

April 2016

# Important Note

Dear RespiFast RG Panel CE customer,

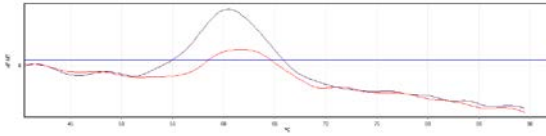
Please note that we have identified an issue with RespiFast RG Panel CE (REF 4693163).

## Overview of affected material

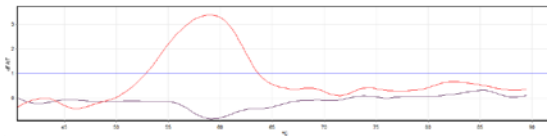
Product name	RespiFast RG Panel CE
Product code	4693163 (REF; QIAGEN® cat. no.)
Lot no.	All
Distributor	QIAGEN GmbH, Qiagen Strasse 1, 40724 Hilden, GERMANY
Legal manufacturer	PathoFinder B.V., Randwycksingel 45, 6229 EG Maastricht, THE NETHERLANDS

## Detailed description

Melting peaks for the coronavirus (CoV) 229E component of the RespiFast RG Panel CE Positive Control may be above the range indicated in the Kit Handbook. These peaks are detected in the FAM™/Cy®5 channel of the RespiFast RG Panel CE reaction with mix 2. Due to normalization of the Cy5 signal for ROX® and Red in the presence of the melting peak for the PIV2 component of the Positive Control in the ROX channel (see Figure 1), a  $T_m$  shift is caused. Please be aware that the  $T_m$  shift of 229E may also occur in clinical double infections with parainfluenza virus type 2 (PIV2) and coronavirus 229E (229E) (Figure 2), whereas these infections are rare. **To maintain adequate calling of 229E melting peaks, the  $T_m$  range of 229E has been changed from 58.5–61.5°C to 58.5°C–63.5°C.**



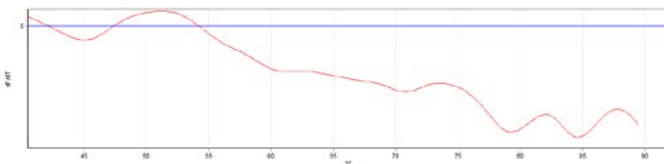
**Figure 1. CoV 229E melting peak in the normalized Cy5 channel of a single coronavirus 229E infection (black) and a double infection of PIV2 and 229E (red).** The  $T_m$  of the 229E infection is called at 60.5°C. This is within the  $T_m$  range of 58.5-61.5°C in the Kit Handbook, as well as within the adjusted  $T_m$  range of 58.5-63.5°C. The 229E melting peak of double infected samples shifts due to normalization, and is called at 61.8°C. The latter is above the  $T_m$  range indicated in the Kit Handbook, but is called positive for coronavirus 229E if adjusted  $T_m$  range is applied.



**Figure 2. The ROX channel of the same samples (CoV 229E infection and a double infection of PIV2 and 229E).** The PIV2 melting peak in the double infected sample (red) is present at 59°C. In the 229E single infected sample (black) there is no peak in ROX.

In addition, the *Legionella pneumophila* melting peak sometimes appears as a double peak (see the footnote to Tables 2 and 14 of the Kit Handbook), which may result in a  $T_m$  below the indicated range when using automated  $T_m$  calling (Figures 3 and 4).

To maintain adequate calling of *L. pneumophila* melting peaks, the  $T_m$  range of *L. pneumophila* has been changed from 50.5–53.5°C to 49.5–53.5°.



**Figure 3. *L. pneumophila* melting peak appearing as a wide single peak that is called automatically at 51.2°C.** This is within the range in the Kit Handbook (50.5–53.5°C) and also within the adjusted  $T_m$  range of 49.5–53.5°C. The sample is positive for *L. pneumophila* in both  $T_m$  ranges.

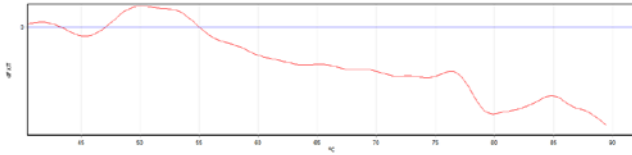


Figure 4. *L. pneumophila* melting peak appears as a double peak with the left part called automatically, at 50.0°C. This is below the Kit Handbook range (50.5–53.5°C). However, with the adjusted  $T_m$  range of 49.5–53.5°C, this sample scored positive for *L. pneumophila*.

Until an official new version of the Kit Handbook is released, please follow the guidance in this important note on results interpretation for coronavirus 229E and *L. pneumophila* when using the RespiFast RG Panel CE Kit. Translations of the *RespiFast RG Panel CE Kit Handbook* and of this important note can be found online from the following QIAGEN webpage listed below. Documents are located on the “Product Resources” tab, under “Kit Handbooks”.

RespiFast RG Panel CE Kit: [www.qiagen.com/shop/old/assay-technologies/complete-assay-kits/human-pathogen-detection/respi-fast-rg-panel-ce](http://www.qiagen.com/shop/old/assay-technologies/complete-assay-kits/human-pathogen-detection/respi-fast-rg-panel-ce).

If you have further questions, please contact QIAGEN Technical Services (see the back cover of our handbooks or visit [www.qiagen.com](http://www.qiagen.com)).

Best regards,

Your QIAGEN team

Trademarks: QIAGEN®, Sample to Insight® (QIAGEN Group); Cy® (GE Healthcare); FAM™, ROX® (Life Technologies Corporation).  
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