Diagnostica Stago S.A.S.
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Asnières, January 30, 2026

For the attention of the Head of Laboratory

Reference : RC-25-0050

FIELD SAFETY NOTICE

Product	Reference	Lots and UDI
STA Liatest D-Di Plus	00662	Refer to appendix lot list

Dear customer,

Based on our traceability records, you have received kits from one or more lots listed in the appendix. Accordingly, we are providing you with this Field Safety Notice. For further information, please see the details below.

✓ **Description:**

After receiving customer complaints, Stago conducted thorough investigations and confirmed the presence of a positive bias in D-Dimer measurements throughout the entire analytical range.

This bias affects the specificity values reported in the test's package insert. The recalculated specificity is 63.9% for Pulmonary Embolism (compared to 75.5% stated in the package insert) and 41.2% for Deep Vein Thrombosis (compared to 55.2% stated in the package insert).

The D-Di parameter is intended for use in conjunction with a clinical pretest probability (PTP) assessment model to exclude pulmonary embolism (PE) and deep venous thrombosis (DVT) in outpatients suspected of PE or DVT. An overestimated result close to the clinical threshold could induce additional medical imaging for the patient. Therefore, given the medical imaging performed, reviewing previous D-Di results from these lots is not required.

This bias does not affect the test's intended use. **Sensitivity and negative predictive value are unchanged. There is no risk of false negatives for suspected PE or DVT**.

Investigations have identified that the positive bias originates from a change in the internal D-Di standard implemented in April 2025. We are actively working to fix the issue and will update you as we make progress and plan next steps.

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✓ **Actions required:**

- As the intended purpose of the kit is to exclude PE and DVT, and its sensitivity and negative predictive value remain unchanged, **it is appropriate to continue utilizing the reagents.**

- Please complete, sign and return to your local representative the attached Acknowledgement Form by email, as directed on the form.

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

Your Competent Administrative Authority has also been notified regarding this matter

For further information, a Frequently Asked Questions document is provided in Appendix 2 to this letter.

For additional information, please reach out to your local contact.

We apologize for any inconvenience this may have caused and appreciate your continued trust. Please rest assured that maintaining the quality of Stago products remains our highest priority and is subject to continual review and improvement

Yours sincerely,

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Appendix 1 : Field Safety Notice RC-25-0050

LIST OF AFFECTED LOTS

Product Code	Product Name	Lot Number	UDI
00662	STA LIATEST D-DI PLUS	272627	(01)03607450006629(11)250212(17)260430(10)272627(241)00662
00662	STA LIATEST D-DI PLUS	272742	(01)03607450006629(11)250225(17)260531(10)272742(241)00662
00662	STA LIATEST D-DI PLUS	273170	(01)03607450006629(11)250402(17)260731(10)273170(241)00662
00662	STA LIATEST D-DI PLUS	273171	(01)03607450006629(11)250401(17)260731(10)273171(241)00662
00662	STA LIATEST D-DI PLUS	273230	(01)03607450006629(11)250415(17)260731(10)273230(241)00662
00662	STA LIATEST D-DI PLUS	273468	(01)03607450006629(11)250513(17)260831(10)273468(241)00662
00662	STA LIATEST D-DI PLUS	273518	(01)03607450006629(11)250521(17)260831(10)273518(241)00662
00662	STA LIATEST D-DI PLUS	273711	(01)03607450006629(11)250624(17)260930(10)273711(241)00662
00662	STA LIATEST D-DI PLUS	274217	(01)03607450006629(11)251001(17)270131(10)274217(241)00662

Note : Lots beyond 274217 will be also affected.

