

Circular Informativa

N.º 113/CD/550.20.001

Data: 30/06/2020

Assunto: **GeneFinder COVID-19 Plus RealAmp Kit**

Para: Divulgação geral

Contacto: Centro de Informação do Medicamento e dos Produtos de Saúde (CIMI); Tel. 21 798 7373;
Fax: 21 111 7552; E-mail: cimi@infarmed.pt; Linha do Medicamento: 800 222 444

Durante a utilização do teste de biologia molecular (RT-PCR) que deteta o RNA do vírus SARS-CoV-2 **GeneFinder COVID-19 Plus RealAmp Kit** do fabricante **OSANG Healthcare Co, Ltd.** verificou-se um elevado sinal de fundo (*background noise/signal*) na reação de amplificação do gene N nos lotes abaixo descritos.

Como consequência, se este sinal de fundo exceder o limiar de deteção e se os gráficos de amplificação não forem verificados, o resultado pode ser interpretado como resultado positivo (falso positivo).

Lotes
2004-R45-18
2004-R45-25
2004-R45-26
2004-R45-49

Este problema pode ocorrer com diferentes equipamentos: Applied Biosystems 7500/7500 Fast Dx (ThermoFisher), CFX96 (Bio-Rad) e ELITE InGenius (ELITechGroup SpA).

De forma a permitir a continuidade da utilização destes lotes, o fabricante elaborou a informação, em anexo, destinada aos utilizadores com um conjunto de ações de corretivas a efetuar nos equipamentos.

Salienta-se que os utilizadores devem ainda verificar o diagrama de fluorescência fornecido pelo equipamento antes de validar os resultados finais do teste.

Em Portugal não foi notificado ao Infarmed qualquer problema semelhante com este teste.

Quaisquer incidentes ou outros problemas relacionados com estes dispositivos médicos para diagnóstico *in vitro* devem ser notificados à Unidade de Vigilância de Produtos de Saúde do Infarmed através dos contactos: tel.: +351 217 987 145; fax: +351 211 117 316; e-mail: dvps@infarmed.pt.

O Vice-Presidente do Conselho Diretivo

(António Faria Vaz)

ANEXO

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



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

Torino, 26/05/2020

TECHNICAL NOTE

OBJECT: Possible background noise for some production lots of the "GeneFinder™ COVID-19 Plus RealAmp Kit".

Dear Customer,

ELITechGroup SpA, distributor of the product "GeneFinder™ COVID-19 Plus RealAmp Kit" - ref. IFMR-45 (produced by OSANG Healthcare Co., Ltd. - South Korea) has received in the last days some reports related to this product.

The reports are related to the production lots numbers shown below:

2004-R45-18

2004-R45-25

2004-R45-26

2004-R45-49

According to our database you may have recently received units of these lots.

Use of products

The products belonging to the lots concerned result to maintain their performance and safety characteristics unchanged, and are NOT subject to any recall, they must be used in any case with the measures described below.

Description of the phenomenon

The phenomenon was associated with the appearance of a high background signal with the amplification reaction of the "N gene".

This has been detected on different types of platforms: **Applied Biosystems 7500/7500 Fast Dx (ThermoFisher), CFX96 (Bio-Rad) and ELITe InGenius (ELITechGroup SpA).**



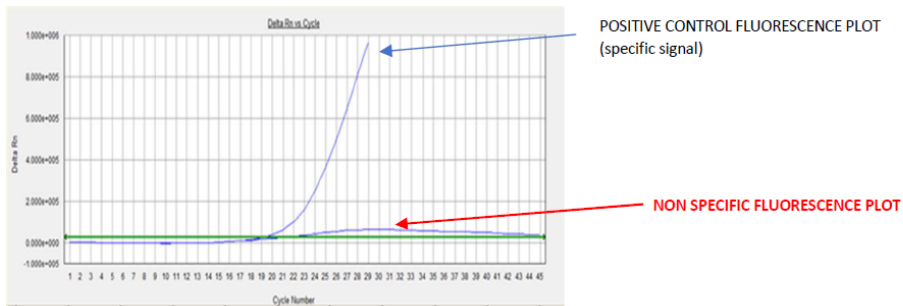
ELITechGroup S.p.A. (con unico socio)
Società soggetta a direzione e coordinamento da parte di ELITechGroup S.a.S.
Capitale Sociale € 1.000.000,00 i.v. Iscritta nel registro delle imprese di Milano
C.F.P.IVA e n° di iscrizione 05239350969 – R.E.A. 1805944

