IRISH MEDICINES BOARD

Notice Information: - Advisory
15 April 2010

Part 1. Product Information

a)	Title:	ARCHITECT Anti-HCV Reagents
b)	Product Name/Type:	ARCHITECT Anti-HCV Reagents
c)	Reference:	SN2010(02)
d)	Manufacturer/Supplier:	Abbott GmbH & Co. KG.

Part 2. Target Audience

a) Target Audience:

Hospital Risk Managers

Hospital Laboratories

Please bring this safety notice to the attention of all who need to be aware of it.

Part 3. Problem/Issue

a) Problem/Issue:

Abbott has determined that S/CO values generated with ARCHITECT Anti-HCV (LN 6C37) may decrease when 25% or less of test volume is remaining leading to:

• Abbott Positive Control values shift down and/or out of range low,

• Non-Abbott Positive Control values shift down and/or out of range low, and/or

• A decrease in patient result values

Part 4. Background Information

a)	Background Information:	Abbott informed the Irish Medicines Board (IMB) that the above issue was identified through customer complaints and confirmed by internal complaint investigations. Abbott has advised the IMB that internal studies have shown a maximum downward shift of 40% for the positive control. Abbott has indicated that the drop in S/CO is due to an inhomogeneity within the assay diluent. It has been confirmed that patient samples may show a decrease in S/CO values comparable to the positive control. This may result in false negative results for low reactive patient samples. The investigation into the root cause of this issue is ongoing.

Part 5. Action to be taken

a)	Action to be taken:	Abbott has issued a Field Safety Notice (FSN) (March 2010) to all Irish customers using the ARCHITECT Anti-HCV assay recommending customers mix the ARCHITECT Anti-HCV assay diluent (LN 6C37J, green bottle label) prior to testing each day of use. A copy of the FSN is also available on the IMB website at the following link: http://www.imb.ie/images/uploaded/documents/FSN/FSNMar2010/FSNSummary_Mar2010_QMSVersion_Final_090410.pdf

Part 6. Enquiries

a) All enquiries should be made to:

IMB RECOMMENDATIONS

The IMB is advising customers to consider the need to conduct a look back study.

The manufacturer has confirmed that all lots from 67599HN00 may be affected by this issue and that they cannot guarantee that previous lots that have since expired were not affected.

Abbott has advised the IMB that samples below 0.6 S/CO do not have an increased risk for false negative results as Abbott has observed a maximum drop of 40% (0.4 S/CO for a sample running at 1.0 S/CO with a positive interpretation).

The IMB recommends that customers who determine the need to conduct a look back study and require further information related to the product issue contact Abbott for further advice.

Enquiries to the manufacturer should be addressed to:

Abbott Diagnostics

Unit 4051 Kingswood Drive

Citywest Business Campus

Dublin 24

Telephone: +353 1 4691561

Fax: +353 1 4691565

E-mail: tara.mcgrath@abbott.com

ENQUIRIES

All adverse incidents relating to a medical device should be reported to

All adverse incidents relating to a medical device should be reported to the:

Human Products Safety Monitoring Department

Irish Medicines Board

Kevin O'Malley House

Earlsfort Centre

Earlsfort Terrace

Dublin 2

Telephone: +353-1-6764971

Fax: +353-1-6344033

E-mail: vigilance@imb.ie

Website: www.imb.ie

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