July 2026

Important Note

Significant updates to *therascreen*® *PIK3CA RGQ PCR Kit Instructions for Use*

Dear valued *therascreen* customer,

This is to inform you that we recently made some significant changes to the *therascreen PIK3CA RGQ PCR Kit Instructions for Use* (HB-2614). Updates to the IFU (R2) detail the steps taken to demonstrate the repeatability and validity of Q546R mutation calling and required updates to Q546R mutation calling/results demonstration that support the inclusion of identified Q546R mutations.

Key edits to the IFU

- **Updates to *therascreen* PIK3CA RGQ PCR Kit assay profiles**
  The *therascreen* PIK3CA FFPE and Plasma Assay Profiles have been updated to address the increased probability of false Q546R mutation positive results caused by non-specific molecular interactions within the Q546R reaction and reinstate accurate detection of Q546R mutations positive results. Consequently, the Important Note for *therascreen* PIK3CA RGQ PCR Kit (HB-2854-001) dated December 2020 **no longer applies**.

  Note: The updated *therascreen* PIK3CA FFPE and Plasma assay profiles are available for download from the related product page at **www.qiagen.com**. Go to **Resources** > **Protocols** to download the applicable assay profile.

  Customers must update to these latest versions of both FFPE and Plasma assay profiles before reinstating use of Q546R calls:

- **therascreen_PIK3CA_FFPE_MDx Assay Profile Version 1.0.1**: For analysis of tissue specimens.

- **therascreen_PIK3CA_Plasma_MDx Assay Profile Version 1.0.2**: For analysis of plasma specimens.

The *therascreen* PIK3CA RGQ PCR Kit is specifically designed for use with Rotor-Gene® Q MDx (US) instrument operating with a computer installed with:

- Rotor-Gene Q AssayManager® v2.1

- Gamma MDx Plug-in version 1.0.0

- therascreen_PIK3CA_FFPE_MDx Assay Profile version 1.0.1 for analysis of tissue specimens

- therascreen_PIK3CA_Plasma_MDx Assay Profile version 1.0.2 for analysis of plasma specimens

Refer to the *Rotor-Gene Q MDx (US) User Manual* information regarding the Rotor-Gene Q MDx (US) instrument. The instrument must be maintained according to the requirements in the user manual.

Refer to *Rotor-Gene AssayManager v2.1 MDx Core Application User Manual* and *Rotor-Gene AssayManager v2.1 Gamma MDx (US) Plug-in User Manual* for further information regarding the software.

- **Additional clinical and performance data**
    - Updated repeatability and reproducibility data for samples containing mutations in Q546R, including C420R, E542K, E545A, E545D, E545G, E545K, Q546E, H1047L, H1047R, and H1047Y
    - Revised Clinical performance section to update progression-free survival (PFS) analysis, concordance, and participant/sample testing data following reanalysis with updated software parameters
- **Troubleshooting and Interpretation**
    - Enhanced troubleshooting guidance for invalid sample flags
    - Added clarification on cross-reactivity handling in MAF samples
- **Specimen Handling and Stability**
    - Clarified specimen storage conditions and maximum storage times for FFPE tissue and plasma
    - Update to General precautions specifically relating to guidance on handling and disposal of *Taq* DNA polymerase

For full details, refer to the latest version of the Instructions for Use available at **www.qiagen.com**

If you have any questions or concerns, please contact your local QIAGEN Technical Service Department through any of the following:

Telephone: 800 362 7737

Email: **TechService-NA@qiagen.com**

Best regards,
QIAGEN