TRIMERO Diagnostics, SL
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3diag - C5 - TIA

ANNEX to IFU: *Architect c* - Application Proposal

REF TD-42571 - C5 Complement - for Turbidimetry

using 3diag - C5 - CAL SET (REF TD-42562)

GENERAL

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Assay	C5 (*1)	*Assay Type*	Photometric
Assay Availability	Enabled	*Run Controls for R. by*	Lot

REACTION DEFINITION

Reaction Mode	End Up	*Primary Wavelength*	340	*Second. Wavelength*	Not Defined
Main Read Time	32 - 33	*Blank Read Time*	18 - 19	*Last Read Required*	33
Sample Blank Type	Self	*Absorvance Range*	Not Defined	*Color Correction*	Not Defined

REAGENT / SAMPLE

Reagent	42571	*R1 Reagent Volume*	98	*R2 Reagent Volume*	42
Diluent Name	Saline	*R1 Water Volume*	45	*R2 Water Volume*	Not Defined
R1 Dispense Mode	Type 0	*R2 Dispense Mode*	Type 1		

Dilution Name	*Sample Volume*	*Dil. Sample Vol.*	*Diluent Volume*	*Water Volume*	*Dilution Factor*	*Default Dilution*
Std 1:1 (*1)	3.5	Not Defined	Not Defined	Not Defined	1.00 (Informative)	Yes (Mark as Default)
D1 1:5 (*1)	25	3.5	100	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
Minumum Absorv.	Not Defined	*Read Time B Range*	Not Defined	*Rate Linearity %*	Not Defined
Maximum Absorv. Variation	Not Defined				

CALIBRATION

CALIBRATION / CALIBRATORS

Calibration Method	Spline (Recommended)	*Calibrator Set*	C5 CAL (*1)	*Replicates*	2 (Recommended)

NOTE: The Concentration of the calibrator level **C5 CAL 1**, used to made the blank, **must be set equal to zero**.

VOLUMES

Cal Level	*Sample Volume*	*Dil. Sample Vol.*	*Diluent Volume*	*Water Volume*	*Dilution Factor*
Blank: C5 CAL 1	1.5	3.5	300	Not Defined	201.00 (Informative)
Cal 1: C5 CAL 2	3.5	Not Defined	Not Defined	Not Defined	1.00 (Informative)
Cal 2: C5 CAL 3	3.5	Not Defined	Not Defined	Not Defined	1.00 (Informative)
Cal 3: C5 CAL 4	3.5	Not Defined	Not Defined	Not Defined	1.00 (Informative)
Cal 4: C5 CAL 5	3.5	Not Defined	Not Defined	Not Defined	1.00 (Informative)
Cal 5: C5 CAL 6	3.5	Not Defined	Not Defined	Not Defined	1.00 (Informative)

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INTERVALS

Full Interval (hours)	Not Defined (*2)	*Adjust Interval (hours)*	Not Defined		
Adjust Type	None (*3)	*Adjust Level*	Not Defined	*Default Ordering Type*	Not Defined

VALIDITY CHECKS

Blank Absorv. Range	Not Defined	*Span*	Not Defined	*Span Absorv. Range*	Not Defined
Expected Cal Factor	Not Defined	*Exp. Cal. F. Toler. %*	Not Defined	*Maximum Curve Fit*	Not Defined

RESULTS

Low Linearity	User Defined (*4)	*High Linearity*	User Defined (*4) (*5)
Gender and Age Spec. Ranges	User Defined		
Name, Range & Rev. Required	User Defined		
Result Units	mg/dl	*Decimal Places*	2 (Recommended)
Correlation Factor	1.0000	*Intercept*	0.0000

NOTES

(*1) Proposal, User defined field.

(*2) Calibration curves have a limited validity, which depends on the particular conditions of use.
We recommend to disable the automatic control of the calibration interval, and re-calibrate when:
- a new lot of reagents is used,
- established internal quality control procedures do not deliver the expected results, or
- after performing maintenance operations on the analyzer.

(*3) The use of the calibration adjustment, with only one or two calibrator levels, is discouraged.

(*4) Linearity Limits can be left undefined, as for non-linear calibrations the analyzer automatically controls and flags samples with signals higher than the highest calibrator.
If the user wants to use the Linearity Limits, we recommend to define it as:
- Low Linearity Limit equal to 2.0 (fixed value), and
- High Linearity Limit equal to Cal Set (REF: TD-42562) Level-6 value.

(*5) High Linearity Limit should be adjusted to the new calibrator values whenever a new lot of Cal Set (REF: TD-42562) with different values is used.

(*6) The number of test per kit can be optimized if 2 kits are transferred into a single container.

(*7) It is recommended to retest samples higher than the upper limit of the assay range at 1:5 dilution.