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Important Note: In Vitro Diagnostic (IVD) EU Quality Management System (QMS) Certificate for PAXgene Blood Collection Tubes (CE-IVD) and QIAsymphony PAXgene Blood ccfDNA Kit (CE-IVD)

Dear Valued Customer,

PreAnalytiX GmbH is proud to inform you that we have received the EU Quality Management System (QMS) Certificate pursuant to Regulation (EU) 2017/746 on In Vitro Diagnostic Medical Devices, Annex IX Chapters I and III (Class A Devices in Sterile Condition) from the EU Notified Body TÜV SÜD in March 2021. This IVDR QMS Certificate will support all CE marked Class A Sterile PAXgene IVD blood collection tubes as they transition into compliance with the EU IVDR 2017/746.

The PreAnalytiX® PAXgene® Blood ccfDNA Tube (CE-IVD) [cat. no 768165; CE 0123] and PreAnalytiX QIAsymphony® PAXgene Blood ccfDNA Kit (CE-IVD) [cat. no. 768566] are now CE marked for In Vitro Diagnostic use according to the EU IVDR 2017/746.

Pre-analytical steps including blood collection, transport, storage, plasma preparation, ccfDNA and gDNA isolation, as well as their documentation for development, verification and validation, were conducted according to the International Standard ISO 20186-2:2019 and ISO 20186-3:2019, "Molecular in vitro diagnostic examinations - Specifications for pre-examination processes for venous whole blood - Part 2: Isolated genomic DNA" and "Part 3: Isolated circulating cell free DNA from plasma," ensuring standardization of the workflow, integrity of the supporting data for the products and state-of-the-art requirements under the IVDR.

IVDR verification and validation studies for the QIAsymphony PAXgene Blood ccfDNA Kit (CE-IVD) were performed with QIAGEN® QIAsymphony SP instruments already installed and in use in the laboratory. Currently, the QIAsymphony SP instrument itself is CE marked according to the still valid EU Directive 98/79/EC.

On May 26, 2022, the five-year transitional period for the new EU Regulation on In Vitro Diagnostic Medical Devices (IVDR 2017/746) will end. PreAnalytiX is actively fulfilling its commitment to timely certification of its In Vitro Diagnostic Medical Devices Directive 98/79/EC (IVDD) portfolio to the EU IVDR 2017/746. Furthermore, in addition to complying with regulatory requirements, we consistently strive to meet our customer's needs by ensuring the continuous availability of all of our products for medical professionals and patients alike. More information about IVDR is available through www.qiagen.com/IVDR-support.

Best regards,

PreAnalytiX