

Ludwigshafen, 22.05.2019

Dear valued BIORON Diagnostics customer,

According to our records you have purchased one or more of the following product from us:

Product name	REF	LOT	Expiry
RealLine Neisseria gonorrhoeae Str-format	VBD4498	diverse	diverse
RealLine Neisseria gonorrhoeae Fla-format	VBD4496	diverse	diverse
RealLine Trichomonas vaginalis / Neisseria gonorrhoeae Str-format	VBD0496	diverse	diverse
RealLine Trichomonas vaginalis / Neisseria gonorrhoeae Fla-format	VBD0495	diverse	diverse
RealLine Chlamydia trachomatis / Neisseria gonorrhoeae Str-format	VBD0457	diverse	diverse
RealLine Chlamydia trachomatis / Neisseria gonorrhoeae Fla	VBD0458	diverse	diverse

Manufacturer:

BIORON Diagnostics GmbH
Rheinhorststr. 18
67071 Ludwigshafen - Germany

Description of the issue:

Based on discrepant results (False positive results) reported from the field, BIORON Diagnostics initiated a complaint investigation to confirm product performance and determine root cause.

The investigations have shown a cross-reaction of the kit with *Neisseria subflava*. This is a commensal Neisseria species found in the upper part of the mouth and respiratory tract. Due to the use of Pilin Gene (PivNG) as target in the Kit other non-pathogenic Neisseria can be detected.

Impact on the product:

When using samples from the nasopharyngeal space, false positive detection of *Neisseria gonorrhoeae* may occur in the presence of *Neisseria subflava*.

Reply form according to QMVA1901 Meldepflichtige Vorkommnisse

Hereby I confirm the receipt and implementation of the field correction measure for: RealLine Neisseria gonorrhoeae	
Printed name	
Name	Customer number
Position	
Faculty/Company, City	
Place, Date, Signature	

Please send back the filled form to:

FAX: +49 621 545 900 68

Email: info@bioron.de

or by Post to:

BIORON Diagnostics
Rheinhorststr. 18
67071 Ludwigshafen
Germany

BIORON Diagnostics GmbH – Rheinhorststr. 18 – 67071 Ludwigshafen (Germany)

Managing Director: Barbara Hassib, HRB 62298 Amtsgericht Ludwigshafen

Phone: +49 621 545 900 70 Fax: +49 621 545 900 68

E-Mail: info@bioron.de Homepage: www.bioron.de