

Ref: VIG-03-2023-03

Lisses, the 23rd of March 2023

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

RE: **INFORMATION / RECOMMENDATION**
A1AT CONTROLS (product number 4771)
Batch number: 28022/01 and 28022/02
Expiry date: 2024/07

Dear Sir / Madam,

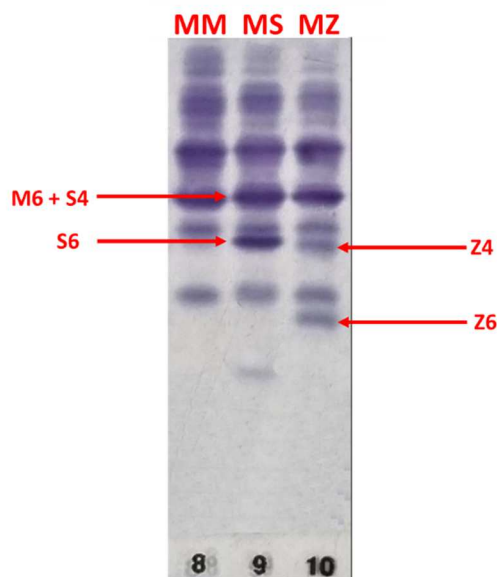
We inform you that a user of these kits observed a labelling inversion between the two pathological controls MS and MZ. The MS vials has the labelling of the MZ one and vice versa.

This labelling inversion concerns two lots of A1AT controls kits:

- 28022/01 (contains MM lot: 28022/01, MS lot: 02032/01 and MZ lot: 01032/01)
- 28022/02 ((contains MM lot: 28022/02, MS lot: 02032/02 and MZ lot: 01032/02)

As a reminder, as described in the package insert of the A1AT CONTROLS, the A1AT Controls are designed for the migration control of the human Alpha-1 antitrypsin isoforms pattern obtained with HYDRAGEL 18 A1AT ISOFOCUSING* isoelectric-focusing procedure. The A1AT Controls should be used as human sera.

Despite, the labelling inversion of the two pathological controls (MS and MZ), the three controls (MM, MS and MZ) migrate as expected and provide the three phenotypes needed M, S and Z (see example of gel below):



Based on the availability of the three controls phenotypes, there is no expected impact on patient results.

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

1. Destruct or return to Sebia all remaining kits of AIAT controls of the incriminated lots in your possession.
2. Fill-in the enclosed form, precisely indicate **the number of kits in your possession, the number of kits destroyed or returned to Sebia**. 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,

Arnaud COLLIN

Vice President Global Regulatory Affairs & Quality

INFORMATION CERTIFICATE

AIAT CONTROLS (product number 4771)

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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-03-2023-03".

☐ To have checked the concerned kit(s)

Total number of kit (s) lot 28022/01 and/or 28022/02 in stock:

Number of destroyed kits:

Number of kits returned to Sebia:

(Place) _____, (Date) _____

Signature :

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