Inviare tutta la corrispondenza alla sede Amministrativa di Torino

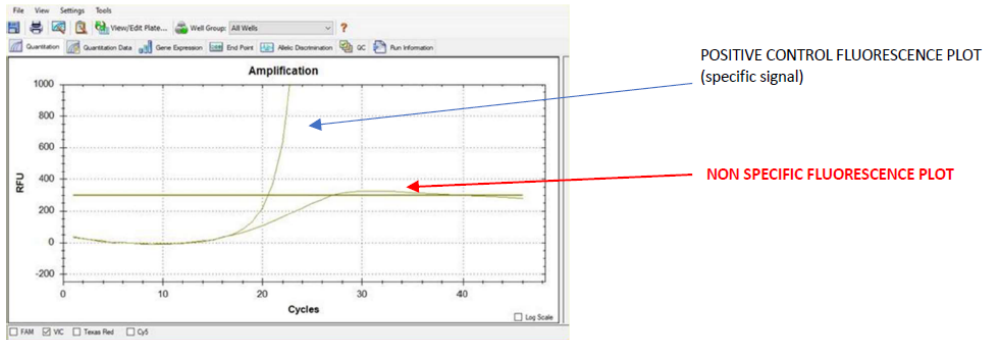


Examples

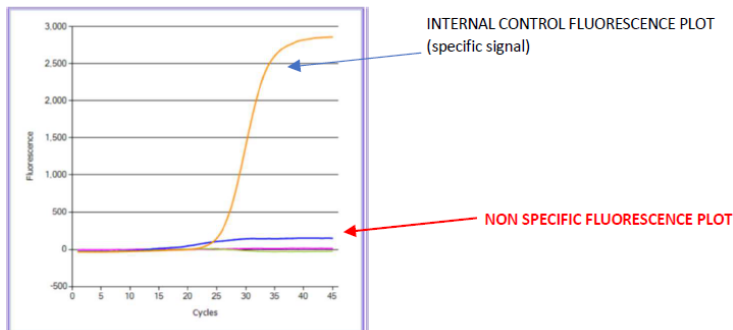
Below are some examples of non-specific fluorescence signals due to "high background found" on different equipment.



Non-specific amplification signal trace on Applied Biosystem 7500 Fast Dx



Non-specific amplification signal trace on CFX96



Non-specific amplification signal trace on ELITE InGenius

Possible Consequences

This background signal, higher than normal, if exceeds the detection threshold and if the amplification graphs are NOT checked, may be interpreted as a positive result.

The Mitigation

For Applied Biosystems 7500/7500 Fast Dx, CFX96 (Bio-Rad) users

A new Assay Protocol has been developed by OSANG Healthcare Co. Ltd. which raises the detection threshold to avoid interference from any non-specific/background signals. Based on internal verification, the sensitivity is not affected by this change.

For the analysis of the tests performed by the products belonging to the production batches shown on the first page of this document, it is recommended to change the threshold values as shown below.

Target	Before				Target	After			
	Threshold		Baseline			Threshold		Baseline	
	ABI	CFX96	Start	End		ABI	CFX96	Start	End
RdRp gene	30,000	300	3	15	RdRp gene	30,000	300	3	15
N gene	30,000	300	3	15	N gene	100,000	1,000	3	15
E gene	30,000	300	3	15	E gene	30,000	300	3	15
IC	10,000	100	3	15	IC	10,000	100	3	15

For ELITE InGenius users

A new Assay Protocol has been developed by the ELITechGroup team that raises the detection threshold to avoid interference from any non-specific/background signals. Based on an internal verification, the sensitivity is not affected by this change.

The new Assay Protocol is currently being installed on ELITE InGenius platforms. If this has not already happened, you will be contacted by authorized ELITech personnel shortly.

Final Conclusions and recommendation

Any user of the "GeneFinder™ COVID-19 Plus RealAmp Kit" product is recommended to check the fluorescence diagram provided by the instrument before validating the final test results.

Current situation

ELITechGroup SpA and OSANG Healthcare Co., Ltd. are working closely together to resolve the issue once and for all and to reduce the possibility that the episodes detected, even if sporadic, may occur again.

Our distribution and technical support network will keep you informed on the developments of the situation.

Best Regards

Distributor

ELITechGroup SpA

QARA Mngr

Sergio Fazari


01/06/2020

Manufacturer

OSANG Healthcare Co., Ltd.

Quality Management Director

Ik-Hyeon Kim


1 / 06 / 2020