November 2017

Subject: PAXgene Blood ccfDNA Tube CE Mark (cat. no. 768165) for In-Vitro Diagnostic use (IVD) and PAXgene Blood ccfDNA Tube RUO (cat. no. 768115) for Research Use Only. Not for Diagnostic use.

Dear PAXgene Customer,

PreAnalytiX is releasing a new CE-marked IVD tube, the PAXgene Blood ccfDNA Tube CE Mark (cat. no. 768165), and will be discontinuing the PAXgene Blood ccfDNA Tube RUO (cat. no. 768115) in countries where this new tube will be made available.

The PAXgene Blood ccfDNA Tube CE Mark IVD (cat. no. 768165) is for In-Vitro Diagnostic Use while the PAXgene Blood ccfDNA Tube RUO (cat. no. 768115) is for Research Use Only (RUO). Not for Diagnostic Use.

No changes have been made to product components, manufacturing processes or the manufacturing site of the two products.

The difference between the PAXgene Blood ccfDNA Tube CE Mark IVD (cat. no. 768165) and the PAXgene Blood ccfDNA Tube RUO (cat. no. 768115) is the product labeling, which clearly describes the intended use of each product.

For more information, or if you have any questions, please contact us at www.preanalytix.com.

Thank you for choosing PAXgene products!

Best Regards,
Your PreAnalytiX Team