

Ref: VIG-08-2021-01

Lisses, on 25 August 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 : 11021/01 - 11021/02
Expiry date : 2023/01 – 2023/02

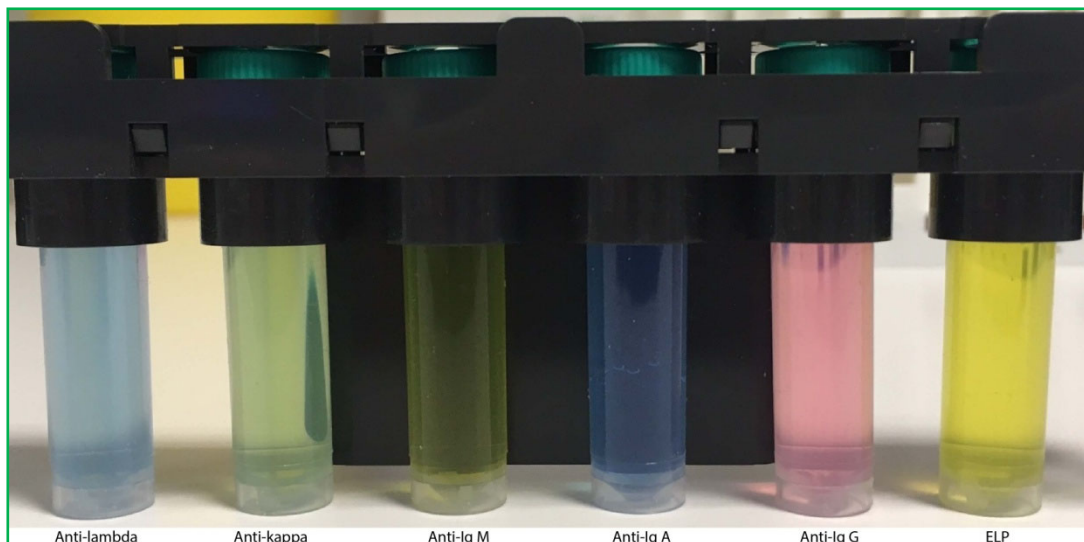
Dear Sir / Madam,

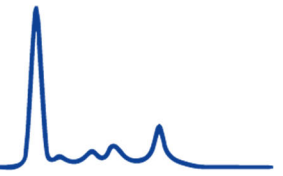
We inform you that a user of these kits highlighted an inversion between the anti-Ig A and anti-Ig M antisera. Our investigations revealed a human error in the packaging flow of these kits, an additional control step has been implemented for a few months in order to mitigate this risk. The concerned batches have been distributed before the new packaging set-ups. It is likely that this inversion affects only very few kits within these batches.

