



Dahlewitz, 2026-03-24

Field Safety Notice

[PAFI-ID 00226, 00227, 00229]

Dear Customer,

There is a product defect in the following product and we request that you implement the measures described.

Product name : TRAb human 1 step RIA

REF : KIPM2042

LOT : 25KIPM204210/1
25KIPM204210/2
25KIPM204210/3
25KIPM204210/4
25KIPM204210/5
25KIPM204210/6

Fault description

Component A, 'Coated Tubes' (test tubes coated with human TSH receptor), of the test kit exhibits a defect in the coating with the specific antigen in the affected batches, which is highly unlikely to occur. If the defect does occur, it affects the majority of the test tubes in a test kit due to manufacturing reasons. Due to this error, the measurement of radioactivity after the test is performed is particularly low for the affected tubes (CPM < 300), which, due to the competitive principle of the test kit, incorrectly indicates a particularly high titer of TSH receptor antibodies. The probability of detecting this error is very high, since a very high proportion of samples (>50%) typically yield comparable maximum antibody titers, which does not correspond to the distribution of titers that would normally be expected.

Measures

For end users:

Please check whether the error described above has occurred in any analyses that have already been performed, or please be on the lookout for it in any upcoming analyses. Results obtained using test kits that exhibit the error described above must be considered invalid. If such a case occurs, please submit the anonymized test results to your distributor for review along with a request for replacement products.

For distributors:

Please pass on these safety instructions to all end users who have received the affected batches from you. Please obtain confirmation from the end user that they have received and implemented the measures, and report the current status of the work to regulatory@medipan.de.