

Ref: VIG-02-2022-01

Lisses, on 04 February 2022

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

RE: URGENT SAFETY NOTICE
CAPI 3 IMMUNOTYPING (product number 2600)
Batch number : 18111/01
Expiry date : 2023/10

Dear Sir / Madam,

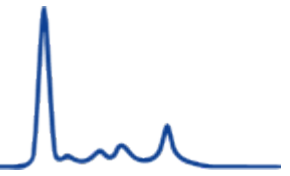
We inform you that a user of these kits highlighted an inversion between the anti-Ig M and anti-Lambda antisera. Our investigations revealed a human error in the packaging flow of these kits, corrective actions have already been implemented to mitigate this risk. It is likely that this inversion affects only very few kits within this batch.

Our traceability indicates that you received this batch number in December, therefore, we kindly ask you to:

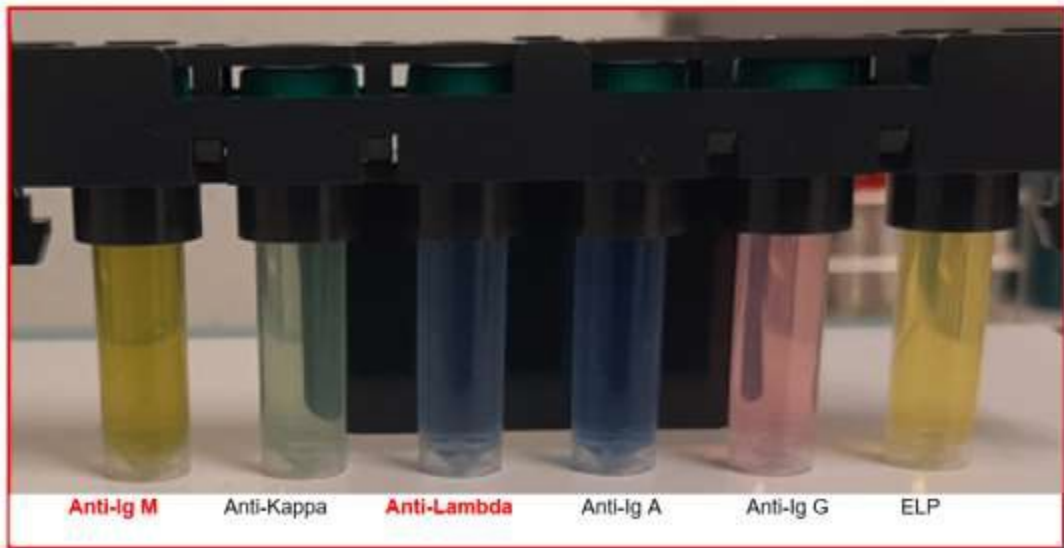
1. Check that the kits in your possession are compliant (see photos below)

Compliant configuration:





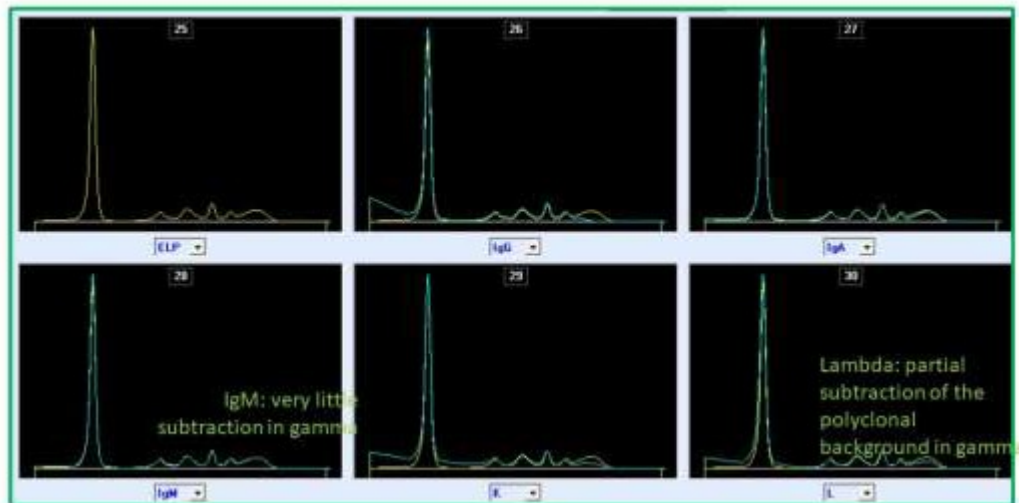
Non compliant configuration:

