Urgent Field Safety Notice
SB-CPS-2016-018

CPS / Immunology
Version 1
26-Jan-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
Type of Action	Field Safety Corrective Action

Dear Valued Customer,

We regret to inform you that we have determined that the performance of the Elecsys® Anti-HAV assay is impacted by certain types of plasma specimens. Therefore, the claim in the assay method sheet regarding acceptable specimens under 'Specimen collection and preparation' will be corrected.

Description of Situation

When Li-heparin and Na-heparin plasma specimens were compared to serum samples during internal investigations the specified required recovery could not be achieved. Values determined with these types of plasma specimens were found to be on average up to 35% below those obtained in serum. False low recovery of samples is likely to occur only for heparin plasma samples within close proximity to the medical decision point of the assay at 20 IU/L. 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.

Based on these finding, the claim in the method sheet regarding acceptable specimens under 'Specimen collection and preparation' will be corrected. Li- and Na-heparin specimens will no longer be acceptable specimen types.

If Li-heparin or Na-heparin plasma specimens are used, erroneous negative anti-HAV results are possible. Taking into consideration the high frequency of occurrence and difficult detectability of the issue, a relevant medical risk cannot be excluded.

For K_3-EDTA and citrate plasma specimens the specified criterion that the recovery compared to serum specimens has to be within 90-110% was broadened to 80-120%. Internal investigations have determined that the usage of K_3-EDTA plasma specimens does not carry the risk of generating erroneous results.

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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.

Communication of this Field Safety Notice (if appropriate)

This notice must be passed on to all those who need to be aware within your organization or to any organization/individual where the potentially affected devices have been distributed/supplied.

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

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The following statement is mandatory in FSNs for EEA countries but is not required for the rest of the World:

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

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

Best regards,

Contact Details

To be completed locally:
Name
Title
Company Name
Address
Tel. +xx-xxx-xxxx xxxx
Email name@roche.com