

April 2022

Customer Letter: New PAXgene® Blood RNA Kit* Protocol on QIAcube® Connect MDx available

Dear Valued Customer,

As part of our commitment to continuously improve the quality of samples for molecular diagnostic testing, we wish to notify all PreAnalytiX® customers using the PAXgene Blood RNA Kit* on the QIAGEN® QIAcube Connect MDx** of the availability of a new protocol version. This protocol update is for users of the QIAcube Connect MDx (cat. no. 9003070) and is optional.

Updating the existing version of the PAXgene Blood RNA CE Kit (Cat No. 762174) and PAXgene Blood RNA FDA Kit (Cat No. 762164) protocol that is being used on installed QIAcube Connect MDx further optimizes product performance within the established, verified and validated product claims and is recommended. Protocol Version 6 further improves the removal of genomic DNA from RNA samples. The existing Protocol Version 5 will remain valid and unchanged.

For download and installation of the new protocol version 6 on your QIAcube Connect MDx, please refer to the “Resources” section on the product webpage of the [PAXgene Blood RNA CE Kit](#) or [PAXgene Blood RNA FDA Kit](#) based on your country of origin.

Additionally, on May 26, 2022, the five-year transitional period (announced in May 2017) for the new EU Regulation on In Vitro Diagnostic Medical Devices (IVDR 2017/746) will end. The PAXgene Blood RNA CE Kit will undergo transition from the in Vitro Diagnostic Medical Devices Directive 98/79/EC (IVDD) to the new EU Regulation on In Vitro Diagnostic Medical Devices (IVDR 2017/746). For use of the upcoming IVDR compliant PAXgene Blood RNA CE Kit (Cat No. 762174) on the IVDD compliant QIAcube Connect MDx, customers will be provided with guidance in a separate letter which can be expected on time in May 2022.

PreAnalytiX continuously works to help enable and improve the diagnosis, treatment and monitoring of disease. If you have any questions related to the QIAcube Connect MDx, please reach out to QIAGEN technical services or your local QIAGEN representative.

Sincerely,

Your PreAnalytiX Team

*The PAXgene Blood RNA Kit is intended for in vitro diagnostic use when combined with the PAXgene Blood RNA Tube.

**Product availability may vary by country specific regulatory requirements and approvals. Contact your country representative or visit www.qiagen.com or QIAGEN technical services for further details.

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