DIAGON
Solutions beyond imagination

110281005AEN
Date of issue: 03.10.2022

CERTIFICATE OF ANALYSIS

PRODUCT NAME:	**DIA-PT5**
REFERENCE NO.:	**81005; 81025; 81050**
LOT NO.:	**941015**
EXPIRY DATE:	**2026 - 10**

TEST	SPECIFICATION	RESULT	CONFORMITY
APPEARANCE:	**DIA-PT REAGENT**	**DIA-PT REAGENT**	
BEFORE RECONSTITUTION	WHITE TO YELLOWISH LYO CAKE	**WHITE TO YELLOWISH LYO CAKE**	**CONFORM**
AFTER RECONSTITUTION	SLIGHTLY OPALESCENT	**SLIGHTLY OPALESCENT**	**CONFORM**
APPEARANCE:	**DIA-PT SOLVENT**	**DIA-PT SOLVENT**	
SOLUTION	CLEAR, COLOURLESS	**CLEAR, COLOURLESS**	**CONFORM**
APPEARANCE:	**DIA-PT REAGENT**	**DIA-PT REAGENT**	
PACKAGING	7ML AMBER VIAL, RED STOPPER, WHITE CAP	**7ML AMBER VIAL, RED STOPPER, WHITE CAP**	**CONFORM**
APPEARANCE:	**DIA-PT SOLVENT**	**DIA-PT SOLVENT**	
PACKAGING	7ML CLEAR VIAL, CONICAL WHITE CAP	**7ML CLEAR VIAL, CONICAL WHITE CAP**	**CONFORM**
FUNCTIONAL TESTING: COAGULOMETER COAG LINE	**RANGE SEC**	**VALUE SEC**	
DIA-CONT I LOT: 940804	10.0 –13.6	**11.9**	**CONFORM**
DIA-CONT II LOT: 940812	19.7 –29.6	**25.2**	**CONFORM**

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.

For in vitro diagnostic use only!

Budapest, 29 November 2024

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Quality Assurance Responsible

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