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Appendix 2 : Frequently Asked Questions

Question	Answers (for customers – laboratories)
Why is Stago issuing a recall for its D-Dimer kits?	Following customer complaints and investigations, Stago has confirmed the presence of a positive bias in D-Dimer measurements with the batches concerned. This bias affects the specificity values currently indicated in the package insert (section §14 "Clinical Performance"). The purpose of this communication is therefore to inform and update the performance information associated with the product.
What type of recall is this?	This is an "information" recall. The products can still be used, but we would like to inform you that the specificity data must be adjusted following complaints and confirmation of a positive bias.
Which products and batches are affected?	• STA Liatest D-Di Plus (ref. 00662) batches 272627, 272742, 273170, 273171, 273230, 273468, 273518, 273711, 274217. Until further notice, future production will also be affected by this positive bias.
What is the nature of the problem detected?	A positive bias is observed in D-Dimer results across the entire measurement range. This bias can be up to +31.4% compared to batches without this bias. According to our tests, this bias corresponds to the maximum bias in the cut-off range. Given the inherent batch-to-batch variability of the product, this bias may be lower. However, we prefer to inform our customers based on the maximum case from our internal tests.

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<table>
<tr><td>Has the cause of the detected problem been identified?</td><td>Investigations have shown that the positive bias stems from a change in the internal D-Di standard implemented in April 2025.</td></tr>
<tr><td>What is the impact of this bias on the clinical performance- s of the test?</td><td>The documented impact is a decrease in specificity compared to the values indicated in the package insert (§14). The recalculated values (based on the maximum bias) are: 63.9% for pulmonary embolism (PE) (vs. 75.5% in the package insert) and 41.2% for deep vein thrombosis (DVT) (vs. 55.2% in the package insert). However, sensitivity and negative predictive value (NPV) are not affected.

For example, below are the bias data for the entire measurement range (based on the maximum bias):

<table>
<tr><th></th><th>Relative difference</th></tr>
<tr><td>DDI bias = 0.27 µg/mL</td><td>31.4%</td></tr>
<tr><td>DDI cut-off bias = 0.50 µg/ml</td><td>25.7</td></tr>
<tr><td>DDI bias = 0.75 µg/ml</td><td>23.4</td></tr>
<tr><td>DDI bias = 1 µg/ml</td><td>22.3</td></tr>
<tr><td>DDI bias = 2 µg/ml</td><td>20.6</td></tr>
<tr><td>DDI bias = 4 µg/ml</td><td>19.7</td></tr>
<tr><td>DDI bias = 7 µg/ml</td><td>19.4</td></tr>
<tr><td>DDI bias = 10 µg/mL</td><td>19.2</td></tr>
</table>
</td></tr>
<tr><td>Can I continue to use these kits to rule out VTE in tested patients?</td><td>Yes. The D-dimer test is intended for use with a pre-test probability (PTP) model to rule out PE/DVT. The bias does not alter the intended use. There is no risk of false negatives for PE/DVT, as sensitivity and NPV remain unchanged.</td></tr>
</table>

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What are the consequences of decreased specificity?	Higher results, especially for samples close to the clinical threshold, imply an increase in false positives. This may lead to additional medical imaging for patients.
What is the clinical performance of the batches concerned in comparison with the state of the art (tests)?	Based on public data (510k files): **Specificity** / PE / DVT Stago: 75.50% ↘63.9% / 55.20% ↘ 41.2% Siemens 5100: 54.50% / 45.10% Siemens 2100: 54.50% / 46.10% Werfen: 49.10% / 43.30% Vidas: 37.60% / 37.60% Vidas with AACO: 51.80% / 51.80% Tina-quant: 50.40% / 45.80%
Can I continue to use the kits I have in stock?	Yes. It is appropriate to continue using the lots affected by the recall, since the primary objective is to rule out PE/DVT and sensitivity/NPV are unchanged.
Should we review/reinterpret the results already obtained with these lots?	No. It is not necessary to review previous results obtained with these lots. If a false positive occurs, the imaging performed confirms the absence of DVT/PE, and therefore retrospective review is not necessary in this context.
When will the problem be corrected?	Stago is actively working to correct the situation. No definitive timeline can be provided at this stage.