MEDIPAN GMBH
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MEDIPAN GMBH • Ludwig-Erhard-Ring 3 • 15827 Dahlewitz / Berlin

Dahlewitz, 14.11.2018

Dear customer,

Important customer information /
FSN (Field Safety Notice)

Corrective action 2018/11/12-3505

Product: Medizym® T.R.A. human, REF 3505
Lots: 2018 3505 03/1, 2018 3505 04/1, 2018 3505 05/1

Problem description: Increased risk of false positive results

Based on customer feedback we have determined that the batches 2018 3505 03/1, 2018 3505 04/1 and 2018 3505 05/1 of our product Medizym® T.R.A. human, REF 3505, shows non-specific reactions with normal sera. During comparison measurements, borderline or weakly positive results occurred frequently in normal sera.
The use of a test of these batches could therefore lead to a false-positive test result.

Due to the increased risk involved in the use of the batches concerned, we ask you to check your stock and not to continue using products from these lots. Please inform us about the remaining test kits by means of the attached feedback form. MEDIPAN will refund the costs for the unused kits and deliver a replacement as soon as possible.

Summary and current status:

Comparative measurements of normal identical donors with different storage intervals showed differences in the thyrotropin (TSH) receptor autoantibody concentration. Sera of obviously healthy blood donors which were tested immediately after blood collection received a borderline or weakly positive to positive evaluation.

The cause of the problem is narrowed down and a solution is being worked on. The risk is no longer present with the next batch.

A false-positive test result does not in itself pose a treatment risk for the patient, as it is used for autoantibody detection against the TSH receptor only to support clinical diagnosis in Graves' disease. Therefore, the results of the above batches should be interpreted with caution.

The repeated testing of the patient sample could therefore be an option for you if the test result does not match the clinical suspicions of the physician. It is up to the laboratory and the attending physician whether testing by other means is appropriate.

Geschäftsführer:
Reinhold Hartwig,
Prof. Dr. Dirk Roggenbuck

Deutsche Bank
Kto-Nr. 593 45 00
BLZ 100 700 00

Landesbank Berlin
Kto.-Nr. 670 001 39 07
BLZ 100 500 00

Handelsregister
Amtsgericht Potsdam,
HRB 6195

Ust.-Id.Nr
DE 811310408

What is the procedure of the corrective action for you?

- Please use the attached fax form or email to inform us of the number of test kits still available so that we can send you a replacement.
- Please destroy the remaining test kits.
- Please forward this notification and inform the responsible authorities.
- If you had any problems with the products of the batches mentioned, please inform us.

Passing on this customer information:

This notification should be forwarded to all affected parties and persons. If you have any further questions, please contact our product manager. You can reach Mr. Büttner at +49 (0) 33708-4417-43.

[redacted]

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