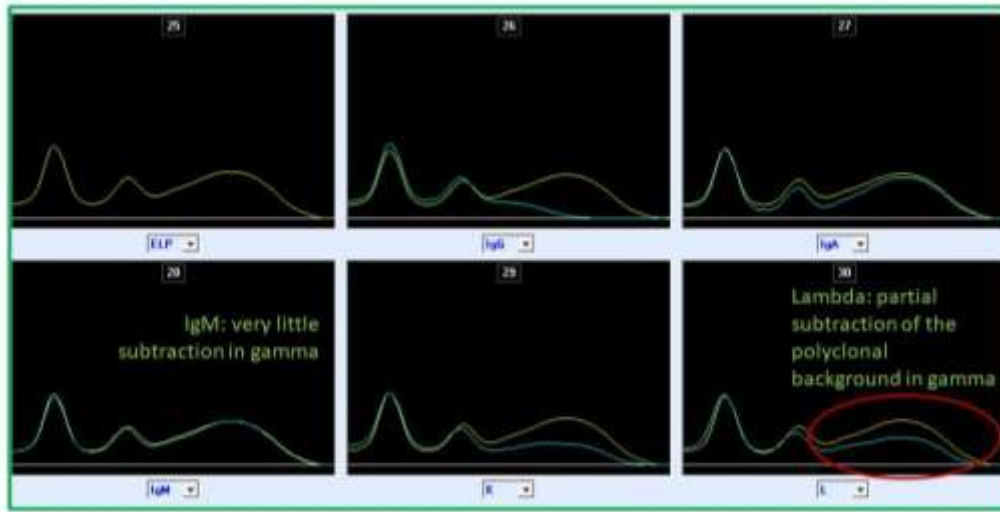


After checking the kits in your possession, **if the kits have the correct configuration, they can be used without prior action, and without any risk.**

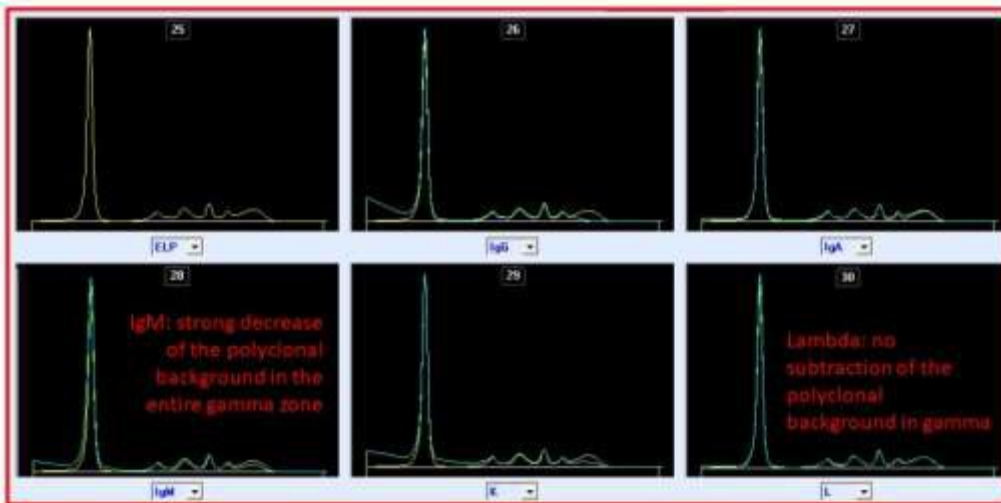
2. If you have used the kits concerned, check if the profiles obtained with these kits are compliant on a sample without significant anomaly.

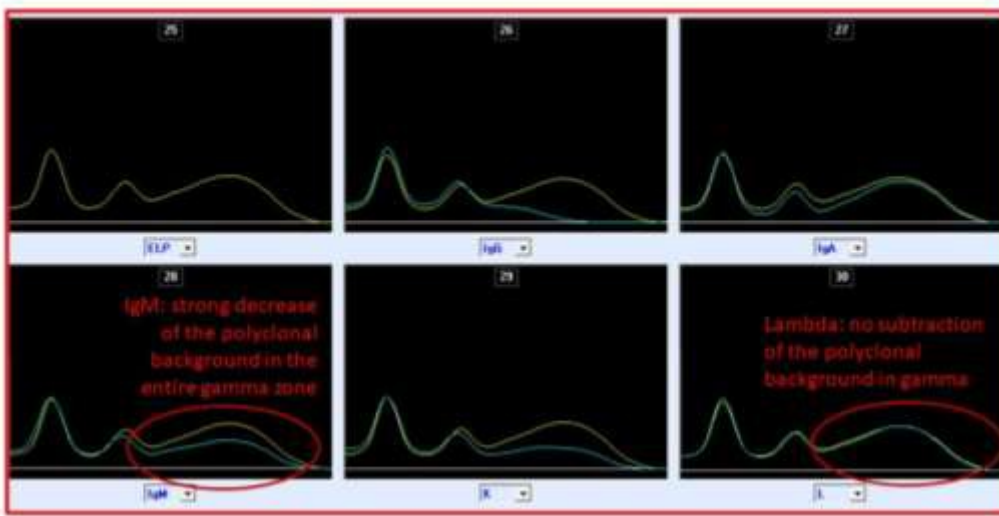
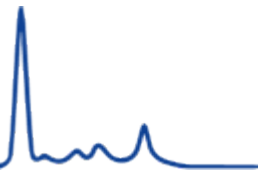
Compliant profiles :





Non-compliant profiles :





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

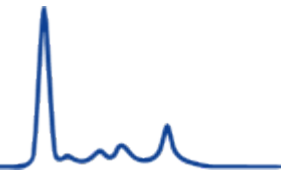
The National authority has been informed about this communication.

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,

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INFORMATION CERTIFICATE
CAPI 3 IMMUNOTYPING (product number 2600)
Batch Number: 18111/01
Expiry date: 2023/10

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-02-2022-01".

- 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 18111/01 received (in stock or used):

Number of **defective kits lot 18111/01** (in stock or used):

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

(Place) _____, (Date) _____

Signature :

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