

Ref: VIG-02-2023-02

Lisses, the 27th of February 2023

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

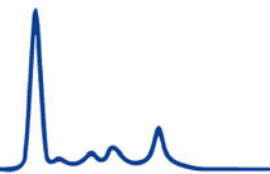
RE: INFORMATION / RECOMMENDATION
CAPILLARYS IMMUNOTYPING (product number 2100)
Batch number: 13042/ 14
Expiry date: 2024/04

Dear Sir / Madam,

We inform you that a user of these kits observed that some antisera segments (= strips) from this specific batch number were lacking the buffer for analysis called ELP solution.

The antisera segments are ready to use; each segment is intended to run one sample. They have 7 wells, each well contains respectively:

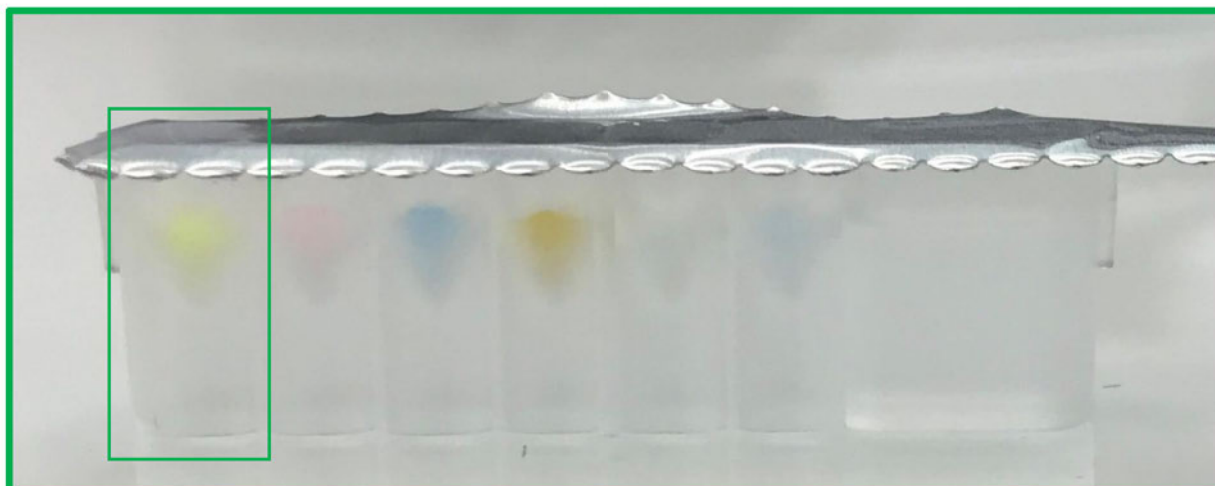
- **a buffer for analysis (ELP solution, yellow),**
 - mammalian immunoglobulins anti-human gamma heavy chains (pink),
 - mammalian immunoglobulins anti-human alpha heavy chains (dark blue),
 - mammalian immunoglobulins anti-human mu heavy chains (yellow green),
 - mammalian immunoglobulins anti-human kappa (free and bound) light chains (light green),
 - mammalian immunoglobulins anti-human lambda (free and bound) light chains (light blue)
- a specific diluent for sample dilution.



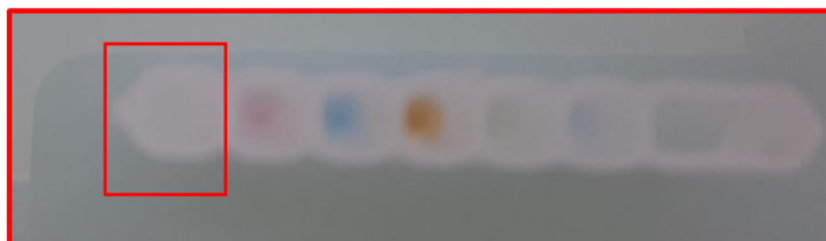
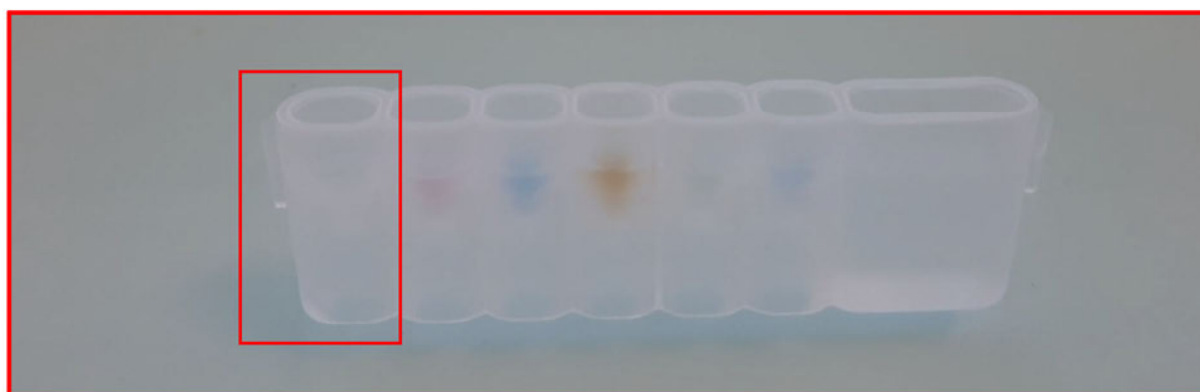
After an initial investigation, we believe that this default is linked to a cellophane issue during manufacturing.

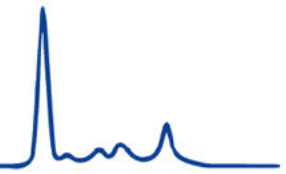
This default is not systematic and can be detected visually as shown in the pictures below:

Compliant antisera segment



Non compliant antisera segment





If the abnormality is not visually detected by the user prior to the analysis, this default does not generate any patient risk as, in the absence of the ELP solution, the superimposition of the antisera patterns with the ELP pattern cannot occur. A rerun of the sample is needed.

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

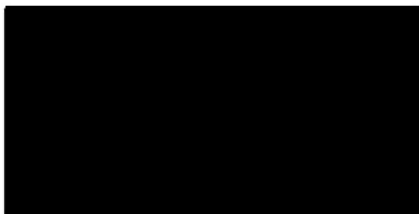
1. Check inside each kit in your possession that the segments are all compliant (ELP solution present – yellow color and volume like the other wells). **If the ELP solution is present, they can be used without prior action, and without any risk.**
2. If the ELP solution is absent, please destroy the segments. Sebia will then replace them as needed.
3. Fill-in the enclosed form, precisely indicate **the number of non-compliant segments (in your possession)** 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.

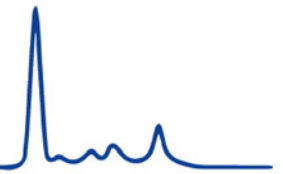
Please do not hesitate to call your local SEBIA contact for further information.

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

Yours sincerely,



Vice President Global Regulatory Affairs & Quality



INFORMATION CERTIFICATE

CAPILLARYS IMMUNOTYPING (product number 2100)

Batch Numbers: 13042/14

Expiry date: 2024/04

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-02-2023-02".

To have checked the concerned kit(s)

Total number of kit (s) lot 13042/14 in stock :

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

(Place) _____, (Date) _____

Signature :

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