

3diag - C1In - TIA

ANNEX to IFU: *Alinity c* - Application Proposal

REF TD-42591 - C1 (Esterase) Inhibitor - for Turbidimetry
 using 3diag - C1In - CAL SET (**REF** TD-42582)

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GENERAL TAB

GENERAL PARAMETERS

Assay Name	CEI ^(*1)	Assay Type	Photometric
Assay Number	System proposes the next available one	Assay Availability	Enabled
Assay Version	ID of assay version	Assay Status	Primary
Date/Time	Date and time of last changes	Run Controls for Reagents by	Lot
Operator	User ID, who modified the definition		

REACTION DEFINITION

Reaction Mode	End Up	Main Read Time	37 - 38	Absorbance Range	Not Defined
Primary Wavelength	340	Flex Read Time	Not Defined	Sample Blank Type	Self Blank
Second. Wavelength	Not Defined	Blank Read Time	20 - 21	Blank Assay	Not Defined
Last Read Required	38	Color Corr. Read Time	Not Defined		

REAGENT

New Reagent flyout - for Reagents

Reagent Name	R-CEI ^(*1)
Reagent Type	R1 and R2
R1 bottle - Reaction Buffer - Use	BUF C1In
R2 bottle - Antiserum Reagent - Use	REAG Ab C1In
Low Alert	15
Number of Test	85 (240 if 2 kits/cartridge are used ^(*2))
Onboard Stability	9999 (Not used ^(*3))

Reagents

Reagent Name	R-CEI	R1 Reagent Volume	90	R2 Reagent Volume	30
Diluent Name	Saline	R1 Water Volume	Not Defined	R2 Water Volume	Not Defined
Diluent Disp. Mode	Type 1	R1 Dispense Mode	Type 1	R2 Dispense Mode	Type 1

SAMPLE

<u>Dilution Name</u>	<u>Sample Volume</u>	<u>Dil. Sample Vol.</u>	<u>Diluent Volume</u>	<u>Water Volume</u>	<u>Dilution Factor</u>	<u>Default Dilution</u>
Std 1:1 ^(*1)	1.7	Not Defined	Not Defined	Not Defined	1.00 (Informative)	Yes (Mark as Default)
D1 1:5 ^(*1)	20	1.7	80	Not Defined	5.00 (Informative)	No (Not Mark as Default)
3rd Dilution Not Defined						

VALIDITY CHECKS

Reaction Check Type	None	Read Time A Range	Not Defined	Calculation Limit	Not Defined
Minimum Absorv.	Not Defined	Read Time B Range	Not Defined	Rate Linearity %	Not Defined
Maximum Absorv. Variation	Not Defined				

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CALIBRATION TAB

CALIBRATION / VALIDITY CHECKS

Calibration Method	Spline (Recommended)	Full Interval Hours	0 (Disabled ^(*4))	Adjust Interval Hours	Not Defined
Factor	Not Defined	Adjust Type	None ^(*5)	Adjust Level	Not Defined
Use Cal Factor From	Not Defined	Maximum Curve Fit	Not Defined	Default Ordering Type	Not Defined
Expected Cal Factor	Not Defined			Blank Absorv. Range	Not Defined
Exp. Cal. F. Toler. %	Not Defined	Span Blank	Not Defined	Span Absorv. Range	Not Defined

CALIBRATORS

New Cal Set flyout

Calibrator Set Name **CEI CAL ^(*1)** Calibrator Set Levels **6**

NOTE: The Concentration of the calibrator level **CEI CAL 1**, used to made the blank, **must be set equal to zero.**

Calibrators

Calibrator Set Name	Select from menu		Replicates 2 (Recommended)		
Cal Level	Sample Volume	Dil. Sample Vol.	Diluent Volume	Water Volume	Dilution Factor
Blank: CEI CAL 1	1.5	1.7	300	Not Defined	201.00 (Informative)
Cal 1: CEI CAL 2	1.7	Not Defined	Not Defined	Not Defined	1.00 (Informative)
Cal 2: CEI CAL 3	1.7	Not Defined	Not Defined	Not Defined	1.00 (Informative)
Cal 3: CEI CAL 4	1.7	Not Defined	Not Defined	Not Defined	1.00 (Informative)
Cal 4: CEI CAL 5	1.7	Not Defined	Not Defined	Not Defined	1.00 (Informative)
Cal 5: CEI CAL 6	1.7	Not Defined	Not Defined	Not Defined	1.00 (Informative)

RESULT TAB

RESULT UNITS

Result Units	mg/dl	Decimal Places	2 (Recommended)	Result Unit UCUM	mg/dl
Correlation Factor	1.0000	Intercept	0.0000		

RESULT PARAMETERS

Low Linearity	User Defined ^(*6)	High Linearity	User Defined ^(*6)
Gender and Age Spec. Ranges	User Defined		

INTERPRETATION PARAMETERS

Name, Range & Rev. Required User Defined

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RETEST RULES TAB (User defined, the proposed parameters have only value as a recommendation)

1st - Retest Rule

Retest Rule Name	CEI DIL1 ^(*1)	Result Indicator	Select Result Range
Result Range	Set as Cal Set (REF: TD-42582) Level-6 value (equal to CEI CAL 6 value) ^(*7)		
To	Not Defined		
Original Dilution	Std 1:1 (Default Dilution)		
<u>Selected Retest Assay</u>	<u>Retest Dilution</u>	<u>Replicates</u>	
CEI	D1 1:5	1	

NOTES

- (*1) Proposal, User defined field.
- (*2) The number of test per kit can be optimized if 2 kits are transferred into a single container.
- (*3) We recommend to disable the Onboard Stability check, and re-calibrate when the QC established procedures do not give the expected results. If, after re-calibration, QC established procedures still not giving the expected results then discard the reagents.
- (*4) We recommend to disable the automatic control of the calibration interval, and re-calibrate when a new batch of reagents is used, or when the QC established procedures do not give the expected results.
- (*5) The use of the calibration adjustment, with only one or two calibrator levels, is discouraged.
- (*6) We recommend to leave the Linearity Limits undefined, and so they will not apply.
 If the user wants to use the Linearity Limits, we recommend to define:
 - the Low Linearity Limit equal to Cal Set (ref: TD-42582) Level-2 value (equal to **CEI CAL 2** value), and
 - the High Linearity Limit equal to Cal Set (ref: TD-42582) Level-6 value (equal to **CEI CAL 6** value).
 Linearity Limits should be adjusted to the new calibrator values whenever a new lot with different values is used.
 For example, for the currently available lots of calibrators (Cal Set - REF: TD-42582), the Linearity Limits will be:
 - for LOT: 582-05: Low Limit = 3.51, and High Limit = 42.10
 - for LOT: 582-06: Low Limit = 3.04, and High Limit = 36.60
- (*7) Result Ranges for the retest rules should be adjusted to the new calibrator values whenever a new lot with different values is used.