

July 2022

Important Note

therascreen[®] FGFR RGQ RT-PCR Kit, REF 874721

Dear *therascreen* FGFR RGQ RT-PCR Kit customer,

QIAGEN has identified a higher than expected No Template Control (NTC) upturn rate that affects the *therascreen* FGFR RGQ RT-PCR Kit (24), REF 874721.

The Instructions for Use and Assay Profile have been updated to reduce the higher than expected NTC upturn rate to below 5%. You may download the updated Instructions for Use and Assay Profile designed for Version 2 kits from www.qiagen.com. The latest Assay Profile is required for you to have the benefit of upgraded Version 2 kits.

Please note that the *therascreen* FGFR RGQ RT-PCR Kit Version 1 (V1) must only be used with *therascreen* FGFR FFPE MDx Assay Profile version 1.0.0, and the *therascreen* FGFR RGQ RT-PCR Kit Version 2 (V2) must only be used with *therascreen* FGFR FFPE MDx Assay Profile version 1.0.3. We advise that the kit labels are checked upon receipt of the kits for their applicable assay version (V1 or V2) to ensure that the correct Assay Profile is used. Table 1 provides further guidance on the kit and its applicable Assay Profile.

Table 1. Identification of (874721) *therascreen* FGFR RGQ RT-PCR Kit (24) versions with applicable Assay Profiles

Kit version	Kit label	Assay profiles
<i>therascreen</i> FGFR RGQ RT-PCR Kit V2 (REF 874721)		<i>therascreen</i> FGFR FFPE MDx Assay Profile version 1.0.3
<i>therascreen</i> FGFR RGQ RT-PCR Kits V1 (REF 874721)		<i>therascreen</i> FGFR FFPE MDx Assay Profile version 1.0.0

The *therascreen* FGFR RGQ RT-PCR Kit Version 2 (V2) has demonstrated that all previously verified and validated performance characteristics of the *therascreen* FGFR RGQ RT-PCR Kit Version 1 (V1) remain valid. Thus, the *therascreen* FGFR RGQ RT-PCR Kit Version 2 (V2) is equivalent to the *therascreen* FGFR RGQ RT-PCR Kit Version 1 (V1).

If you have any queries, please contact QIAGEN Technical Services.

With kind regards,

QIAGEN

www.qiagen.com