Significance of amino acid analysis in the clinical diagnostic field

IVDR Regulation replaces IVDD Directive in Europe

Lab leader and quality assurance manager Dr. Jessica Walkowiak

HENNIGSDORF, GERMANY, February 22, 2023 /EINPresswire.com/ -- In the field of clinical diagnostics, there is a constant push for legal regulations. At the beginning of May 2022, the “Regulation” IVDR (EU In Vitro Diagnostics Regulation) 2017/746 came into force, which will gradually replace Directive IVDD 98/79/EC (In Vitro Diagnostics Directive). This will change the regulatory requirements for the approval of IVD products in the European Union. This often affects equipment such as laboratory equipment or medical devices, which includes their components such as consumables.

How does membraPure GmbH deal with these changes?

“Our amino acid analyzer ARACUS falls into class A and has been approved according to IVDR since August 2022” reports our laboratory manager and quality management representative, Dr. Jessica Walkowiak.

“For the so-called eluent kit, we are aiming for a classification according to Class B and there is still enough time due to the provided transition period until May 26, 2027.”

At the same time, there are different gradations in the area of certification and classification according to IVD products, which contain the exact intended use. Our eluent kit is intended for “detection of free amino acid homocysteine, determination of concentration and amino acid profile in human blood and urine for medical diagnostics”.
Dr. Jessica Walkowiak, Laborleiterin und Qualitätsmanagementbeauftragte membraPure

Because the eluent kit is classified as an “Other IVD” under Directive 98/79/EC, it may not be used in the European Union for the detection of phenylketonuria (PKU). “The exclusion for PKU will remain in the future, as a different classification will be applied, which will entail further evidence and documentation”, Ms. Walkowiak continued. “The consistent realization of the regulations ensures a constant improvement of internal procedures and processes!”, Ms. Walkowiak concludes satisfactorily.

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