Urgent Field Safety Notice
FSN-RPD-2015-009

RPD / Speciality Testing / Coagulation
Version 1
20-April-2015

Immunoglobulin Interference with D-Dimer Gen.2

Product Name	D-DI2 / D-Dimer Gen.2
Product Description (all platforms)	Tina-quant D-Dimer Gen.2 / D-Dimer Gen.2 assay

Impacted Products, GMMI / Part No, Lot No

Product	GMMI	Lot No.
D-DI2 (cobas c, Integra)	04912551190	all
D-DI2 (cobas c111)	05077753190	all
D-DI2 (cobas c 701/c702)	05172381190	all
D-DI2 (Roche/Hitachi 902/912/MODULAR P)	04912497190	all
D-Dimer Gen.2 (Coasys Plus C)	05934281140	all

Instrument/System

Coasys® Plus C coagulation analyzer
cobas c 501 module
cobas c 502 module
cobas c 311 analyzer
cobas c 701 module
cobas c 702 module
COBAS INTEGRA® ***400 plus*** analyzer / system
COBAS INTEGRA® 800 analyzer / instrument
cobas c 111 analyzer
MODULAR *ANALYTICS* P-MODULE
Roche/HITACHI 902
Roche/HITACHI 912

Type of Action Field Safety Corrective Action (FSCA)

Immunoglobulin Interference with D-Dimer Gen.2

Dear valued D-Dimer Gen. 2 Customer,

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 inserts 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 were demonstrated by immune adsorption chromatography which showed that the falsely elevated results are eliminated when immunoglobulins are removed from the sample in this manner.
The interference may depend on the immunoglobulin level and/or the structure of the immunoglobulin molecule itself.

The current wording in the package inserts is correct, but only related to gammopathy and needs to be extended in order to cover other types of immunoglobulin interferences. The wording will be adapted accordingly.

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 any increased coagulant and fibrinolytic activity and should lead to further medical investigation based on the symptoms. Therefore false positive D-Dimer results can lead to unnecessary diagnostic measurements.

There has been no change of the given assay performance compared to the past. Rather investigations have revealed that the interference cannot be restricted to gammopathy cases only as described in current versions of package inserts.

Actions taken by Roche Diagnostics

The package insert of all D-Dimer Gen. 2 applications on all platforms 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."

Immunoglobulin Interference with D-Dimer Gen.2

Actions to be taken by the customer/user

Please be aware that the current wording in the package inserts is correct but is only related to gammopathy and needs to be extended in order to cover other types of immunoglobulin interferences. The package insert of all D-Dimer Gen. 2 applications 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.

The undersigned confirms that this notice has been notified to the appropriate Regulatory Agency.

We apologize for the inconvenience this unanticipated situation may cause and hope for your understanding and your support.

Sincerely,

Contact Details

To be completed locally:
Name
Title
Company Name

Address
Tel. +xx-xxx-xxxx xxxx
Email name@roche.com