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.:	**960521**
EXPIRY DATE:	**2028 - 05**

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:951201	10.9-14.8 SEC	**12.2 SEC**	**CONFORM**
DIA-PT LIQUID LOT: 960115	10.1-13.7 SEC	**12.4 SEC**	**CONFORM**
DIA-PT R LOT: 950918	8.7-11.8 SEC	**10.5 SEC**	**CONFORM**
DIA-PTT LOT: 960416	36.1-48.8 SEC	**43.2 SEC**	**CONFORM**
DIA-PTT LIQUID LOT:951009	28.9-39.1 SEC	**33.1 SEC**	**CONFORM**
DIA-FIB LOT: 950406	2.12-3.18 G/L	**2.47 G/L**	**CONFORM**
DIA-TT LOT:950724	19.7-29.6 SEC	**25.3 SEC**	**CONFORM**
DIA-AT III (FIIA) LOT:960221	79.0-107.0 %	**100.0 %**	**CONFORM**
FUNCTIONAL TESTING: COAGULOMETER COAG LINE	**DIA-CONT II RANGE**	**DIA-CONT II VALUE**	
DIA-PT LOT:940716	20.8-31.2 SEC	**26.6 SEC**	**CONFORM**
DIA-PT LIQUID LOT: 960115	19.5-29.3 SEC	**24.7 SEC**	**CONFORM**
DIA-PT R LOT: 950918	16.4-24.7 SEC	**20.0 SEC**	**CONFORM**
DIA-PTT LOT: 960416	63.9-86.5 SEC	**77.3 SEC**	**CONFORM**
DIA-PTT LIQUID LOT:951009	66.2-89.6 SEC	**73.8 SEC**	**CONFORM**
DIA-FIB LOT: 950406	0.71-1.67 G/L	**1.23 G/L**	**CONFORM**
DIA-TT LOT: N/A	N/A	**N/A**	**N/A**
DIA-AT III (FIIA) LOT: 960221	38.0-64.0 %	**49.0 %**	**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, 06 August 2026

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

Quality Assurance Responsible

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