

TRIMERO Diagnostics, SL

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3diag - IgD - TIA

REF TD-42651 - IgD Immunoglobulins - for Turbidimetry

ANNEX to IFU: cobas® 6000 (c501)

Proposal of Application - using 3diag - IgD - CAL SET (REF TD-42642)

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<u>ANALYZE</u>					
Assay:	2 Point End	Time/Point:		[10] [37] [70] [0] [0]	
Wavelenght (2nd/Pri.):	[Cancel] [600]	Sample Vol. (Norm.):		rm.):	[11] [3] [99] Dil.Fact.=1:10
Sample Volume (Dec.):	[2] [3] [158] Dil.Fact.=1:80	Sar	Sample Volume (Inc.):		[35] [3] [70] Dil.Fact.=1:3
Diluent:	[951 - Saline] [1]	R1 Volume (Bottle "a" of pack MULTI):		[100] [0] [Inactive]	
R2 Volume (Bottle "b" of pack MULTI):	[0] [0] [Inactive]	[O] [Inactive] R3 Volume (Bottle "c" of pack l		MULTI):	[40] [0] [Inactive]
Linearity Limit/Prozone Limit:	Not Defined Absorvance Limit:		imit:	[32000] [Increase]	
Cell Detergent:	[Detergent 1] Stirring Lev		evel:	[2]	
Stirring Setting (UP - LOW-M1/M2/M3): Leave pre-defined configuration				tion (A	All Fields = Stirrring)
Cassete Type A (Reagent/No. Test/Vol. Use): (*1) a: [R1] [130] [13.0] - b: [Cancel] [icel] [0	0] [0] - c: [R3] [130] [5.2]
<u>CALIBRATION</u>					
Calibration Type:	[Spline]	Point:		[6]	
Span - Weight:	[6] ^(*2) - [0]	Update Type:		[none] [0] [0]	
SD Limit:	[999]	Duplicate Limit (%/Abs.):		[99] [32000]	
Sensitivity Limit:	[-99999] [99999]	S1 Abs. Limit:		[-32000] [32000]	
<u>RANGE</u>					
Unit:	mg/dl] Proposal, User Defined		Decimal Places:		[1] Proposal, User Defined
Data Mode:	[Active]	Automatic Rerun:		erun:	User Defined
Technical Limit - Low:	(*3)	Technical Limit - High:		(*4)	
OTHER (Calibrators)					
Std. Code, Rack and Conc. (#16):	(*5)				
Sample Volume (#16):	[20] [3] [80] [20] [3] [80]	[20] [3] [80]	[20] [3] [80]	[20] [[3] [80] [20] [3] [80]
Dilution Factor (#16):	1:5 1:5	1:5	1:5	1:5	1:5
<u>NOTES</u>					
 (*0) The definition of these parameters is based on the <i>Roche</i>'s document "<i>cobas c pack MULTI</i>" (Doc. Code: 04929578001V1 - Version: 2006-08, V 1 Español). For any doubt or further information, please refer to this document. (*1) Calculated using the dead volumes and equations detailed in the Instructions of the "<i>cobas c pack MULTI</i>". (*2) The use of the calibration update, with only one calibrator level, is discouraged. (*3) User Defined (equal to Level-2 calibrator value multiplied by 2 (=Sample Dil./Calib. Dil.=10/5) (recommended)). (*4) User Defined (equal to Level-6 calibrator value multiplied by 2 (=Sample Dil./Calib. Dil.=10/5) (recommended)). (*5) User Defined, for the concentrations (lot specific) see the values of the 6-Level Calibrator Set (REF: TD-42642), on the table of assigned values of the IFU. 					