

Important Note

Dear *artus*® CT/NG QS-RGQ Kit user,

This note is intended to inform you of changes to the Instructions for Use for the following:

	Catalog number (REF)
<i>artus</i> CT/NG QS-RGQ Kit	4569365

QIAGEN has become aware that late signals in the orange channel can occur in rare occasions for true *Neisseria gonorrhoeae*-negative samples. Additional analyses performed by us demonstrated that applying a cut off of 40 Cts reduces the probability of false positive results. Thus QIAGEN has decided to include this cutoff at 40 Cts for the orange channel (*N. gonorrhoeae*) into the Instructions For Use.

When applying this cut off, the limit of detection (LOD) for the assay is shifted from 6.89 CFU/ml to 10.32 CFU/ml for urine samples. This shift is not considered to be clinically significant. Furthermore, application of this cut-off resulted in a shift in diagnostic specificity from 99.8% to 100%. The LOD of this assay for swabs as well as other parameters described in the Performance Characteristics were not affected.

NOTE

The following in the Instructions for Use were adjusted accordingly:

- Performance Characteristics for the *artus* CT/NG QS-RGQ Kit, dated July 2017
- QIASymphony RGQ Application Sheet for QIASymphony RGQ application *artus* CT/NG QS RGQ Kit (sample type: swabs in eNat, 400 µl), dated July 2017
- QIASymphony RGQ Application Sheet for QIASymphony RGQ application *artus* CT/NG QS RGQ Kit (sample type: urine in eNat, 400 µl), dated July 2017
- New Assay Profile (if Rotor-Gene AssayManager used for analysis) - AP_artus_CTNG_sample400_QS_V2_0_0.iap.

Please download the updated documents from www.qiagen.com

To use this new cut off value, please perform the following:

- For automatic analysis with Rotor-Gene AssayManager: Download the updated version of the Assay Profile from the web page and install according to page 9 of the Application Sheets.
- For manual analysis with the Rotor-Gene Q software 2.1 or higher: see relevant Application Sheet on page 14 (urine) or page 16 (swabs).

For users of Rotor-Gene AssayManager

Please pay special attention to the interpretation instructions provided on page 11 of the Application sheets to ensure correct application of the cut off. Cts above 40 in the NG channel will produce an "INVALID" status with the flag "CT_ABOVE_ACCEPTED_RANGE". Provided the internal control (IC) is detected and valid, this result can be reported as a valid NG-negative sample, and no retesting of the sample is required.

- This Important Note is now part of the Service Package and its translations are available on the QIAGEN website:
www.qiagen.com/products/artusctngqsrqkitce
- Translations of the Handbook, the Performance Characteristics and the Application Sheet are available from the QIAGEN website:
www.qiagen.com/products/artusctngqsrqkitce

Please forward this information to all individuals and departments within your organization that use this product. Please also review this notice with your laboratory/medical director.

If you have further questions, please contact your local QIAGEN Technical Services Department:

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Best regards,

Your QIAGEN team