QIAGEN GmbH
QIAGEN Strasse 1
40724 Hilden
Germany

31th January 2020

Urgent Field Safety Notice

Rotor-Gene Q Software Version 2.3.4 (REF 9019101)

Attention: Lab Director/Manager, Medical Director, Risk Manager, and Safety Officer

We would like to inform you that QIAGEN has identified an issue with Rotor-Gene Q Software Version 2.3.4. This issue has been observed **only** when using the Rotor-Gene Q with Software version 2.3.4 while using the Export function of the Laboratory Information Management Systems (LIMS) for Quantitative analysis.

Description of the issue

When using the Rotor-Gene Q with Software Version 2.3.4 completing a LIMS export, the .csv file reports the calculated concentration result value as a logarithmic value. (see Fig. 1)

Fig.1

Standard Calculated Concentration:

Type	Ct	Ct Comme	Given Con	Calc Conc (
Standard	37.11		5.00E+01	4.72E+01
Standard	33.26		5.00E+02	5.69E+02
Standard	30.03		5.00E+03	4.60E+03
Standard	26.31		5.00E+04	5.06E+04
Positive Cc	29.47			6.58E+03

Logarithmic Value Error:

Type	Ct	Ct Comme	Given Con	Calc Conc (
Standard	35.62		5.00E+01	1.66E+00
Standard	31.75		5.00E+02	2.76E+00
Standard	28.42		5.00E+03	3.70E+00
Standard	24.94		5.00E+04	4.68E+00

This issue can affect the following instruments:

Catalogue number	Product Name
9002000	Rotor-Gene Q MDx 2Plex
9002001	Rotor-Gene Q MDx 2Plex no PC
9002010	Rotor-Gene Q MDx 2Plex HRM
9002011	#Rotor-Gene Q MDx 2Plex HRM no PC
9002020	Rotor-Gene Q MDx 5Plex
9002021	Rotor-Gene Q MDx 5Plex no PC
9002029	Rotor-Gene Q MDx 5plex, PrioPLUS
9002030	Rotor-Gene Q MDx 5Plex HRM
9002030R	Rotor-Gene Q MDx 5Plex HRM refurbished
9002031	Rotor-Gene Q MDx 5Plex HRM no PC
9002040	Rotor-Gene Q MDx 6Plex
9002041	Rotor-Gene Q MDx 6Plex no PC90275010
9019101	Rotor-Gene Q Software
9023241	RGQ 2.3SW CD
9001680	Rotor-Gene Q 2Plex no PC
9001680R	Rotor-Gene Q 2Plex no PC Refurbished
9001690	Rotor-Gene Q 2Plex HRM no PC
9001690R	Rotor-Gene Q 2Plex HRM no PC Refurbished
9001700	Rotor-Gene Q 5Plex no PC
9001700R	Rotor-Gene Q 5Plex no PC Refurbished
9001710	Rotor-Gene Q 5Plex HRM no PC
9001710R	Rotor-Gene Q 5Plex HRM no PC refurbished

This issue can affect the following QIAGEN IVD kits:

Catalogue number	Product Name
4514363	*artus* BK Virus QS-RGQ Kit (24)
4514263	*artus* BK Virus RG PCR Kit (24)
4514265	*artus* BK Virus RG PCR Kit (96)
4503363	*artus* CMV QS-RGQ Kit (24)
4503263	*artus* CMV RG PCR Kit (24)
4503265	*artus* CMV RG PCR Kit (96)
4501363	*artus* EBV QS-RGQ Kit (24)
4501263	*artus* EBV RG PCR Kit (24)
4501265	*artus* EBV RG PCR Kit (96)

Catalogue number	Product Name
4506366	*artus* HBV QS-RGQ (72)
4506356	*artus* HBV QS-RGQ Kit (24)
4506363	*artus* HBV QS-RGQ Kit (24)
4506263	*artus* HBV RG PCR Kit (24)
4506265	*artus* HBV RG PCR Kit (96)
4518356	*artus* HCV QS-RGQ Kit (24)
4518363	*artus* HCV QS-RGQ Kit (24)
4518366	*artus* HCV QS-RGQ Kit (72)
4538366	*artus* HCV QS-RGQ Kit V2
4518253	*artus* HCV RG RT-PCR Kit (24)
4518263	*artus* HCV RG RT-PCR Kit (24)
4518265	*artus* HCV RG RT-PCR Kit (96)
4513363	*artus* HI Virus-1 QS-RGQ Kit (24)
4513366	*artus* HI Virus-1 QS-RGQ Kit (72)
4513253	*artus* HI Virus-1 RG RT-PCR Kit (24)
4513263	*artus* HI Virus-1 RG RT-PCR Kit (24)
4513265	*artus* HI Virus-1 RG RT-PCR Kit (96)
4502363	*artus* VZV QS-RGQ Kit (24)
4502263	*artus* VZV RG PCR Kit (24)
4502265	*artus* VZV RG PCR Kit (96)
4532265	*artus* JCV RG PCR Kit (96)
4555263	*artus* M.tuberculosis RG PCR Kit (24)
4555265	*artus* M.tuberculosis RG PCR Kit (96)
4504263	*artus* Parvo B19 RG PCR Kit (24)
4511263	*artus* SARS RG RT-PCR Kit (24)

IMPORTANT: This issue can also impact quantitative Life Science Assays on the RGQ. Please contact QIAGEN Technical Services through the contact details provided in this letter if you have any concerns.

