

Product line SERION ELISA *classic*

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Dear Ladies and Gentlemen,

As a result of feedback from a customer, we inform you about a possible problem regarding the new software version 2.06.3 for the Immunomat instrument.

If the reagent check function is deactivated, the Immunomat may, provided vials of different conjugate strengths are simultaneously in the Immunomat during automated test processing, pipette the wrong conjugate of the same immunoglobulin class. Use of the wrong vial was observed as soon as the vial initially used was empty and the Immunomat switched to the next vial. Incorrect pipetting operations have so far only been detected if, contrary to the instructions in the instructions for use, the reagent check has been deactivated. Currently we are still in the evaluation phase in order to be able to evaluate the extent of this error.

Until we come to a final assessment of the situation, we would ask you to ensure that the reagent check function is activated on each Immunomat run. We have not so far been made aware of any cases of incorrect evaluations of patient samples.

If you have disabled the reagent check against the requirements in the instructions for use, we recommend that you reactivate it immediately.

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As a precautionary measure, our technical support staff have already started to replace the software version 2.06.3 with software version 2.06. for all customers operating an Immunomat.

Although when, with activated reagent check, no errors have been detected, we wish to exclude the possibility and do our utmost to maintain our customer's trust in the high quality of the Immunomat.

We are in very close communication with the manufacturer of the Immunomat and its associated software and we are confident that we will be able to provide you with further information in the very near future.

Kind Regards

Institut Virion\Serion GmbH

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