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

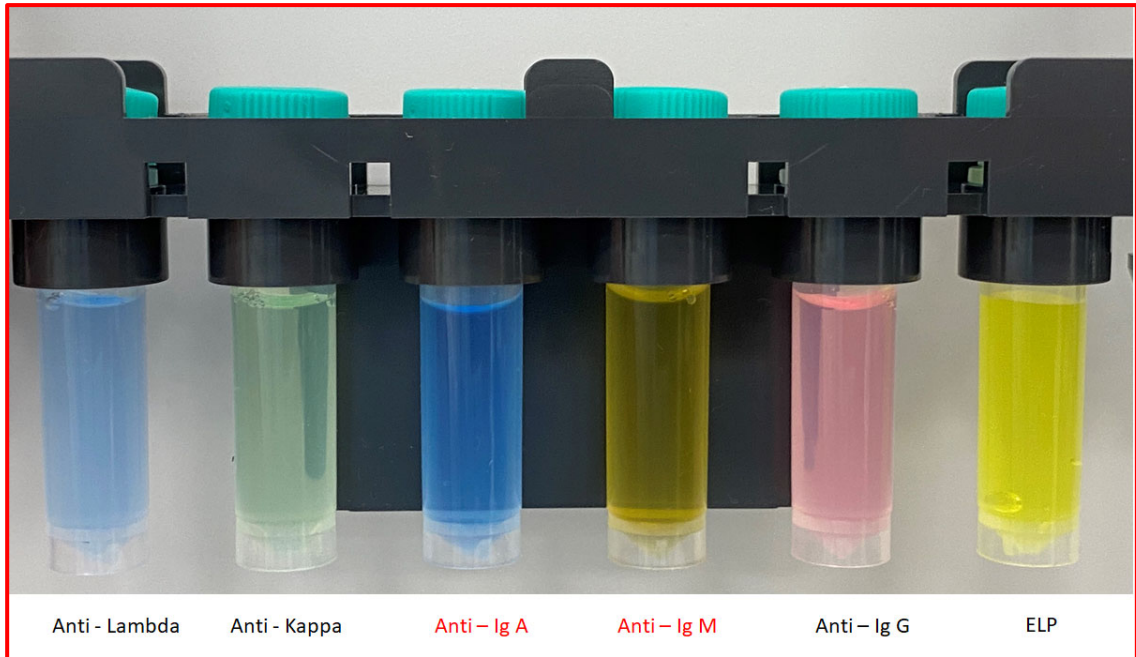
1. Check that the kits in your possession are compliant (see photos below), if they do not, please specify the number of kits which must be resent to you and return or destroy the affected kits.

Compliant configuration:





Non compliant configuration:

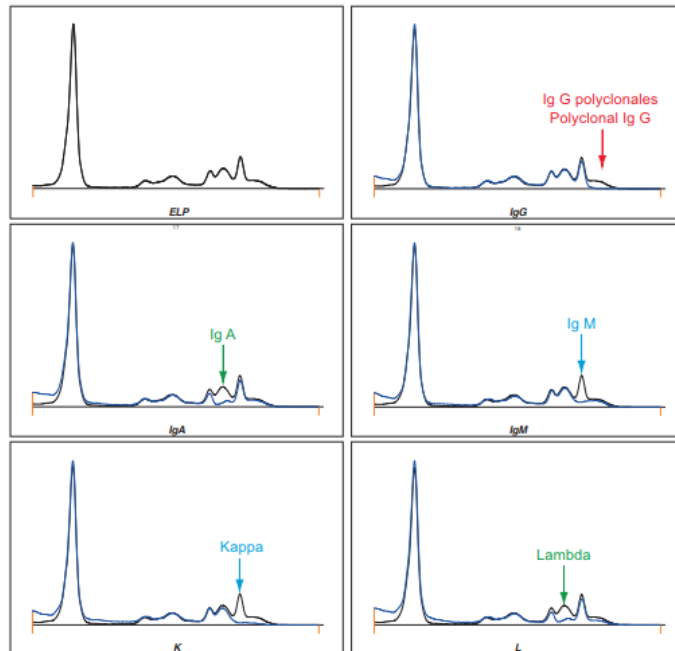


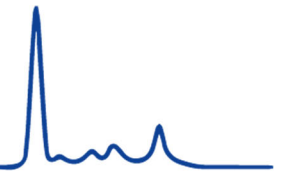
2. If you have used the kits concerned :

- (a) Check that the IT / IF Control profiles obtained with these kits are compliant, by comparing them with the image given in the control instructions for use.

