



Dahlewitz, 23.09.2024

Field Safety Notice

Dear Customer,

There is a product defect in the following product and we request that you implement the measures described. Please inform us in writing about the receipt of these safety instructions and the implementation of the measures at regulatory@medipan.de.

Product name : Medizym® anti-GAD M

REF : 3507

LOT : 24350702/1

Fault description

Some test kits may not produce a specific test reaction. This manifests itself in the fact that the validity criteria specified in the instructions for use are not fulfilled and no sufficiently differentiated standard curve is produced by the calibrators supplied. The test can therefore not be analysed.

If the validity criteria were met during processing, the test worked correctly despite this message and the results are valid.

Measures

For end users:

Please return all remaining test kits to the manufacturer and check the validity of the results already generated with the affected LOT for validity!

For distributors:

Send all remaining test sets back to the manufacturer! Instruct your end users to send all remaining test kits back to the manufacturer and check the results already generated with the affected LOT for validity!