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From: Marc BORENSZTEJN
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DIAGNOSTICA STAGO
3 allée Thérésa
92665 ASNIERES SUR SEINE
FRANCE

To: Yi-Tee LIM
ALL EIGHTS PTE LTD – SINGAPORE

Date: Asnieres, October 17, 2017

Reference: RC-17-0019

URGENT – FIELD SAFETY NOTICE
Néoplastine® CI Plus ② (ref. 00374)
Néoplastine® CI Plus ⑤ (ref. 00375)
STA - Néoplastine® CI ⑤ (ref. 00605)
STA - Néoplastine® CI Plus ⑤ (ref. 00606)
See list on appendix 02

Number of pages including this one: 2 + 4 enclosed documents

Dear Distributor,

According to our records, you or your customers have received one or several kits of reagents (lots listed on appendix 02).

This letter contains specific instructions for use of these lots and further information about this Field Safety Notice.

✓ **Identification and description of the defect:**

Following a customer complaint, Stago has investigated and confirmed a defect of homogeneity within lot for lots listed on appendix 02.

Some reagents vials will give prolonged Prothrombin Time (decreased PT %) and it will affect both Quality Control and patients plasmas
The defect is easy to detect since **the Quality Control values are outside their ranges in time and/or in percentage**.

The root cause investigations have found the issue is a vial manufacturing problem which can result in an inconsistent seal of the vial and therefore may compromise the contents

Internal investigations have shown that the occurrence of the defect within lot is low (average of 2% of the vials). On a defective vial, clotting times are longer with an average of 13% on a normal plasma and 26% on abnormal plasma.

✓ **Actions :**

We are asking you to:

☐ **To stop sending lots listed on appendix 02 and, if necessary, to destroy your remaining kits according to current local regulations.**

- ☐ **To inform all your affected customers about the issue and the specific instructions for use (run a Quality Control test at every change of vial). For this purpose, please find enclosed an information letter (*appendix 04*) and a coupon answer (*appendix 05*) to send them (or a strict translation).**

- ☐ **To return to us, by fax or e-mail, the enclosed form (*appendix 03)*, completed and confirming that you have read this letter (once all the concerned users have been informed and acknowledged receipt of this Field Safety Notice) and a certificate of destruction established by an approved organisation.**

The Competent Administrative Authority of the country of origin (France) has been informed.

We let you inform your Competent Administrative Authority about this issue if requested by your current local regulations.

For additional information, please contact us.

Please accept our apologies for this inconvenience. We thank you in advance for your support.

Yours sincerely,

[redacted]

Marc BORENSZTEJN
Operational Director
Expertise & Qualification
Global Services & Assistance
Diagnostica Stago

Copy : Post Market Surveillance department

Reference: RC-17-0019

URGENT – FIELD SAFETY NOTICE

APPENDIX– LIST OF CONCERNED LOTS

DEVICES	REFERENCES	LOTS	EXPIRY DATE
Néoplastine® CI Plus ②	00374	115080	2018-01
		251241	2018-10
Néoplastine® CI Plus ⑤	00375	250080	2018-02
		251762	2019-02
		251940	2018-12
STA - Néoplastine® CI ⑤	00605	251064	2018-09
		251725	2019-02
STA - Néoplastine® CI Plus ⑤	00606	250041RX	2018-02
		250077	2018-02
		250246RU	2018-03
		251492	2018-09
		251308	2018-10
		251626	2019-01
		251730	2019-02
		251772	2019-02

Form to send back to Stago

by fax: +331.55.02.12.68

or

by e-mail: faxasa@stago.com

COUPON ANSWER – INFORMATION STATEMENT

Reference: RC-17-0019

URGENT – FIELD SAFETY NOTICE

Néoplastine® CI Plus ② (ref. 00374)
Néoplastine® CI Plus ⑤ (ref. 00375)
STA - Néoplastine® CI ⑤ (ref. 00605)
STA - Néoplastine® CI Plus ⑤ (ref. 00606)

See list on appendix

Name (in full):

Position:

Company:

Country:

☐ **I certify that I have read the Stago letter on 2017/10/17 about the instruction for use for lots listed on appendix.**

☐ **I have identified and contacted all my customers affected by this recall and I have informed them about the instructions for use.**

☐ **I have stopped the delivery of the concerned lots and I destroy my remaining stock. I note hereafter the quantity of kits destroyed:**

Reagent	Ref.	Lot	Number of concerned customers	Total number of boxes destroyed

☐ **I send to Stago a certificate of destruction established by an approved organization.**

Date:

Signature:

COUPON ANSWER – INFORMATION STATEMENT

Reference: RC-17-0019

URGENT – FIELD SAFETY NOTICE

Néoplastine® CI Plus ② (ref. 00374)
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STA - Néoplastine® CI ⑤ (ref. 00605)
STA - Néoplastine® CI Plus ⑤ (ref. 00606)

See list on appendix

Name (in full): .....
Position: .....
Company: .....
Country: .....

☐ **I certify that I have read the Stago letter on 2017/10/17 about the instruction for use for lots listed on appendix.**

☐ **I certify to have informed my colleagues about this Field Safety Notice.**

Date:

Signature:

For submission to the Head of Laboratory

(CITY), October 17th 2017

Reference: RC-17-0019

URGENT – FIELD SAFETY NOTICE
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STA - Néoplastine® CI Plus ⑤ (ref. 00606)
See list on appendix

Dear Madam, Dear Sir,

According to our records, you have received in your laboratory one or several kits of reagent (lots listed on appendix).

This letter contains specific instructions for use of these lots and further information about the defect.

✓ **Identification and description of the defect:**

Following a customer complaint, Stago has investigated and confirmed a defect of homogeneity within lot, for lots listed in the appendix.

Some reagents vials will give prolonged Prothrombin Time (decreased PT %) and it will affect both Quality Control and patients plasmas.
The defect is easy to detect since **the Quality Control values are outside their ranges in time and/or in percentage**.

The root cause investigations have found the issue is a vial manufacturing problem which can result in an inconsistent seal of the vial and therefore may compromise the contents
Internal investigations have shown that the occurrence of the defect within lot is low (average of 2% of the vials). On a defective vial, clotting times are longer with an average of 13% on a normal plasma and 26% on abnormal plasma.

If Quality Control are tested on each vial of reagent and if results are found within their ranges, there is no clinical risk for the patient.
Otherwise, as patient results are interpreted in a global clinical context, we leave at your discretion the decision to review previous patient results on a case by case basis.

✓ **Actions :**

If you have in your laboratory, any of the lots among those listed in the appendix, we are asking you to:

- **If it is not already done, run a Quality Control test at every change of vial.**
- **Return to your local distributor, by fax or e-mail, the enclosed form completed and confirming that you have read this letter.**

The Competent Administrative Authority of the country of origin (France) has been informed.

Your Competent Administrative Authority has also been informed regarding this issue. (**Japan +Taiwan VOIR PJ).**

For additional information, please contact your local distributor

Please accept our apologies for this inconvenience. We thank you in advance for your support.

Yours sincerely,