ELITechGroup S.p.A
Administrative and Operative Site
Sede Amministrativa ed Operativa
C.so Svizzera, 185
10149 Torino (TO) - Italia
Tel : +39 011 97 61 91 Fax : +39 011 93 67 611
egspa.emd.info@elitechgroup.com
www.elitechgroup.com

ELITechGroup
EMPOWERING IVD

Registered Office
Sede Legale
Corso Italia, 22
20122 Milano (MI) - Italia

Our Reference: FSN 19/01-ENG
Date: June 19th 2019

Field Safety Notice regarding a Corrective Action

Object: possible error in result interpretation obtained with the *Mycoplasma genitalium* (MG) target of the STI PLUS ELITe MGB® Kit in association with the *ELITe InGenius®* instrument.

Product Ref.	Product Name
RTS400ING	STI PLUS ELITe MGB® Kit

Dear Customer,

herewith, we ELITechGroup SpA intend to inform you about an anomaly recently discovered during the quality control of the product indicated above.

Important Premise

This notice consists exclusively of a safety instruction through a recommendation described below and does NOT in any way concern the withdrawal of batches already placed on the market.

Rationale of the Field Safety Notice and Event Description

Our "Quality Control" Team has detected the following anomaly on a new production lot of the kit in question. The lot has NOT been released on the market.

In the test with a highly positive simulated sample for the MG target, the Report produced by the ELITe InGenius instrument showed a negative results for the MG target.

ELITechGroup
EMPOWERING IVD

In particular:

- in the summary section of the Report, called "Run Summary", the sample in question was "Negative" for the MG target,

- while in the "Track Report", the fluorescence plot showed a curve clearly associated with a positive reaction but characterized by a very negative baseline value.

The product lot concerned has been declared NOT compliant and therefore NOT authorized for sale.

State of the Investigation

On the basis of the investigation conducted, the anomaly was linked both to the composition of the lot concerned and to the very high concentration (around 10^6 copies / mL) of the MG target. This association led to a misinterpretation of the fluorescence curve by the analysis software.

The repetition of the event is considered unlikely as it is linked to a specific production lot (the event has NEVER occurred with the 6 lots previously produced and marketed), and at very high target concentrations (which is not frequent in the clinical practice).

However, as there is a residual risk that this phenomenon may occur randomly in very specific and difficult to predict situations, ELITech has modified the Assay Protocols associated with the product in order to completely exclude the possibility that a false negative result will be generated in the future.

Impact on tests previously performed with the product concerned and Immediate Actions

Although we have no evidence that the phenomenon described may have occurred with the product on the market, and therefore purely for precautionary purposes, we invite you to retrospectively review the negative results obtained in your Laboratory for the MG target with the product "STI PLUS ELITe MGB kit" .

Any samples that are negative for MG presenting a clearly positive reaction curve (with obvious fluorescence ramp) and negative baseline in the Track Report, must be considered positive samples for the MG target.

In the next weeks, we will contact you to update the Assay Protocols on the ELITe InGenius platforms in use at your laboratory. In the meantime, until the aforementioned update, we recommend you also to adopt in the future sessions the same verification suggested above for the retrospective analysis of the data.

We also ask you to inform us through our Technical Support team of any cases that present abnormal characteristics similar to those described in this document.

Our staff is available to provide further information and perform any checks following the sharing of analysis data.

You can contact the Technical Support at the following address: ingenius.support@elitechgroup.com.

ELITechGroup
EMPOWERING IVD

Further actions requested to customers

- Please complete the attached form (pag 4/4, last page of this notice) and send it back to **ELITech,** as confirmation of the receipt of this Safety Notice, by one of the modalities listed above:
    - the **fax number +39 011 936 76 11 (attn. Sergio FAZARI)**
    - e-mail **egspa.vigilance@elitechgroup.com**
    - direct delivery to the **local technical-commercial network**

- please retain a copy of this communication and forward it to anyone within the Laboratory who may be using the product object of this Notice.
- If deemed useful, provide additional information and comments regarding the experience with products similar to those covered by this Safety Notice.
-

FOR DISTRIBUTORS: a copy of this Notice has to be forwarded to any customers of yours who use the item(s) of interest.

This note has been sent to the Competent Authorities of the Countries where the product has been distributed.

We apologize for any inconvenience and we invite you to contact our local Technical Support or directly our Offices for clarifications.

Thank you for your collaboration.

Best Regards,

Sergio FAZARI
Quality Assurance & Regulatory Affair

ELITechGroup
EMPOWERING IVD

"Safety Notice Confirmation of Receipt" form

Field Safety Notice nr: **FSN 19/01-ENG**

Product Description: **STI-PLUS ELITe MGB kit**

Product Ref. **ref. RTS400ING**

Batch or Product S/N **NA**

Field Safety Notice Object: **Possible error in result interpretation obtained with the *Mycoplasma genitalium* (MG) target of the STI PLUS ELITe MGB® Kit product in association with the *ELITe InGenius®* instrument.**

We kindly ask you to fill this form and to return it to ELITech by one of the modalities listed above:

- **fax number +39 011 936 76 11 (c.a. Sergio FAZARI)**
- e-mail **egspa.vigilance@elitechgroup.com**
- direct delivery to the **local technical-commercial network**

The return of this form certifies that you received the above Field Safety Notice and that you have understood its contents including any requested actions.

FOR DISTRIBUTORS: in addition to what is written above, the return of this form from you, certifies also that you have forwarded this Notice to any customers of yours who use the item(s) of interest

ADDITIONAL INFORMATION AND COMMENTS FROM THE CUSTOMER

_____

_____

_____

Customer_____ Signature_____

Stamp_____ Date_____/_____/_____

Company and City_____