

# PRODUCT INFORMATION LETTER



Malmö, Sweden  
6<sup>th</sup> of November 2019

Dear valued customer,

We hereby inform you that the Positive Control component label lacks a subheading in the kit  
**IMMUNOSCAN® CCPlus**

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<b>Products affected:</b>	IMMUNOSCAN® CCPlus – IVD & RUO kits <b>RA-96PLUS and RA-96PLUS RUO</b>
<b>Affected batches:</b>	ZS 2177, ZS 2097, ZS 1885, ZS 1952, ZS 1087, XS 3096, XS 2617.
<b>Time period:</b>	Batches have been shipped to customers during 2019.
<b>Description:</b>	The label of the Positive Control from affected batches lacks a subheading with the information of quality control specification (ratio and concentration).
<b>Customer impact:</b>	Product performance is unaffected and according to specification. No risk for malfunction or patient safety exist. Quality control specification (concentration and ratio) of the Positive Control are stated in the Certificate of Analysis and has been unchanged since 2016. Certificate of Analysis is available on Svar Life Science website.


We apologize for the inconvenience this might have caused you. If you have any questions, please do not hesitate to contact us directly.


Yours sincerely,

Christine Mellborg  
Product Manager

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