

Ref: VIG-05-2021-01

Lisses, on 31 May 2021

To the attention of: Directors of Health Establishments
Persons in charge of Laboratories
Local Correspondents of Vigilance

RE: INFORMATION / RECOMMENDATION
CAPI 3 IMMUNOTYPING (product number 2600)
Batch numbers : 04021/01 - 04021/02
Expiry date : 2023/01

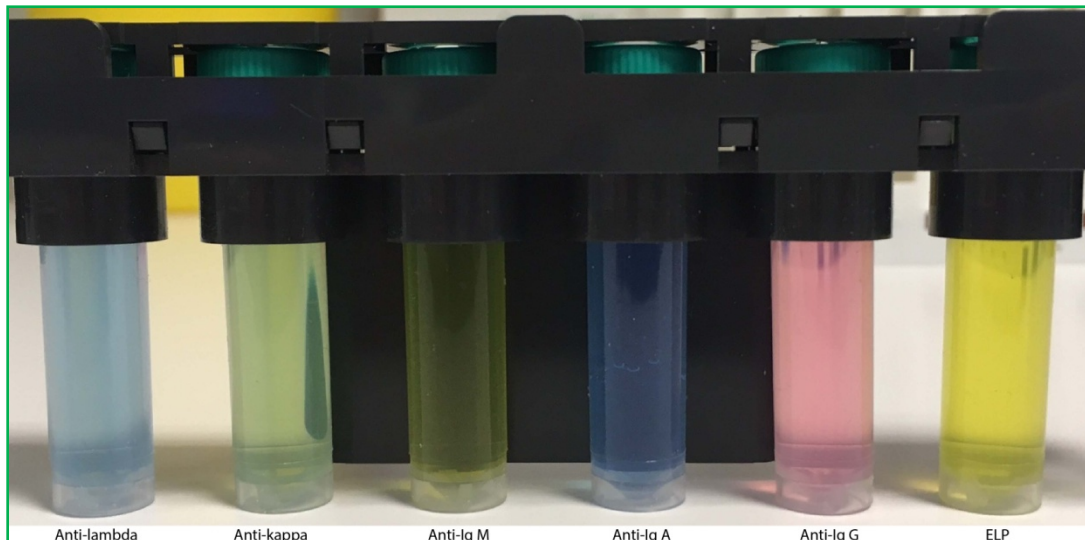
Dear Sir / Madam,

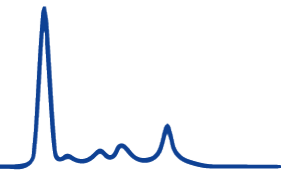
Some users had highlighted an inversion between anti-Ig G and anti-Ig A on some of these kits. Our investigations revealed a human error in the packaging of these kits.

Our traceability indicates that you are a user of these batch numbers, therefore, we kindly ask you to:

1. Check that the kits in your possession are conform (see photos below), if they do not, please specify the number of kits which must be resent to you and return or destroy the affected kits.

Compliant configuration:



