

GENEPROOF PCR TESTS IN IVDR QUALITY ARE ON THEIR WAY TO THE FIRST LABORATORIES IN EUROPE.

Brno, Czech Republic, 10th May 2023

In January 2023, GeneProof was one of the first companies in Europe to obtain the EU Quality Management System Certificate according to the European IVDR regulation. GeneProof is now launching its first IVDR kits and offers its customers an unbeatable advantage of working with cutting-edge products that are in line with the demanding requirements of European legislation for *in vitro* diagnostics. The first IVDR kits are being manufactured for the Czech and Slovak market.

For GeneProof, producing and offering products in compliance with the (EU) 2017/746 Regulation (IVDR) represents a major milestone with the promise of continued success in the future. The IVDR certification process was challenging and required a large investment of resources and finances. GeneProof can now offer the first IVDR kits from the Immunocompromised-Transplanted Panel (CMV, EBV, VZV, HSV), with more to come in the future.

"The new European Union legislation for *in vitro* diagnostics has set strict rules for manufacturers and laboratories working with these medical devices. That is why there is great demand for our GeneProof PCR kits on the European market. High quality is also the reason for the increased demand from marketing outside of the European Union, and we are proud to be able to satisfy our customers' needs. However, the first IVDR kits are initially being manufactured for the Czech and Slovak markets," adds GeneProof Sales Director Tomáš Mohelský.

Contact:

Eva Pažoutová
eva.pazoutova@geneproof.com

About ALPCO-GeneProof

ALPCO was founded in 1991 as an importer and distributor of immunoassay-based products for the North American life science markets. The company has since evolved into a leading producer of novel immunodiagnostic reagents for specialty testing laboratories. In 2022, ALPCO merged with GeneProof, a Czech Republic-based provider of specialty molecular diagnostic solutions. Founded in 2005, GeneProof offers a portfolio of more than 50 IVDD and 6 IVDR PCR test kits for infectious diseases and genetic mutations, as well as a suite of proprietary instrumentation for clinical laboratories of all sizes. For additional information, please visit www.alpco.com and www.geneproof.com.