Field Safety Notice
SBN-CPS-2016-018

CPS / Immunology
Version 1
07-Feb-2017

Anti-HAV Impact of certain plasma types

Product Name	Anti-HAV
Product Description	Elecsys® Anti-HAV
GMMI / Part No Device Identifier	04854977190
Production Identifier (Lot No./Serial No.)	All Lots within shelf life.
Type of Action	Field Safety Corrective Action (FSCA)

Dear Valued Customer,

The procedure for comparing plasma to serum samples has changed since the launch of the anti-HAV assay in 2001. The new procedure led to the discovery of the Elecsys® Anti-HAV assay recovery being impacted by certain types of plasma specimens. The claim in the assay method sheet regarding acceptable specimens under 'Specimen collection and preparation' will therefore be corrected.

Description of Situation

During internal investigations, the recoveries of Li-heparin and Na-heparin plasma specimens were found to be on average up to 35% below those obtained in serum. False low recovery of heparin plasma samples is likely to occur within close proximity to the medical decision point of the assay (20 IU/L). Detectability of the false low recovery is difficult since a direct comparison of serum and plasma samples from the same patient and same blood draw will most unlikely to occur. Based on internal data generated by testing 4000 blood donors and routine samples approx. 0.1% of samples were close to the cut-off of 20 IU/L. Considering the difficulty in detection and frequency of occurrence, medical risk cannot be excluded.

Based on the above findings, Li- and Na-heparin specimens will no longer be acceptable specimen types.

For K_3-EDTA and citrate plasma specimens the specified criterion that the recovery compared to serum specimens was broadened to 80-120%. Internal investigations have determined that the use of K_3-EDTA plasma specimens does not carry the risk of generating erroneous results.

Roche Diagnostics Asia Pacific Pte Ltd
8 Kallang Avenue
#10-01/09 Aperia Tower 1
Singapore 339509
Tel. +65 – 6272 7500
Fax +65 – 6371 6633

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Actions to be taken by the customer/user

Please consider the limitations of the new 'Specimen collection and preparation' wording in the assay instructions as listed below immediately:

Specimen collection and preparation

Only the specimens listed below were tested and found acceptable.

Serum collected using standard sampling tubes or tubes containing separating gel.

K_3-EDTA and sodium citrate plasma.

Criterion: Mean recovery within 80-120 % of serum value
Stable for 7 days at 2-8 °C, 3 months at -20 °C. The samples may be frozen 6 times.

For plasma treated with lithium heparin or sodium heparin, the values found were up to 35 % lower than those obtained in serum.

The sample types listed were tested with a selection of sample collection tubes that were commercially available at the time of testing, i.e. not all available tubes of all manufacturers were tested. Sample collection systems from various manufacturers may contain differing materials which could affect the test results in some cases. When processing samples in primary tubes (sample collection systems), follow the instructions of the tube manufacturer.

Centrifuge samples containing precipitates and frozen samples before performing the assay.

Re-testing:
In case you suspect discrepant results with Li- and Na-heparin plasma specimens or have specific questions, re-testing might be advisable in concordance with relevant clinical information.

Actions taken by Roche Diagnostics

A corrected version of the Elecsys® Anti-HAV assay method sheet will be made available soon.

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Asia Pacific Pte Ltd

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Communication of this Field Safety Notice

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

We apologize for any inconvenience this may cause and thank you for your understanding and support.

Respectfully yours,

Lu Ai Ing
Regulatory Affairs Manager

Julia Sadeli
Senior Product Manager

Contact Details
Name: Julia Sadeli
Title: Senior Product Manager
Contact No.: 98312504
Email: Julia.sadeli@roche.com

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ACKNOWLEDGMENT RECEIPT

This is to acknowledge the receipt of Roche Field Safety Notice Reference No. SBN-CPS-2016-018 dated 07 Feb 2017, regarding an issue with Anti-HAV Impact of certain plasma types.

Received by:

_____
Name & Signature

_____
Hospital & Stamp

_____
Date

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#10-01/09 Aperia Tower 1
Singapore 339509
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