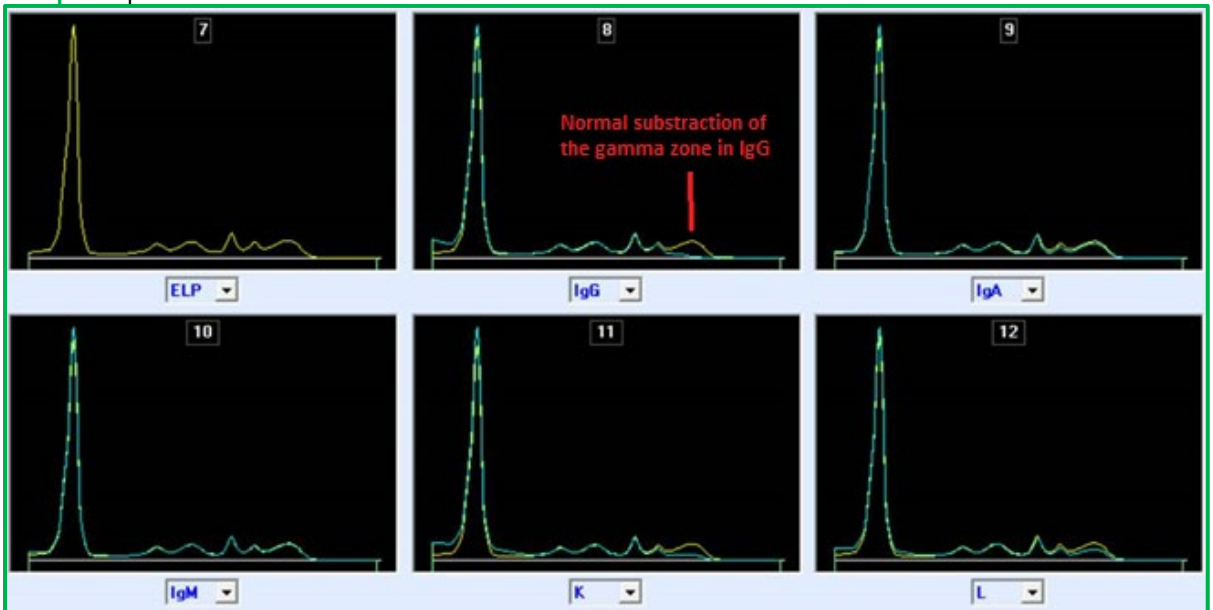


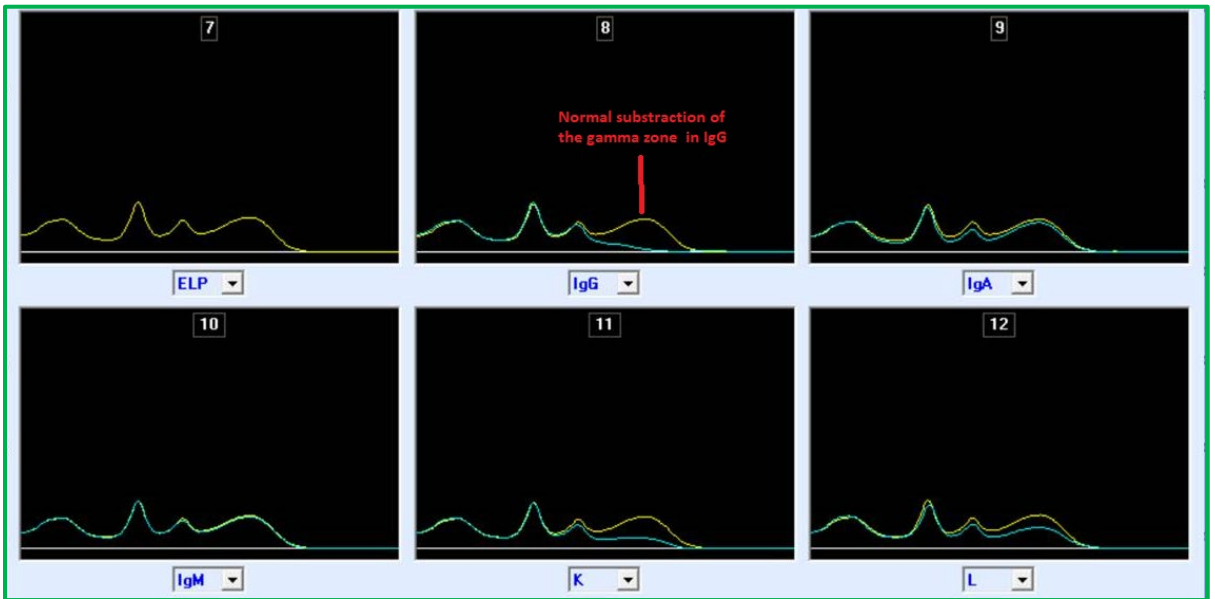
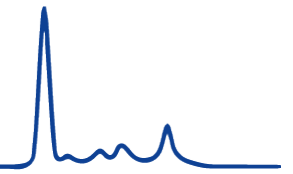
Non compliant configuration:



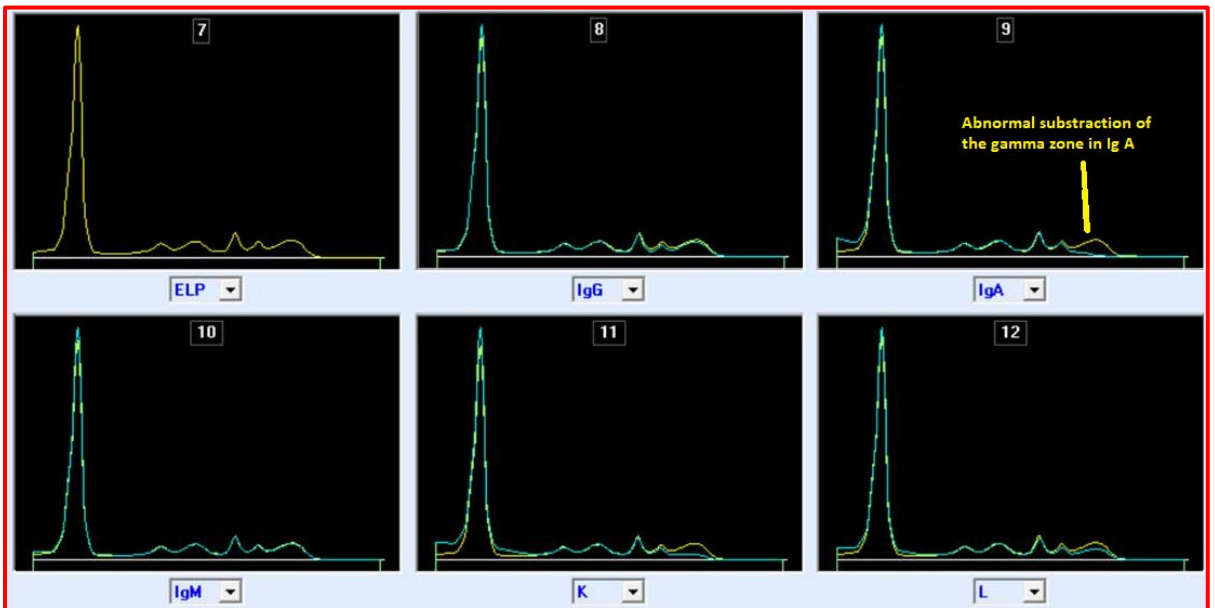
2. If you have used the kits concerned, check if the profiles obtained with these kits are compliant.

