

National validation of the Alegria 2 by the University Hospital of Dubrava in Croatia

Customer
Testimonial
April 2024

Meet Dr. Lovorka Đerek and Ksenija Kukuruzović Živković from the University Hospital of Dubrava, who are sharing their experience with the Alegria 2.

OBJECTIVES OF THE STUDY

- **Validating nationally the Alegria 2** following CLSI EP 15-A2 guidelines
- **Introducing new tests in their routine** Anti-tTG, anti-DGP and anti-β2GPI
- **Improving their TAT** for a better patient follow-up

FACTS

- **Current routing testing on ELISA:** ANA, ENA, anti-dsDNA, anti-Cardiolipin, anti-MPO and anti-PR3.
- **Turn Around Time:** 1 month (Usually around 2 weeks)



Lovorka Đerek, Assistant Professor, Ph.D.,
European Specialist in Laboratory Medicine (EuSpLM)

Ksenija Kukuruzović Živković, M.Sc., resident of medical
biochemistry and laboratory medicine

Could you present your laboratory and autoimmunity activity?

Dr Đerek: We work for the Clinical department for laboratory diagnostic in University Hospital of Dubrava, Croatia. The unit for autoimmune diagnostics was established 30 years ago. All analysis is accredited according to ISO 15189.

Currently, we are analyzing samples for most of the University Hospital Dubrava departments, in particular for Clinical Immunology, Allergology, and Rheumatology units, as well as for the Nephrology and Dialysis sections.

We are a medium-sized diagnostic lab, performing ELISA tests for autoantibodies research for ANA, ENA, anti-dsDNA, anti-Cardiolipin, anti-MPO, and anti-PR3.

"I think the instrument will provide us the possibility of giving the results to the clinicians within a timeframe fitting clinical needs and will help to optimize the patients' care pathway."

Lovorka Đerek, Assistant Professor, Ph.D., EuSpLM

Due to the increase in requests, we are expanding our testing capacity. The main goal is to provide high-quality results following international guidelines and local requirements and expand our future offer with other parameters, introducing the determination of anti-tTG, anti-DGP, and anti-β2GPI autoantibodies.

As we are the partners of the clinicians, we need to follow the clinics cases in the right way and at the correct timing.

That is why, we want to integrate an instrument and technology which deliver reliable, continuous and fast results.

The challenge is to improve our current turn-around-time (TAT) and leverage a technology that allows us to give results in one working day, especially for critical parameters like anti-MPO, and anti-PR3.

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You recently performed an evaluation of the Alegria 2 system. Could you describe your protocol and what were your conclusions?

Dr Đerek: We evaluated ANA screening, anti-dsDNA, anti-cardiolipin IgG and IgM, anti-B2GPIIgG and IgM, Anti-tTG IgA and anti-DGP, anti-MPO and anti-PR3. Between 30 to 50 samples were used to perform the analysis.

We did the internal validation following the CLSI EP15-A2 guidelines to ensure the reliability of the results and we enjoy the experience.

The obtained CV for each marker met our internal criteria as well as the one stated by the manufacturer.

In conclusion, the Alegria 2 and its associated products provide a suitable and alternative method for our routine testing.

Mrs Kukuruzovic Živković: The Alegria 2 instrument has a friendly-user software and being a random-access automation, it helps you to speed up the sample upload process and the entire daily workflow. This walk-away system really suits our requirements and needs.



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Based on your experience how would the Alegria 2 fit with your daily routine? What are your plans and needs for the future?

Dr Đerek: Adding Alegria 2 in our routine will be important especially for the emergency assays such as anti-MPO and anti-PR3. It will also allow us to add more analysis such as anti-tTG or anti-β2GPI to our existing panel.

I think the instrument will provide us the possibility of giving the results to the clinicians within a timeframe fitting clinical needs and will help to optimize the patients' care pathway.

In other words, it will meet our requirements by reducing our TAT for a better follow-up of patients.

Moreover, the Alegria 2 is fitting for medium load laboratories like ours.

Mrs Kukuruzovic Živković: Thanks to the monostrip technology, it is more practical and efficient for us as we don't have to batch samples to perform the analysis. We can therefore organize the workflow of our department differently.

It is a walkaway system and has the perk of not needing calibration thanks to the SMC® technology. The footprint is perfect for us, and everything fits the limited space we have in the laboratory.

Dr Đerek: We will, in the future, add more assays such as Anti-GBM for example.