



EuroFlow MM MRD EQA scheme 2025

Contents

Ει	uroFlow MM MRD EQA scheme 2025		
	The EuroFlow MM MRD EQA scheme 2025		
	Data analysis and performance evaluation		
	Educational meeting		
	Timelines		
	Registration		
	Appeals		
	Complaints		
	Participation fee		
	Organization		
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The EuroFlow MM MRD EQA scheme 2025

The objective of the Multiple Myeloma Minimal/Measurable Residual Disease (MM MRD) external quality assessment (EQA) scheme is to provide an external control on data analysis and interpretation of real life MRD samples from patients with MM after therapy. The scheme is based on the Next Generation Flow (NGF) for MM MRD methodology (Flores-Montero et al., 2017) and it consists of a dry part only.

Participants are provided with 3 MM MRD cases (2 flow cytometry standard (FCS) files per case) by the EQA provider. These FCS data files were generated by a EuroFlow reference center using the NGF for MM MRD methodology applied to bone marrow samples from patients with MM during post treatment follow up. Participants analyze the FCS files and report their conclusions for several parameters: distribution of plasma cells and other cell populations, the calculated analytical sensitivity, the phenotypic pattern of aberrant/clonal plasma cells, an interpretation regarding MRD status, and the overall conclusion of the analysis as for a final report. All EQA results are submitted by the participants via an online datasheet in the ESLHO EQA Portal.

As EQA provider, ESLHO offers the MM MRD scheme in collaboration with the EuroFlow EQA Committee. The EuroFlow EQA Committee is composed of members of the EuroFlow Consortium (www.euroflow.org). Two unique rounds of the MM MRD scheme are offered in 2025: one in spring and one in autumn.

Data analysis and performance evaluation

Data analysis, performance evaluation, and preparation of the reports is supported by qualified and experienced experts within the EuroFlow Consortium. Performance evaluation is based on comparison of the participant's results to the consensus reference interpretation of the 3 MM MRD





cases, which is defined by at least two experts. Performance evaluation is based on the reported percentage of abnormal plasma cells detected in each FCS file and is scored as follows:

- Satisfactory:

- Negative MRD sample when reference is also negative.
- Positive MRD sample when reference is also positive and there is a difference of ≤20% in the percentage of abnormal plasma cells detected as compared to the reference.

- Warning:

- Positive MRD sample when reference is also positive and there is a difference of >20% but <50% in the percentage of abnormal plasma cells detected as compared to the reference.

- Critical:

- Positive MRD sample when the reference is negative.
- Positive MRD sample when reference is also positive but with a difference of ≥50% in the percentage of abnormal plasma cells detected as compared to the reference.

Additionally, informative comparisons with the reference interpretation will be provided for the following parameters:

- Lower limit of detection (%)
- Lower limit of quantitation (%)
- Signs of hemodilution (No/Yes)
- The number of analyzed cellular events (Adequate/Lower than the recommended standard)

Finally, for all parameters, all participants' results will be summarized as median (range) or percentage of participants' result in concordance with the reference interpretation, according to the nature of the variable (quantitative or qualitative, respectively). This allows participants to compare their results with the peer group. Additionally, a graphical representation of each individual participant's data compared to the group's data is created. This allows participants to visually compare their results with others in the round in an anonymized fashion. Each participating laboratory will be provided with an EQA certificate that includes a performance report, general information regarding the round, and an overview of common mistakes.

Educational meeting

All EuroFlow schemes' EQA rounds offered in 2025 will be concluded with an educational meeting, which will include all rounds performed throughout the year. Participation is free of charge for two representatives per participating laboratory. During the meeting, the rounds' results will be shown (anonymized), possible problems and pitfalls will be discussed, and there will be the opportunity to receive direct feedback. More information regarding the educational meeting will be announced on the ESLHO EQA Portal.





Timelines

Activity	Date
Registration for rounds 1 & 2 (spring & autumn)	7 Feb – 28 Feb 2025
Round 1: Distribution of round instructions	3 Mar 2025
Round 1: Reporting of results	3 Mar – 31 Mar 2025
Round 1: Distribution of certificates	Aug 2025
Round 1: Appeals period	3 weeks following distribution of certificates
Round 1: Distribution of final certificates	Sep 2025

Activity	Date
Registration for round 2 (autumn)	29 May – 31 Aug 2025
Round 2: Distribution of round instructions	1 Sep 2025
Round 2: Reporting of results	1 Sep – 29 Sep 2025
Round 2: Distribution of certificates	Jan 2026
Round 2: Appeals period	3 weeks following distribution of certificates
Round 2: Distribution of final certificates	Feb 2026

Registration

Registering for the EuroFlow MM MRD EQA scheme 2025 can be done via the ESLHO EQA Portal.

Appeals

Appeals regarding performance results can be submitted within 21 calendar days following the release of the EQA certificate via the <u>ESLHO EQA Portal</u>. A clear description of the appeal should be included and illustrating figures are recommended.

Complaints

Complaints related to ESLHO's EQA program, or specifically to the EuroFlow MM MRD EQA scheme, can be submitted at any time via the Complaints form that is available on the <u>ESLHO EQA Portal</u>.

Participation fee

ESLHO offers the MM MRD 2025 rounds free of charge to participants of the EuroFlow Consortium.

Organization

The Flow Cytometry Units at the Hematology Department of the University Hospital of Salamanca, and at University of Salamanca (Salamanca, Spain) operate as the lead expert laboratories of the MM MRD scheme, with Dr. Juan Flores-Montero in the role of lead subject-matter expert. In addition, other EuroFlow subject-matter experts provide support with case selection, determination of consensus results, data analysis, performance evaluation, and reporting.





Name	Organization/Institute	Role	Tasks					
ESLHO								
Prof. Dr. Jacques J. M. van Dongen	ESLHO, Zutphen, NL	EQA Program Coordinator	Final responsibility over EuroFlow EQA program; authorizes the MM MRD round report.					
Dr. Bart Lubbers	ESLHO, Zutphen, NL	EQA Officer	Responsible for organization and operation of the MM MRD scheme by ESLHO.					
Evelien Rijkers	ESLHO, Zutphen, NL	EQA Officer	Supports in the organization and operation of the MM MRD scheme.					
Lead expert laboratory								
Dr. Juan Flores- Montero	Flow Cytometry Units, Hematology Department of the University Hospital of Salamanca and University of Salamanca, Salamanca, Spain	Lead subject-matter expert	Designed the original MM MRD QA scheme. Expert input on/review of the results and the summary. Responds to participants' inquiries about the technical aspects of the scheme, and participant results. Provides targeted help to participants.					
	Other expert laboratories							
Dr. Naděžda Brdičková	Charles University, Prague, CZ	Subject-matter expert	Assists in preparing the rounds. Data management and analysis of the data submitted. Prepares the certificates. Prepares the round summary with feedback to the participants.					
Dr. Paula Fernandez	Kantonsspital, Aarau, Switzerland	Subject-matter expert	Case selection, expert analysis, input for determination of consensus results					
Dr. Leire Burgos Rodríguez	University of Navarra, Pamplona, ES	Subject-matter expert	Case selection, expert analysis, input for determination of consensus results					
Dr. Joana Caetano	Champalimaud Foundation, Lisbon, Portugal	Subject-matter expert	Case selection, expert analysis, input for determination of consensus results					

For more information or in case you have questions about the MM MRD scheme, or other EuroFlow EQA schemes, please contact <u>EuroFlow.EQA@eslho.org</u>.