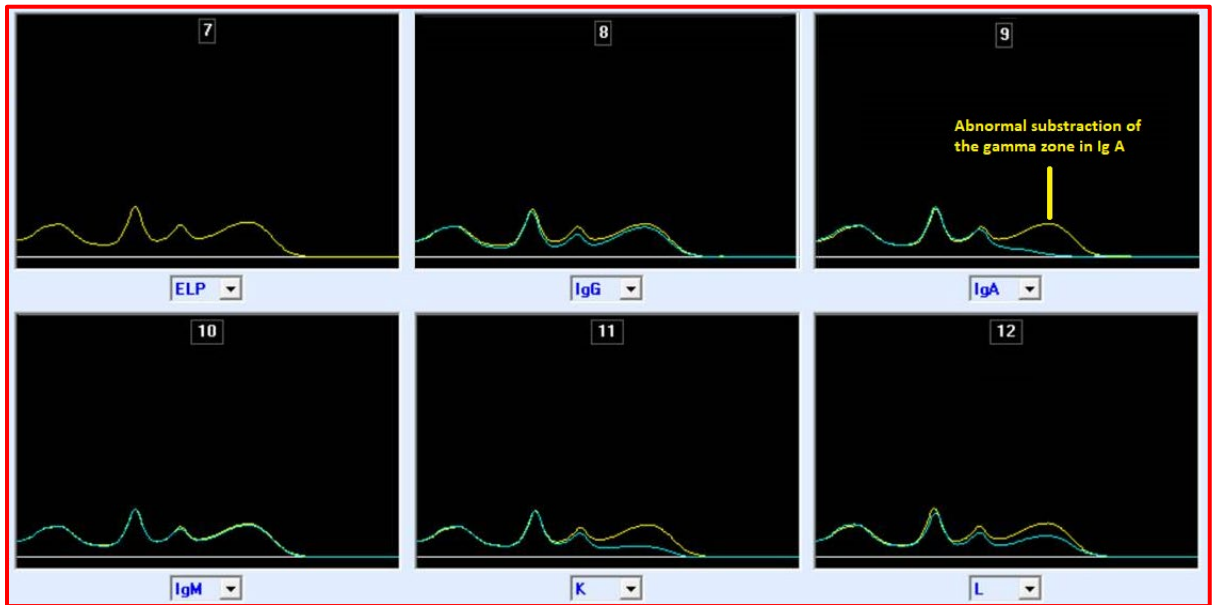
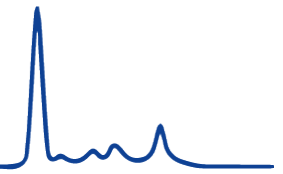
Compliant profiles :





Non-Compliant profiles :





3. Fill-in the enclosed form, precisely indicate the number of non-compliant kits in your possession or used and if necessary, fill in the destruction form. Send us back all the forms by e-mail.

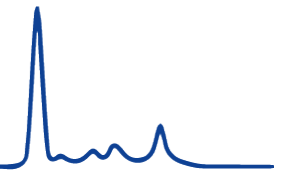
The French Health Products Safety Agency (ANSM) has been informed about this communication.

Please do not hesitate to call your local SEBIA contact for further information.

We apologize for any inconvenience caused and we thank you for your confidence in Sebia.

Yours sincerely,

A. Collin
Vice President Global Regulatory Affairs & Quality



INFORMATION CERTIFICATE
CAPI 3 IMMUNOTYPING (product number 2600)
Batch Numbers: 04021/01 - 04021/02
Expiry date: 2023/01

Please fill out this document and return it to us upon reception

Laboratory Stamp (mandatory)

We certify, Madam, Mister.....

- To have taken knowledge of the mail "VIG-05-2021-01".

- To have checked the concerned kit(s) and/or to have checked the profiles obtained with the concerned kit(s) at receipt of this mail.

Number of returned **non-compliant** kits :

Number of destroyed **non-compliant** kits :

(Place) _____, (Date) _____

Signature :

SEBIA Parc technologique Leonard de Vinci CP 8010 91008 EVRY CEDEX FRANCE	Tél.: + 33 1 69 89 80 80 E-mail: sebia@sebia.com
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