



c. València 558, 4t 2a - 08026 Barcelona +34 93 244 86 79 - info@3diag.com

> NIF: ES B66739772 Inscrita R.M. Barcelona Tomo 45329, Folio 165, Hoja 484362

REF TD-42591 - C1 (Esterase) Inhibitor - for Turbidimetry

## 3diag - C1In - TIA - ANNEX to IFU: Architect c

Application Proposal - using 3diag - C1In - CAL SET (REF TD-42582)

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GENERAL + REACTION DEFINITION			
Assay Type:	[Photometric]	Availability:	[Enabled]
Reagent Type:	[R1+R2]	Run Controls by:	[Lot] or [Kit] (User Selected)
Reaction Mode:	[End Up]	Wavelenght (Prim./Sec.):	[340] [None]
Read Times (Main) - Last Req. T.:	<b>[32] [33]</b> - [33]	Abs. Range - Color Correction:	Not Defined
Sample Blank Type:	[Self]	Blank Read Time:	[18] [19]
REAGENT / SAMPLE + VALIDITY CHECKS			
Reagent Name:	User Defined	Diluent/Disp. Mode:	[Saline] [Type 0]
R1 - Volume/Water/Disp. Mode:	[120] [] [Type 0]	R2 - Volume/Water/Disp. Mode:	[40] [] [Type 1]
Dilution - Name/Sample/Dil.	S./Diluent/Water/Default:	[STANDARD] [20] <b>[14]</b> [80] []	[Default] Dil. Factor = 1:5
Dilution - Name/Sample/Dil.	S./Diluent/Water/Default:	[D-1:25] [5] <b>[14]</b> [120] []	[] Dil. Factor = 1:25
Dilution - Name/Sample/Dil. S./Diluent/Water/Default: Not Defined			
Reaction Check:	[None]	Maximum Absorvance Variation:	Not Defined
CALIBRATION PARAMETERS			
Calibration Method:	[Spline] or [Logit-4] (user de	fined)	
Calibrator Set:	User Defined	Replicates:	[2] (minimum recommended 2)
Cal. Level (Blank) - Conc./Sample/Dil. S./Diluent/Water: [Water] [0] [14] [] []			[] Dil. Factor = 1:1
Cal. Level (1 to 6) - Conc./Sample/Dil. S./Diluent/Water:		[Cal 1 to 6] [ <sup>*2)</sup> ] [20] <b>[14]</b> [80	] [] Dil. Factor = 1:5
Full Interval:	Not Defined (recommended)	Adjust Type:	[None] (*3)
Blank Absorvance Range:	Not Defined	Span - Span Absorvance Range:	Not Defined
Expected Cal Factor - ECF % Tol.:	Not Defined	Max. Curve Fit (Logit-4 Method only):	Not Defined
<u>RESULTS</u>			
Result Units:	[mg/dl] or [mg/l] (User Def.)	Decimal Places:	User Defined
Correl factor - Intercept:	[1.0000] [0.0000]	Gender and Age Specific Ranges:	User Defined
Dil. Default Range - Low Linearity:	[(*4)]	Dil. Def. Range - High Linearity:	[ <sup>(*5)</sup> ]
<u>NOTES</u>			
	ations see the values table of stment, with only one or two e.	sferred into a single container. the IFU of the Calibrators (REF: TD-4258 calibrator levels, is discouraged.	2).

- (\*5): Lot Specific, equal to Cal 6 value.
- (\*6): It is recommended to retest samples higher than the upper limit of the assay range at 1:25 dilution.