

# Urgent Field Safety Notice

## SBN-RPD-2015-002

RPD / Immunology  
Version 1  
11-Feb-2015

### CMV IgM – Restricted use of Diluent Universal lots

<b>Product Name</b>	CMV IgM		
<b>Product Description</b>	Elecsys CMV IgM assay		
<b>Impacted Products, Part No, Lot No</b>	<b>Product</b>	<b>Part No</b>	<b>Lot No.</b>
	CMV IgM	04784618190	179689
	CMV IgM	04784618190	182962
	Diluent Universal (2x 36mL)	03183971122	175913
	Diluent Universal (2x 36mL)	03183971122	178383
	Diluent Universal (2x 36mL)	03183971122	178386
	Diluent Universal (2x 36mL)	03183971122	180209
	Diluent Universal (2x 36mL)	03183971122	183652
	Diluent Universal (2x 16mL)	11732277122	176099
	Diluent Universal (2x 16mL)	11732277122	176899
	Diluent Universal (2x 16mL)	11732277122	183653
	<b>SW Version</b>	Not applicable	
<b>Type of Action</b>	Field Safety Corrective Action (FSCA)		

Dear Valued Elecsys CMV IgM Customer,

Internal results demonstrate that some lots of Diluent Universal may have an influence on the CMV IgM results and may lead to low or false negative results with two lots of the the Elecsys CMV IgM assay.

#### Description of Situation

During our regular Quality Control (QC) activities, we have observed a potential reduction in the signal of the Elecsys CMV IgM assay (04784618190) when used in combination with some specific lots of Diluent Universal (03183971122 and 11732277122). This situation, which was observed using internal control samples, may have an impact when routine clinical samples are used. An extensive study of all possible reagent lot combinations allowed us to determine which ones may generate this outcome. A complete list of these combinations is provided in the table above. Please note that only those **highlighted part numbers** are locally distributed CMV IgM reagent (since Dec 14) and Diluent Universal.

## CMV IgM – Restricted use of Diluent Universal lots

Internal investigation results confirmed that a certain lot of a specific component used in the Diluent Universal caused the signal reduction of an internal control sample in the Elecsys CMV IgM assay. This internal control sample showed a high reactivity against one specific antigen included in the CMV IgM assay.

Therefore, patient samples with high reactivity against this specific antigen may be affected by reduced cutoff index (COI) values, which may lead to a false negative result when any of the combinations mentioned in the page 1 are used. This combination of reagent lots has been globally available since 23 September, 2014. Please note that locally, the combination of reagent lots has been available since Dec 2014.

The signal reduction has only minor effects on the calibrators and controls (PreciControl CMV IgM) and therefore is likely to remain undetected, resulting in false non-reactive CMV IgM results and undetected acute CMV infections. In summary, there is a reasonable probability that the use of affected diluent lots will lead to delayed or wrong diagnosis and/or treatment of acute CMV infection.

The performance of the Elecsys CMV IgM assay is well within specification when other lots of Diluent Universal (other than the ones mentioned in page 1) are used.

All other Elecsys assays may be used with the Diluent Universal lots mentioned above. This has been investigated internally and we have confirmed that performance specifications are met. This is independent of whether any other Elecsys assay uses a pre-dilution or a dilution of a high concentration sample. The same situation applies to Diluent Universal 2 (05192943190) in combination with Elecsys AMH assay and Elecsys HGH assay.

The purpose of this Field Safety Notice (FSN) is to inform of this situation and clarify the extent of the recommended field action activities.

### **Actions taken by Roche Diagnostics**

The lot of the component causing the issue and used in Diluent Universal has been Quality Control (QC) rejected and will not be used anymore. Future QC releases of the component of concern will be optimized to prevent any reoccurrence of this situation in the future.

We will ensure the supply of Diluent Universal kit lot 181121 (2x 16mL), which is currently available on the market and is suitable to be used in combination with all Elecsys CMV IgM assay lots.

### **Actions to be taken by the customer/user**

#### **Prospective actions**

The Diluent Universal kit lots mentioned in page 1 must not be used in combination with the Elecsys CMV IgM assay (lots 179689 and 182962). They can continue to be used in combination with other Elecsys CMV IgM assay lots as well as with other Elecsys assays.

All subsequent lots of Diluent Universal will be suitable to be used in combination with the Elecsys CMV IgM assay with the exception of the Diluent Universal lots specified in page 1.

# CMV IgM – Restricted use of Diluent Universal lots

## Retrospective actions

Locally, negative Elecsys CMV IgM patient samples tested with the combination of CMV IgM lot179689 and Diluent Universal lot 176099 and 176899, whose results fell within the COI range of 0.5-0.7 COI, should be reviewed in conjunction with the patient's medical history, clinical examination, available diagnostic parameters, and other findings. Appropriate patient re-testing with unaffected lots may be advisable.

Considering that you may want to inform and/or consult with the health care providers who requested those tests, we are providing a template of a letter for such communication.

## 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](mailto:sg.regulatory@roche.com)

# CMV IgM – Restricted use of Diluent Universal lots

## ACKNOWLEDGMENT RECEIPT

This is to acknowledge the receipt of Roche Safety Board Advisory Notice: CMV IgM – Restricted use of Diluent Universal lots, dated 11-Feb-2015, regarding some lots of Diluent Universal may have an influence on the CMV IgM results and may lead to low or false negative results with two lots of the the Elecsys CMV IgM assay.

Received by:

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Name & Signature

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Hospital & Stamp

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Date