

## Urgent Field Safety Notice

**Product Name:** PA0552 - Bond Ready-to-Use Primary Antibody PAX-5 (1EW)  
PA0210 - Bond Ready-to-Use Primary Antibody Alpha-Methylacyl-CoA Racemase (EPMU1)  
PB0614 - Bond Ready-to-Use ISH CMV Probe  
PB0589 - Bond Ready-to-Use ISH EBER Probe  
PB0645 - Bond Ready-to-Use ISH Kappa Probe  
PB0669 - Bond Ready-to-Use ISH Lambda Probe  
PB0809 - Bond Ready-to-Use RNA Negative Control Probe  
PB0785 - Bond Ready-to-Use RNA Positive Control Probe  
NCL-L-AMACR - Novocastra Liquid Mouse Monoclonal Antibody Alpha-Methylacyl-CoA Racemase (AMACR, p504S)

**Reason:** Products not performing as expected with specified detection kits

**Date:** 06 January 2016

**Attention:** Pathology Department / Dealer

### Details on affected devices:

This Urgent Field Safety Notice is applicable to all of the following antibody and probe products only when used in combination with the specified lots of detection kits:

Product Code	Used in combination with:	
	Detection Kit	Affected Detection Kit Lots
PA0552 (All Lots) PA0210 (All Lots) PB0614 (All Lots) PB0589 (All Lots) PB0645 (All Lots) PB0669 (All Lots) PB0809 (All Lots) PB0785 (All Lots)	DS9800 Bond™ Polymer Refine Detection Kit	42314, 42388, 42474, 42486, 42499, 42555, 42570, 42579, 42627, 42645, 42683, 42780, 42802, 42823, 42852, 43050
NCL-L-AMACR (All Lots)	RE7280 Novolink™ Polymer Detection Kit	406039270, 406039398

### Description of the problem:

Leica Biosystems recently became aware that the product / detection kit combinations identified above may not provide adequate staining when used according to the Instructions for Use. If the products are used according to their Instructions for Use with appropriate positive controls, the failure to adequately stain would be apparent to the user on the control tissue and on the patient tissue. The absence of adequate staining of tissue is likely to result in a delay in obtaining the results of IHC / ISH staining and, in a worst-case scenario, could cause a delay in the diagnosis or classification of a neoplasm.

It should be noted that the Bond Polymer Refine and Novolink Polymer detection kits are intended for use with a large number of other products and that the identified kit lots function as specified except when used with the antibody and probe product codes listed in the table above. This notice only applies to the combined use of the specified product codes and the affected detection kits lots; i.e., the detection kit lots can continue to be used with other antibody and probe products in accordance with their Instructions for Use.

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## ACTIONS REQUIRED

- Do not use or continue to use the listed antibodies / probes with the specified detection kits.
- Order replacement detection kits for use with the listed antibodies / probes
- There is no need for retrospective review of tissue staining if appropriate positive controls were properly used and interpreted during the immuno / in situ staining.

Please contact your local Leica representative if you have any questions or concerns, or alternatively please contact us at the following email address;

[Combination.Products@LeicaBiosystems.com](mailto:Combination.Products@LeicaBiosystems.com)

### Transmission of this Field Safety Notice:

Kindly pass this notice primarily to the end users where the product has been sold and to all those within your organisation who need to be aware of this issue.

Your cooperation in this matter is greatly appreciated and we sincerely apologise for any inconvenience this may have caused.

Regards,

### Contact reference person:

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The undersigned confirms that the relevant Competent Authorities are aware.

Signature

A handwritten signature in blue ink, appearing to read "P. Lloyd".