

Wiesbaden, .....

**Important Information!**

Dear .....,

we have to inform you, that our quality control department detected that in single cases the following IMTEC autoimmune ELISAs may contain microbiologically contaminated enzyme conjugate:

ITC60001	IMTEC ANA Screen	Lot ANAQ215	Verfall 31.07.2009
ITC70001	IMTEC ANA Screen (Cut-off)	Lot ANAC209	Verfall 31.07.2009

This concerns single conjugate vials of kits of the above mentioned lots. In the case of such contamination, the tests no longer function according to the specifications (controls, calibrators no longer produce the absorbance limits as specified in the instructions for use), consequently false results from patient specimen cannot be generated.

At the moment we are intensively evaluating the root cause of this contamination. Because this is not yet confirmed, for safety measures we like to inform you that we cannot 100% exclude that conjugates of other products than the ones mentioned above are not concerned as well.

Please inform your clients accordingly.

Of course HUMAN will replace all test kits which show such contaminations and therefore do not work properly. Please contact our customer service accordingly.

HUMAN and its product line of IMTEC autoimmune diagnostics stand for innovative and high quality products and we continuously work to further improve our own quality demands for the benefit of our clients.

With best regards,  
Human GmbH

Customer Service Department