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RESEARCH AND PRODUCTION COMPANY
DIAGNOSTIC SYSTEMS Ltd.

Advisory notice # 120

Product: DS-EIA-HIV-AGAB-SCREEN
Cat. # I-1656/1.2, I-1652/1.2, I-1654/1.2 (no lots released), I-1654
Lot # 097187
Expiry date: 2020-02-21

Dear customers!

The instruction for use (rev. 015, 2015-06-25 and rev.017, 2019-02-25) and MSDS (rev. 007, 2015-01-27 and rev.008, 2019-03-25) contains inadequate information regarding concentration of preserving agents in following reagent of the kit (Table 1).

Table 1.

Label	Preserving agent	Information about preserving agent concentration	
		The correct concentration according to technical documentation	Concentration provided in the IFU (rev. 015, 2015-06-25, rev.017, 2019-02-25) and MSDS (rev.008, 2019-03-25 and rev. 007, 2015-01-27)
Conjugate-1 (concentrated 11-fold)	Thimerosal	0,02%	0,01%
Conjugate-2 (concentrated 11-fold)	Phenol	0,01%	0,02%
Conjugate-2 diluent	Gentamicin sulfate	0,001%	Unspecified
AB Positive Control, Inactivated	Thimerosal	0,02%	0,025%
Negative Control, Inactivated	Thimerosal	0,06%	0,01%

Please note, that all patient results, got by using kits of I-1654, lot 097187 exp. 2020-02-21 are valid. The identified non-conformity does not affect the quality and safety of the product. According to risk analysis, concentration of gentamycin sulfate, phenol, thimerosal in the semi-products is not much than 0,1%, so they do not represent chemical hazard for consumers.

Information regarding correct concentrations of preserving agents will be include in the instruction for use and the MSDS as corrective action.

We terribly apologize for the inconvenience and the delivered troubles, and we will be very grateful for your understand and support.

This advisory notice must be published to all concerned.

Quality Director



Marina Kokoreva
18.07.2019

I hereby confirm that this Advisory Notice has been read, understood and published to all concerned.

Date

Name/Signature

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Product Promotion specialist