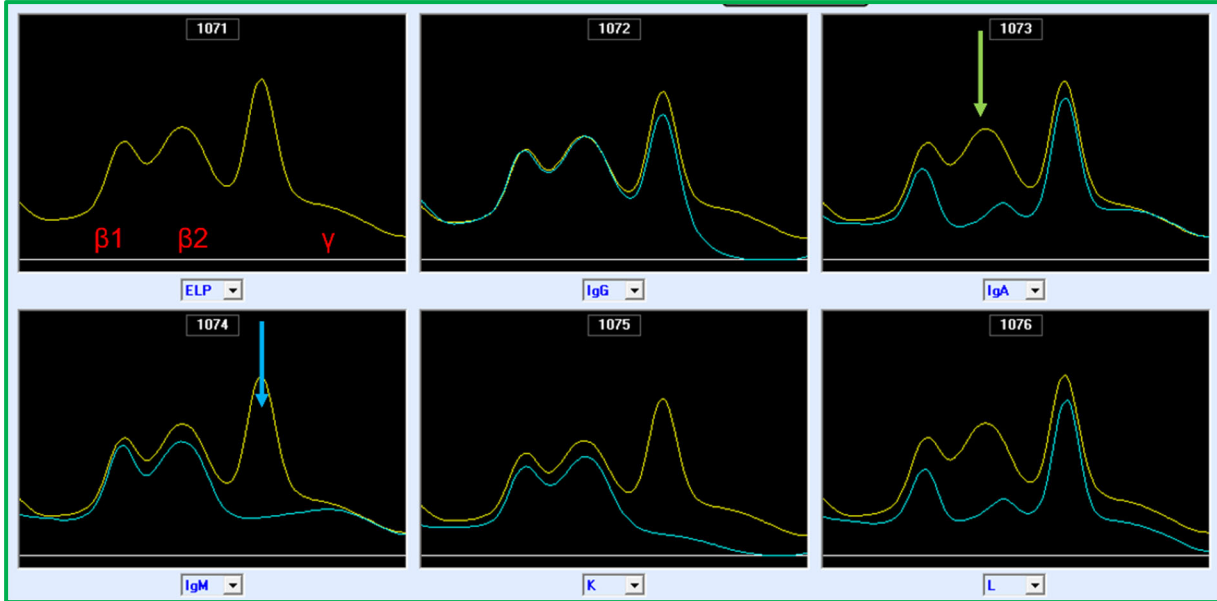
Example with IT / IF Control lot 22011/01

Reference Image:

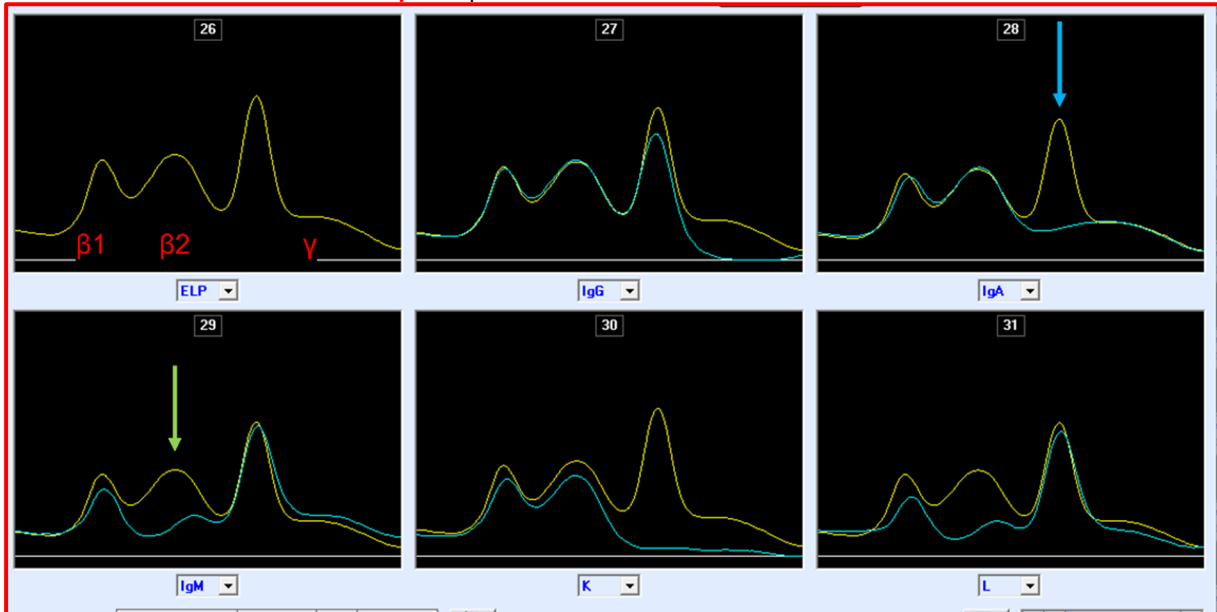


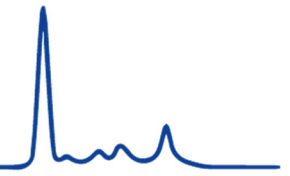


IT / IF Control lot 22011/01 **compliant** profiles:



