Field Safety Notice

FSN-RPD-2015-009

RPD / Specialty Testing / Coagulation
Version 1
27-April-2015

Immunoglobulin Interference with D-Dimer Gen.2

Product Name	D-Dimer Gen.2
Product Description	D-Dimer Gen.2 assay

Impacted Products, GMMI / Part No, Lot No

Product	GMMI	Lot No.
D-DI2 (cobas c, Integra)	04912551190	all

Instrument/System	**cobas c** 501 module
Type of Action	Field Safety Corrective Action (FSCA)

Dear Valued Customer,

Executive Summary

Specific immunoglobulins can cause an interference with D-Dimer Gen. 2 assay in rare cases. The interference may depend on the immunoglobulin level and/or the structure of the immunoglobulin molecule itself. The current wording in the package insert is correct but only related to gammopathy and needs to be extended in order to cover other types of immunoglobulin interferences.

Description of Situation

A patient case was reported to Roche regarding discrepant results between Coasys Plus C and the STAGO D-Dimer for the D-Dimer Gen. 2 assay. There was overestimation of the sample measurement with the Coasys Plus C system leading to a false positive D-Dimer result. This issue is sample specific. Immunoglobulins (IgM) interfere with the D-Dimer Gen. 2 reagent leading to falsely increased D-Dimer results. The presence of the immunoglobulins was demonstrated by immune adsorption chromatography which showed that the falsely elevated results are eliminated when immunoglobulins are removed from the sample. The interference may be dependent on the immunoglobulin level and/or the structure of the immunoglobulin molecule.

Recent cases have shown that the interference may also occur with specimens from patients not presenting gammopathy. The current package insert correctly includes gammopathy as one of the interference. Moving forward, the package insert will be extended to cover other types of immunoglobulin interferences.

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Immunoglobulin Interference with D-Dimer Gen.2

The occurrence of the immunoglobulin interferences remains rare and has been estimated at less than 1 case per 100'000 determinations of D-Dimer Gen. 2.

The detectability is difficult and might become evident only after further diagnostic tests.

D-Dimer is a sensitive marker for increased coagulant and fibrinolytic activity. Elevated D-Dimer levels may be caused by deep vein thrombosis (DVT), pulmonary embolism (PE), disseminated intravascular coagulation, atrial flutter or dissections of the aorta. However, increased D-Dimer levels may also reflect other causes associated with fibrin formation such as trauma, pregnancy complications, malignant diseases or vascular abnormalities. Therefore, elevated D-Dimer values should lead to further medical investigation based on symptoms that the patient presents. According to the guidelines, no treatment should start before the thrombosis has been confirmed in other diagnostic procedures. For this reason, it is not likely that falsely elevated D-Dimer levels will lead to a wrong therapy.

All other claims for D-Dimer Gen. 2 remain unchanged.

Actions taken by Roche Diagnostics

The package insert of D-Dimer Gen. 2 application will be updated. The changed wording will be:
"In rare cases (less than 1 reported case per 100'000 tests) certain immunoglobulins can cause a non-specific agglutination leading to falsely high results."

Actions to be taken by the customer/user

Please be informed that the current package insert correctly relates to gammopathy and will be extended to cover other types of immunoglobulin interferences. The package insert of all D-Dimer Gen. 2 application will be updated accordingly.

Communication of this Field Safety Notice

Please transfer this notice to other organizations/individuals on which this action has an impact.

Please maintain awareness of this notice and resulting action for an appropriate period to ensure the effectiveness of the corrective action.

We sincerely apologize for any inconvenience caused by this issue and hope for your understanding and support.

Sincerely,

Roche Diagnostics Asia Pacific Pte Ltd
Email: sg.regulatory@roche.com

Immunoglobulin Interference with D-Dimer Gen.2

ACKNOWLEDGMENT RECEIPT

This is to acknowledge the receipt of Roche Safety Board Advisory Notice: FSN-RPD-2015-009, dated 27-Apr-2015, regarding immunoglobulin interference with D-Dimer Gen.2.

Received by:

_____

Name & Signature

_____

Hospital & Stamp

_____

Date

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