capacity** for emerging/re-emerging pathogens in the EU
- **Update & optimize diagnostic technologies** (molecular, serological) with clinical validation

4. Specific action-level indicators for reporting purposes

1. **Number of patents** filed and/or granted relating to the activities under the grant.
2. Performance metrics of the developed diagnostic tests, such as **analytical** and **clinical sensitivity and specificity**, and **time to result**, benchmarked against established gold-standard methods.
3. **Number of pathogens** against which the developed tests were validated and/or received regulatory approval.
4. Number of prototypes or tests manufactured.
5. Number of new diagnostic tests / molecular assays validated.
6. Number of new diagnostic tests that contribute to the earlier detection of vector borne diseases.
7. Number of improved existing products in terms of accessibility, affordability and/or accuracy.

5. Expected impact and results

- Improve diagnostic capabilities that will lead to earlier detection of VBDs, enabling prompt treatment initiation and reducing disease transmission.
- Stimulate research and innovation to develop new diagnostic tests in the field of VBDs.
- Support global health initiatives focused on attaining goals for international health security.

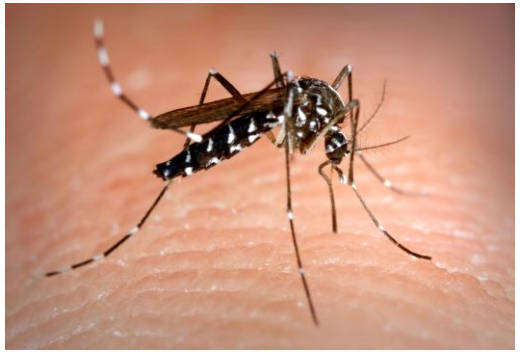
6. Key Parameters

Call for proposals for the development of new diagnostic tests for vector-borne diseases

- Budget per topic: **10.000.000** Eur
- Expected number of signed Grant Agreements (GAs): **2-3**
- Expected project duration: **36 months - 48 months**.
- Consortium composition: Proposals can be submitted either by a single applicant or a consortium (no minimum requirement).
- Targeted applicants: Secondary or higher education establishments, research organisations, hospitals and other healthcare institutions, NGOs, developers and other private entities or public bodies with an expertise in diagnosis development

7. Timetable and deadlines

Timetable and deadlines (indicative)	
Call opening:	4 September 2025
Deadline for submission:	4 December 2025 – 17:00:00 CET (Brussels)
Evaluation:	January - February 2026
Information on evaluation results:	March - April 2026
GA signature:	August 2026



8. Deliverables & Milestones

Deliverables

- **Initial Assay Design Report** → concept, novel features, feasibility, intended use
- **EU Regulatory Strategy Report** → CE-marking (IVDR), performance evaluation plan
- **Clinical Study/Trial Package** → registry entry, protocol, ethics/regulatory approvals
- **Manufacturing & Scalability Plan** → production capacity, quality, rapid scale-up
- **Accessibility & Affordability Strategy** → availability in low-resource EU settings, long-term sustainability
- **Analytical & Clinical Performance Report** → sensitivity, specificity, reproducibility, comparison vs. standard of care

Milestones

- Study protocol(s) submitted to regulatory/ethics authorities
- Prototype design finalised with confirmed specifications
- Analytical validation completed (sensitivity, specificity, reproducibility)
- Midpoint enrolment achieved for clinical performance studies (if applicable)

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Thank you for your attention

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