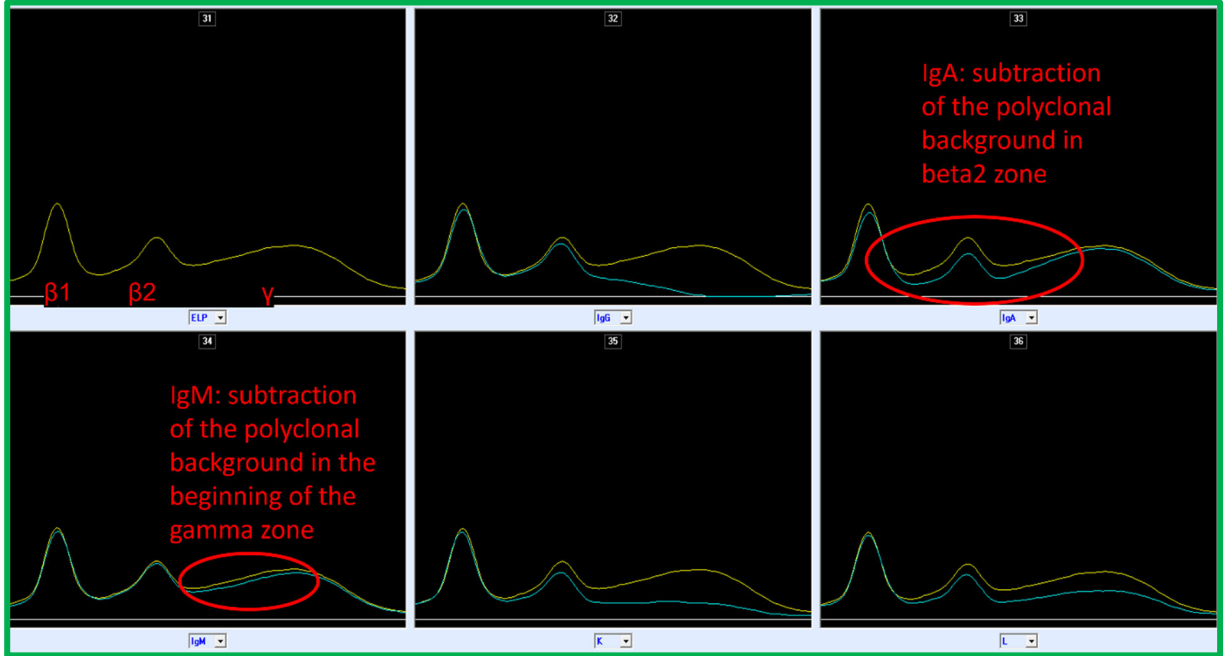
IT / IF Control lot 22011/01 **non-compliant** profiles:



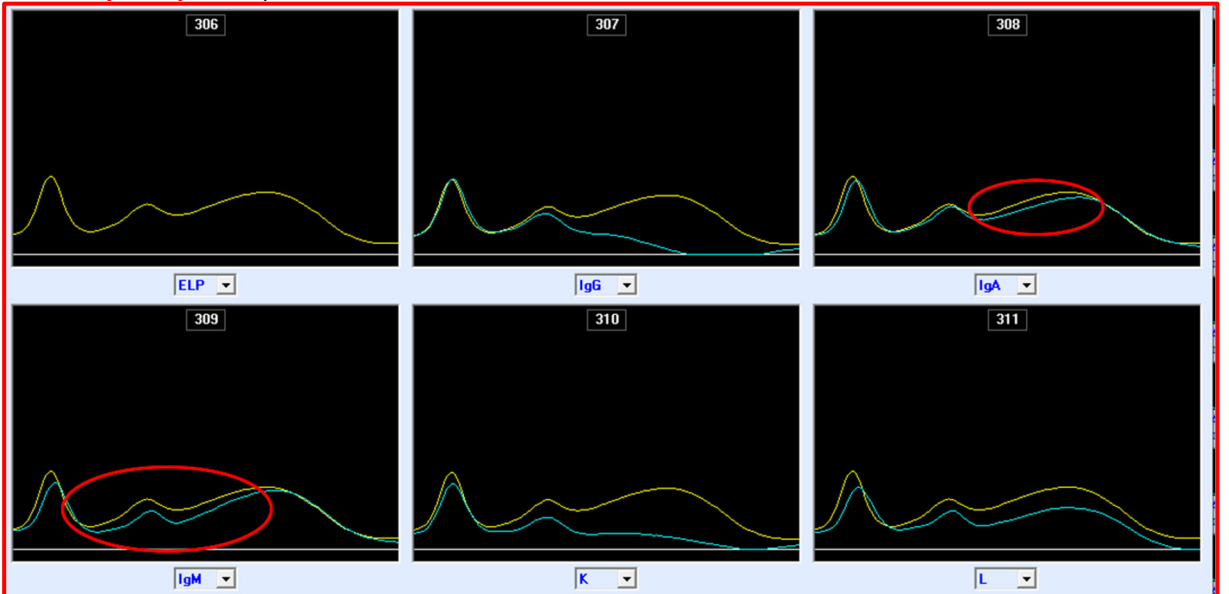


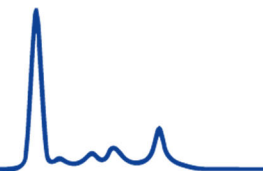
(b) If you are not using the IT / IF Control, check the compliance of the profiles by observing the subtraction of the polyclonal background in IgA and IgM on patient samples:

Compliant patient profiles:



Non-compliant patient profiles :





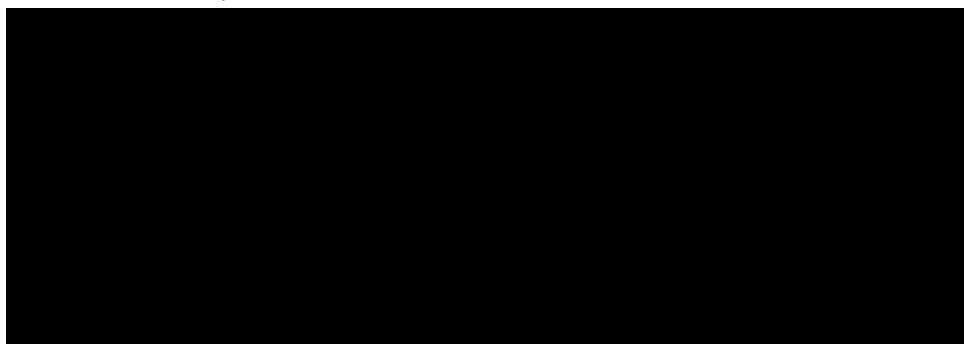
3. Fill-in the enclosed form, precisely indicate the number of non-compliant kits in your possession or used and if necessary, fill in the destruction form. Send back all the forms by e-mail to your local SEBIA contact.

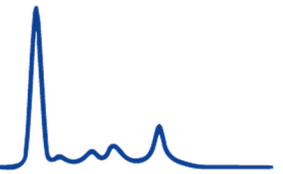
The French Health Products Safety Agency (ANSM) has been informed about this communication.

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,





INFORMATION CERTIFICATE
CAPI 3 IMMUNOTYPING (product number 2600)
Batch Numbers: 11021/01 - 11021/02
Expiry date: 2023/01 – 2023/02

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-08-2021-01".

- 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.

Total number of kit (s) lot 11021/01 and 11021/02 in stock or used:

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

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

(Place) _____, (Date) _____

Signature :

