

Quality comparison materials

20 March 2026

With the implementation of the IVDR (In Vitro Diagnostic Medical Devices Regulation), the requirements for Internal Controls have become significantly stricter. Under the previous IVDD (In Vitro Diagnostic Directive), these materials were not CE marked. However, the IVDR now mandates that Internal Controls must be CE-marked.

Cost Implications

Obtaining CE marking for these materials involves substantial costs, which would result in a significant price increase. For many laboratories, this would not be financially sustainable.

Decision

To address this issue, we have decided to replace the current Internal Controls with **Quality Comparison Materials**. This change means the materials will no longer fall under the CE marking requirements of the IVDR. **The composition of the materials will remain unchanged**, but the **intended purpose** will be modified. The quality comparison materials, ERNDiM has developed in collaboration with MCA Laboratories (Netherlands, scheme organizer for the quantitative and hybrid ERNDiM EQA schemes), will be still available via the ERNDiMQA website as an additional service to the users of the ERNDiM external quality control schemes. The range of analytes and their concentrations are still designed in close collaboration with the respective scientific advisers of the corresponding EQA programs. The range of quality comparison materials might be expanded in future, guided by requests of ERNDiM participants.

Benefits

This approach offers a cost-effective solution that allows laboratories to continue working with reliable quality materials, without the financial burden of CE certification. At the same time, the quality and consistency of the analyses remain safeguarded.

Data management system

The existing data management system is also available for most of the quality comparison materials, now called the Quality Comparison System (QCS).

Laboratories using the ERNDiM quality comparison materials have the option to use this, and we encourage users to voluntarily submit their results. The strength of the data management system is that it does not only monitor the data of the laboratory but also compares the lab's results with other labs using the same batch of quality comparison materials. Increased participation enhances the reliability of the running mean, establishing it as the most accurate estimate of the assigned value.

Detailed information on the ERNDiM Quality Comparison System can be found on: www.ERNDiMQA.nl, under General Information\Webshop\Quality Comparison Materials.

Please note that all orders and payments for the Control Materials must be made directly with MCA Laboratories and not with ERNDiM.

| Quality Comparison Material | Content of a package | Use QCS |
|-----------------------------|---|---------|
| Acylcarnitines | 6 vials with low concentrations and 6 vials with high concentrations | Yes |
| Amino Acids | | Yes |
| Organic Acids | | Yes |
| Pterins in Urine | | Yes |
| Purines & Pyrimidines | | Yes |
| Special Assays in Serum | | Yes |
| Special Assays in Urine | | Yes |
| Homocysteine | 6 vials with a low, medium, or high concentration | No |
| Cystine in WBC; protein | 6 vials with a low, medium, or high concentration | No |
| Cystine in WBC; cystine | | No |