Potential risks associated with the Issue

If an operator is using the Rotor-Gene Q (RGQ) with Rotor-Gene Q Software Version 2.3.4 for quantitative analysis when exporting using the LIMS export function, there is a risk that results in the created .csv file and will be significantly under the expected value. This could be reflected in the LIMS and could lead to a false negative result, which could lead to serious medical consequences such as the suspension or non-initiation of treatment.

Please note that all other RGQ software result outputs and Rotor-Gene Q software(s) are **NOT** affected by this issue

Actions to be taken by the Customer/User:

1) Discontinue use of the Rotor-Gene Q instrument in the following specific conditions:

- The Rotor-Gene Q instrument is running Software 2.3.4 using the export function to LIMS

2) Upgrade to the latest version of the Rotor-Gene Q Software which resolves the issue – version 2.3.5. This is expected to be available on 1st February 2020. Please visit the QIAGEN website to upgrade: www.qiagen.com/resources/resourcedetail?id=9d8bda8e-1fd7-4519-a1ff-b60bba526b57&lang=en. Apart from correcting this fault, no other changes to the software have been implemented.

3) Complete the Acknowledgement of Receipt form and return it to QIAGEN.

Detection of affected batches

Laboratory personnel and clinicians are advised to consider a patient's previous test results, other diagnostic tests, anamnesis and current clinical condition when interpreting results from this software. If the results do not match the patient's clinical presentation, or incongruences are found with previous and concomitant tests or the results are otherwise unexpected, the patient sample should be retested using an alternate test method or a reference laboratory. Clinical interventions deemed necessary should not be delayed on the basis of results from this software.

If you suspect that your runs are affected, perform this procedure to verify the results:

1. Open the suspected .csv
2. Check the values under Calculated concentration column, then compare the values to the Given Concentration column.

Alternatively, checking the concentration in the standard and/or positive controls will highlight the issue as the Calculated concentration in the .csv file will be significantly lower than expected.

Finally, a comparison of the .csv file with the .pdf files generated by the software will show a discrepancy in the "Calculated concentration" field(s).

QIAGEN's commitment to resolving the issue

QIAGEN recognizes that this issue may impact your workflow and have developed a fix in the latest version of the Rotor-Gene Q Software Version 2.3.5 which will be available through the link provided above.

IMPORTANT NOTE TO IMPORTERS, DISTRIBUTORS AND COMMERCIAL PARTNERS

Please quarantine your Rotor-Gene Q inventory with the software version 2.3.4 CD. The table below lists the Rotor-Gene Q Instruments & serial number ranges which were delivered with the CD containing Rotor-Gene Q Software Version 2.3.4. Serial numbers are interpreted as RMMYYXXX (RGQ, Month, Year, Number). Please also notify your customers with this letter and request acknowledgement accordingly and confirm that the affected CDs have been destroyed. QIAGEN will contact you with further instructions.

Catalogue Number	Product Name	All serial numbers later than:
9001700	Rotor-Gene Q 5Plex	R0919104
9001720	Rotor-Gene Q 6Plex	R0919115
9002020	Rotor-Gene Q MDx	R0910300

Completion of the Acknowledgement of Receipt form

To ensure that all affected users are notified and according to applicable national statutory provisions, we are obliged to provide proof of notification in the market to the authorities. Therefore, please complete and sign the included Acknowledgement of Receipt form and email it to QIAGEN Quality Assurance at **Quality.Communications@qiagen.com**.

We regret any inconvenience caused by this situation. If you have further questions, please contact QIAGEN Technical Services Department**.**

- QIAGEN Subsidiaries: https://www.qiagen.com/about-us/contact/global-contacts/subsidiaries/
- QIAGEN Commercial Partners and Importers: https://www.qiagen.com/about-us/contact/global-contacts/distributors-and-importers/

Best Regards,

Your QIAGEN team

Rotor-Gene Q Software Version 2.3.4 (REF 9019101)

Acknowledgement of Receipt form

(Please complete form using block letters)

I hereby acknowledge that I have received, read and understood the included Urgent Field Safety Notice described above. We have taken the necessary actions as suggested by this notice:

- The information was forwarded to all individuals and departments within our organization using this product. The notice was forwarded to the end user.
- We reviewed this notice with our laboratory/medical director.
- We confirm we have destroyed the affected items "Rotor-Gene® Q Software Version 2.3.4 CD REF 9023241"
- For commercial partners only: This notice was forwarded to our customers.
- For commercial partners only: We ceased the distribution of the affected products. We followed-up on the Acknowledgements of Receipt with our customers.

Laboratory/Company name:	
Instrument serial number(s):	
Please confirm the discontinued use of the Rotor-Gene Q Software Version 2.3.4.* ☐ **YES** **DATE:** _____ ☐**N/A** (not using the RGQ Software Version 2.3.4) *Please contact QIAGEN Technical Services if you are unsure of how to find out which version you are running	
Please confirm that the Rotor-Gene Q Software has been upgraded to Version 2.3.5: ☐ **YES** **DATE:** _____	
Address:	
Contact name:	Title:
Email address:	Phone number:
Signature:	Date: