

Dear Sir/Madame,

Thank you so much for downloading this **ten-minute easy-to-fill questionnaire** from our website and for taking part in this survey about end user's point of view regarding the future of Lyme Disease (LD) diagnosis and the features of the diagnostic tool we are working in. Your comments will be very valuable for building a better solution.

As you know, we are a Pan-European consortium of 7 partners working on a European co-funded collaborative Project called **Highly sensitive and specific low-cost lab-on-a-chip system for Lyme disease diagnosis (HILYSENS)** aiming at developing a highly-sensitive, specific and robust diagnostic tool, easy to use and interpret, allowing specific and sensitive detection of acute, chronic and autoimmunity associated LD.

This new diagnostic tool is based on the **lab-on-a-chip technology** and will consist on a small microfluidic chip (approximately of the size of a credit card) containing specific antigenic proteins and peptides to detect the serological response to acute and chronic Borrelia infections. An **analyser** and **user-friendly software** will also be developed to detect and process the fluorescence signal of the assay.

We would kindly ask you to fill the questionnaire, save it in your computer, and **send** it to angel.honrado@aromics.es with reference "*HILYSENS questionnaire*".

This questionnaire will be available for downloading during the whole project life. We would appreciate if you could **spread the word among your colleagues** so we can get the highest amount of inputs.

We would like to invite you to keep visiting the official **Project website** (<http://www.hilysens.eu>) where you can subscribe the RSS in order to be updated on the latest news about the project execution.

We would like to thank you for your time and invite you to follow-up the HILYSENS achievements that we hope will bring some light in the future of this harmful disease.

Yours sincerely

THE HILYSENS CONSORTIUM

HILYSENS

Questionnaire on Borrelia infection / Lyme disease diagnosis

COUNTRY: _____

INSTITUTION SIZE (STAFF): _____

1. TYPE OF CENTRE/INSTITUTION

- Hospitals and other Public Health institutions
- Laboratory analysis
- Dealers of equipment, manufacturers
- Others (please specify): _____

2. DOES YOUR INSTITUTION HAVE AN IN-HOUSE CLINICAL LABORATORY?

- Yes (go to question #6)
- No, I outsource the analysis (keep reading*)

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3. WHY DO YOU OUTSOURCE YOUR TESTS? (MORE THAN ONE ANSWER CAN BE CHOSEN) *

- My institution does not have appropriate facilities
- The institution does not perform enough test to invest in its own facilities
- Test are too time-consuming and labour intensive
- Test require highly-skilled staff
- Other (please specify): _____

4. HOW MUCH ARE YOU PAYING PER TEST? *

- Below 200 EUR
- Between 200 and 600 EUR
- Above 600 EUR
- I do not know

5. IF THERE WERE AN EASY-TO-USE, COST-EFFECTIVE TESTING SYSTEM GIVING RELIABLE RESULTS IN LESS THAN ONE HOUR, WOULD YOU IMPLEMENT IT WITHIN YOUR FACILITIES? *

- Yes
- No
- I do not know

6. HOW MANY ANALYSES DO YOU PERFORM PER YEAR?

- Less than 10
- 10-100
- More than 100
- More than 1,000
- More than 10,000

7. HOW OFTEN DO YOU PERFORM THESE ANALYSES?

- Daily
- Weekly
- Monthly
- Every 6 months
- Others (please specify): _____

8. WHAT ARE THE CURRENT TOTAL COSTS TO TEST ONE PATIENT (*PLEASE CONSIDER THE COSTS FOR REAGENTS, PERSONNEL, EQUIPMENT, ETC*)?

- Below 100 EUR
- Between 100 and 400 EUR
- Above 400 EUR
- I do not know

9. WHICH KIND OF TEST(S) DO YOU USE CURRENTLY?

- Bacterial culture in selective media
- Immunoassay based methods (ELISA, Immunoblot...)
- DNA-based methods (PCR...)
- Others (please specify): _____

10. HOW LONG DOES IT TAKE TO OBTAIN THE RESULTS OF THE ANALYSIS (*SAMPLING TIME INCLUDED*)?

- Less than a hour
- Less than a day
- Less than a week
- Less than a month
- More than a month

11. WHICH ARE THE MAIN DISADVANTAGES, IF ANY, OF YOUR DETECTION METHOD(S)? (MORE THAN ONE ANSWER CAN BE CHOSEN)

- Lengthy times to obtain results
- High costs per analysis
- High costs of the equipment
- Need for specialised staff
- Lack of accuracy
- Labour intensive and/or time consuming
- Sensitivity of the test system
- Specificity of the test system
- Others (please specify): _____

12. HOW OFTEN WOULD YOU USE THIS NEW EQUIPMENT?

- Daily
- Weekly
- Monthly
- Every 6 month
- Annually
- Others (please specify): _____

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13. WHAT WOULD YOU CONSIDER A REASONABLE PRICE FOR AN ANALYSER LIKE THE ONE DESCRIBED ABOVE?

