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Lübeck, 5. November 2020

Information: EUROLINE Sample buffer, lot D200114AB

Dear friends, dear partners

At EUROIMMUN we place great value on ensuring excellent quality of our products. It is always our priority to meet our customers' expectations and assure the reliability of our products.

Today, we must inform you about an alteration regarding

Lot D200114AB of the EUROLINE sample buffer.

Due to a production error, that is, a lack of preservative, there have been very rare cases of mould formation in the product.

Herewith, we want to inform you that you have ordered one or more of the test kits which contain an item of the concerned sample buffer lot. Please find below a list of the affected products and their lot numbers.

We have performed comprehensive analyses to clarify whether the lack of preservative may have led to potential contamination and subsequently affected the analytical performance of the respective test. This is not the case. Hence, all of your customers' results obtained with the affected kits are valid.

The affected reagent was applied in different test systems, in parallel with a reference, in order to determine the influence of potential contamination, e.g. ubiquitous moulds, on the serological test result.

Sera from healthy blood donors as well as patient sera were investigated in nearly 90 incubations on 36 different autoantigens and the results obtained with the affected lot were compared with those of a reference lot.

The coefficient of variation of both buffer lots was 0.99. The test result was in no case affected by the lack of preservative and a possible contamination associated therewith.

Therefore, we are sure that the production error has not affected the analyses performed with the affected buffer lots, nor their results.



In order to prevent this error from occurring again, we have reacted according to our quality management system and initiated and implemented suitable corrective and preventive actions.

If you or your customers request the deficient sample buffer be replaced, we of course will replace the deficient sample buffer free of charge, as soon as possible upon your request. Please Cc Dr [REDACTED] in your order to avoid any delays. Also, please try to place only one complete order in this matter as opposed to several smaller ones. This will also help streamline the process in case sample buffer replacements will be requested.

We apologise for any inconvenience caused by this product query. If you have any questions, please [REDACTED]

Best regards from Lübeck,

[REDACTED]

[REDACTED]

Head of Product
Management Reagents

References

- Lot-specific product list



Lot-specific product list

Product	Description	Lots
DL 1111-2 G	Neuronal Antigens Profile 2	D200309AD
DL 1111-41 G	Neuronal Antigens Profile 41	D200309AI
DL 1111-6 G	Neuronal Antigens Profile	D200310AD
DL 1111-7 G	Paraneoplastic Neurological Syndromes 12	D200312AN
DL 1300-4 G	Autoimmune Liver Diseases	D200309AB
DL 1360 A	Autoimmune Gastrointestinal Diseases IgA	D 200326AM
DL 1530 G	Myositis Profile	D200318AF
DL 1530-4 G	Autoimmune Inflammatory Myopathies 16 Ag	D200309AE
DL 1590-1 G	Anti-ENA Profile Plus 1	D200312AM
DL 1590-3 G	ANA Profile 3	D200313AK, D200313AL
DL 1590-30 G	ANA Profile 3 plus DFS70	D200317AI, D200304AL
DL 1590-31 G	ANA Profile et Mi-2 et Ku	D200313AI
DL 1590-33 G	ANA Profile et Mi-2, Ku, DFS70	D200312AH
DL 1590-9 G	ENA Profile 9 Ag	D200312AI
DL 1910 G	Coeliac Disease Profile IgG	D200320AA