

Urgent FIELD SAFETY NOTICE: *artus C. trachomatis* Plus kits

November 6, 2015

Dear valued customer,

Please note that we need to revise a product claim of the *artus C. trachomatis* Plus kits due to internal investigations (see table below for affected kits).

The *artus C. trachomatis* Plus kits are designed to detect a 106 bp region of the *Chlamydia trachomatis* chromosome and a 111 bp region of the cryptic plasmid of *C. trachomatis*; however, the kits fail to detect the chromosomal target.

The *artus C. trachomatis* Plus kits do not detect cryptic-plasmid-free variants of *C. trachomatis*. Based on discussions with independent experts and a review of current literature, these are considered very rare (five isolates have been identified to date).

Overview of affected kits

	Cat. no. (REF)
<i>artus C. trachomatis</i> Plus RG PCR Kit (24) CE	4559263
<i>artus C. trachomatis</i> Plus RG PCR Kit (96) CE	4559265
<i>artus C. trachomatis</i> Plus LC PCR Kit (24) CE	4559063
<i>artus C. trachomatis</i> Plus LC PCR Kit (96) CE	4559065
<i>artus C. trach.</i> PLUS RG PCR Kit (768) CE	4559267

According to our records, you have received at least one of the affected kits listed above. Please see below and over page for actions to be taken by the customer/user and other important notes.

Actions to be taken by the customer/user

- Be aware that cryptic-plasmid-free variants of *C. trachomatis* (which are considered very rare) are not detected by *artus C. trachomatis* Plus kits.
- Evaluate validity of negative patient results obtained and review this notice with your laboratory / medical director.

Note the following

- Detection of the 111 bp region of the *C. trachomatis* cryptic plasmid is not affected by this issue
- Positive results generated with the affected kits should still be interpreted as true positives
- Detection of the Swedish new variant strains, which have a deletion in the cryptic plasmid, is not affected by this issue

Communication of this Field Safety Notice

Important: Forward this information to all individuals and departments within your organization that have received or used this product. If you are not the end user, please forward the notice to the product end user.

Commercial partners: Please forward this information to your customers.

We sincerely apologize for any inconvenience this may cause and thank you in advance for your assistance. If you have any questions, please contact your local QIAGEN Technical Services Department:

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With kind regards,

Your QIAGEN Team