DIAGON
Solutions beyond imagination

110291010AEN
Date of issue: 03.10.2022

CERTIFICATE OF ANALYSIS

PRODUCT NAME:	**DIA-CONT I-II**
REFERENCE NO.:	**91010; 91020**
LOT NO.:	**950224**
EXPIRY DATE:	**2027 - 02**

TEST	SPECIFICATION	RESULT	CONFORMITY
APPEARANCE:	**DIA-CONT I**	**DIA-CONT I**	
BEFORE RECONSTITUTION	YELLOWISH LYO CAKE	**YELLOWISH LYO CAKE**	**CONFORM**
AFTER RECONSTITUTION	YELLOW	**YELLOW**	**CONFORM**
APPEARANCE:	**DIA-CONT II**	**DIA-CONT II**	
BEFORE RECONSTITUTION	YELLOWISH LYO CAKE	**YELLOWISH LYO CAKE**	**CONFORM**
AFTER RECONSTITUTION	YELLOW	**YELLOW**	**CONFORM**
APPEARANCE:	**DIA-CONT I**	**DIA-CONT I**	
PACKAGING	7ML CLEAR VIAL, RED STOPPER, WHITE CAP	**7ML CLEAR VIAL, RED STOPPER, WHITE CAP**	**CONFORM**
APPEARANCE:	**DIA-CONT II**	**DIA-CONT II**	
PACKAGING	7ML CLEAR VIAL, RED STOPPER, RED CAP	**7ML CLEAR VIAL, RED STOPPER, RED CAP**	**CONFORM**
FUNCTIONAL TESTING: COAGULOMETER COAG LINE	**DIA-CONT I RANGE**	**DIA-CONT I VALUE**	
DIA-PT LOT: 940716	11.2 –15.1 SEC	**13.3 SEC**	**CONFORM**
DIA-PT LIQUID LOT: 940102	11.1 –15.0 SEC	**12.8 SEC**	**CONFORM**
DIA-PT R LOT: 940530	8.7 –11.8 SEC	**10.3 SEC**	**CONFORM**
DIA-PTT LOT: 940211	36.3 –49.1 SEC	**41.6 SEC**	**CONFORM**
DIA-PTT LIQUID LOT: 940403	34.9 –47.2 SEC	**40.2 SEC**	**CONFORM**
DIA-FIB LOT:940208	1.76 –2.64 G/L	**2.26 G/L**	**CONFORM**
DIA-TT LOT:940312	22.4 –33.6 SEC	**27.2 SEC**	**CONFORM**
DIA-AT III (FIIA) LOT: 940321	70.0 –94.0 %	**81.0 %**	**CONFORM**
FUNCTIONAL TESTING: COAGULOMETER COAG LINE	**DIA-CONT II RANGE**	**DIA-CONT II VALUE**	
DIA-PT LOT: 940716	19.5 –29.3 SEC	**24.5 SEC**	**CONFORM**
DIA-PT LIQUID LOT:940102	18.6 –28.0 SEC	**22.9 SEC**	**CONFORM**
DIA-PT R LOT: 940530	14.8 –22.3 SEC	**18.7 SEC**	**CONFORM**
DIA-PTT LOT:940211	70.9 –95.9 SEC	**83,7 SEC**	**CONFORM**
DIA-PTT LIQUID LOT: 940403	74.3 –100.5 SEC	**85.3 SEC**	**CONFORM**
DIA-FIB LOT: 940208	0.71 –1.66 G/L	**1.09 G/L**	**CONFORM**
DIA-TT LOT: N/A	N/A	**N/A**	**N/A**
DIA-AT III (FIIA) LOT:940321	37.0 –62.0 %	**50.0 %**	**CONFORM**

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The above-mentioned product has been tested in the Quality Control Laboratory of DIAGON Ltd using conventional procedures. The product has met the criteria of the specified test parameters.

The information given is based on the performed verification procedure and the obtained test results and believed to be correct. However, both the information and the product are offered without warranty for any use different than the ones specified in the product's Instruction for Use.

This reagent is obtained from substances of human origin. Each donor unit used in the preparation of this reagent tested with HBsAg, anti-HIV 1-2, anti-HCV, anti-TP screening tests and found to be non-reactive. Consequently, it should be treated as potentially infectious and handled with the appropriate precautions.

For in vitro diagnostic use only!

Budapest, 02 April 2025

DIAGON LTD
HUNGARY
1047 Budapest, Baross u. 48-52.

Quality Assurance Responsible

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