

ZeptoMetrix® awarded In Vitro Diagnostic Regulation (IVDR) Certification

Buffalo, NY, October 3, 2023 — ZeptoMetrix® is pleased to announce it has been awarded an IVDR Quality Management System certificate from British Standards Institution BSI, NB 2797, one of the notified bodies under the new EU In Vitro Diagnostics Regulation (IVDR). This certificate applies to the majority of the current portfolio of CE marked ZeptoMetrix NATtrol™ quality control products that are the industry's preferred brand for molecular diagnostic testing and are supplied ready-to-use as independent third-party quality control materials. With this significant certification step completed, ZeptoMetrix will focus on the implementation of updated product labelling over the next several months.

"ZeptoMetrix is delighted with our smooth and efficient transition to IVDR" commented Glenn Harrall, Global Vice President of Quality, ZeptoMetrix. "This transition reflects ZeptoMetrix continuous investments in quality programs, regulatory compliance and demonstrates our ongoing quality commitment to our partners and customers".

"Achieving this certification milestone is further demonstration of ZeptoMetrix commitment to supporting European clinical laboratories with reliable, innovative quality controls." said Evangeline Gonzalez, President, ZeptoMetrix.

For more information on ZeptoMetrix and NATtrol products, visit www.zeptometrix.com.

About ZeptoMetrix®

ZeptoMetrix, an Antylia Scientific company, is an established industry leader in the design, development, and delivery of innovative, quality solutions to the infectious disease diagnostics market. Our expertise and abilities in molecular diagnostics, including external quality controls, verification panels, proficiency panels, customized and OEM products/services, have set the industry standard for performance and reliability and make ZeptoMetrix the preferred choice for independent third-party quality control materials.