- Under 2,500 EUR
- 2,500-5,000 EUR
- More than 5,000 EUR

14. WHAT WOULD YOU CONSIDER A REASONABLE PRICE FOR A TEST LIKE THE ONE DESCRIBED ABOVE?

- Under 25 EUR
- 25-50 EUR
- More than 50 EUR

15. WHAT SIZE DO YOU EXPECT FROM THE ANALYSER DEVICE?

- Computer desktop (medium)
- Coffee machine (Nespresso™ like)
- Telephone (not mobile phone)
- Size is not a critical feature to consider
- Others (please specify): _____

16. HOW IS THE SAMPLE INSERTED IN YOUR CURRENT ANALYSIS:

- Pipetting
- Automatically
- Others (please specify): _____

17. WHAT KIND OF SAMPLE DO YOU USE CURRENTLY IN YOUR ANALYSIS?

- Blood
- Serum
- Spinal fluid
- Other (please specify): _____

18. DO YOU CURRENTLY USE DRY REAGENTS?

- Yes
- No

19. LYME LATE DIAGNOSIS OR MISDIAGNOSIS. WHAT, IN YOUR OPINION, IS THIS DUE TO? (MORE THAN ONE ANSWER CAN BE CHOSEN)

- Physicians' lack of expertise
- Relatively high cost of traditional tests, which require long shifts of specialized laboratory operators
- Lack of sensitivity of traditional tests that can detect only some stages of the infection and only when symptoms are present. (Please specify the stages of the infection)
 - Stage 1 (Bulls eye rash)
 - Stage 2 (acute organ manifestations)
 - Stage 3 (chronic organ manifestations)
- Lack of specificity of traditional tests, that are prone to both false positives and false negatives
- Other (please give details): _____

20. A DIAGNOSTIC DEVICE FOR LYME DISEASE SHOULD BE...

- Reliable, with enough specificity to single out Lyme from other possible diseases.
- Capable of detecting different stages of the disease.
- Able to detect the disease stage for the right therapeutic decisions
- Clearly cost-effective compared to the costs of delayed treatment
- Other (please briefly give your opinions) : _____

21. THE ANALYSER DEVICE SHOULD PERFORM...

- One test at a time
- 2, 4, 8, 15 tests at the same time (please mark an amount)
- Multi-testing is not a critical feature to consider

22. WHAT KIND OF RESULT FORMAT DO YOU EXPECT FROM THE ANALYSER DEVICE?

- Positive / Negative / Undefined (an expert interpretation is required) / Problem with test
- Positive / Negative / Problem with test
- Just values that an specialist interpret himself
- Result format is not a critical feature to consider

23. HOW WOULD YOU LIKE THE OUTPUT OF THE TEST TO BE PRESENTED TO THE CLINICIANS?

- Print out on paper
- File on memory stick
- Direct electronic entry to electronic patient journal system
- Automatic e-mail to the remitting doctor
- Output format is not a critical feature to consider
- Other (please specify): _____

24. HOW DO YOU EXPECT TRACEABILITY OF EACH ANALYSIS OCCUR?

- Manually entry of data on analyser device keyboard
- Manually entry of data on analyser device touch screen keyboard
- Automatic entry thanks to operator barcode reading of analysis sample barcode (reader fixed to analyser device)
- Automatic entry thanks to operator barcode reading of analysis sample barcode (hand-held reader of analyser device)
- Automatic entry thanks to automatic reading of data through contactless technology (like RFID).
- Other (please specify): _____

25. DO YOU HAVE ANY OPINION, WISH OR CONCERN REGARDING LYME DISEASE DIAGNOSIS YOU WOULD LIKE TO BRING TO OUR ATTENTION? (PLEASE SPECIFY BRIEFLY)
