

3diag - IgD - TIA

ANNEX to IFU: *Architect c* - Application Proposal

REF TD-42651 - IgD Complement - for Turbidimetry

using **3diag - IgD - CAL SET** (**REF** TD-42642)

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GENERAL

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

REACTION DEFINITION

Reaction Mode	End Up	Primary Wavelength	604	Second. Wavelength	Not Defined
Main Read Time	32 - 33	Blank Read Time	18 - 19	Last Read Required	33
Sample Blank Type	Self	Absorbance Range	Not Defined	Color Correction	Not Defined

REAGENT / SAMPLE

Reagent	42651	R1 Reagent Volume	120	R2 Reagent Volume	48
Diluent Name	Saline	R1 Water Volume	Not Defined	R2 Water Volume	Not Defined
R1 Dispense Mode	Type 0	R2 Dispense Mode	Type 1		

<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 1:10 (*1)	12	3.6	108	Not Defined	10.00 (Informative)	Yes (Mark as Default)
D1 1:80 (*1)	2	3.6	158	Not Defined	80.00 (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
Max. Absorv. Variation	Not Defined				

CALIBRATION

CALIBRATION / CALIBRATORS

Calibration Method	Spline (Recommended)	Calibrator Set	IGD CAL (*1)	Replicates	2 (Recommended)
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NOTE: The Concentration of the calibrator level **IGD CAL 1**, used to made the blank, **must be set equal to zero**.

VOLUMES

<u>Cal Level</u>	<u>Sample Volume</u>	<u>Dil. Sample Vol.</u>	<u>Diluent Volume</u>	<u>Water Volume</u>	<u>Dilution Factor</u>
Blank: IGD CAL 1	1.5	3.6	300	Not Defined	201.00 (Informative)
Cal 1: IGD CAL 2	20	3.6	80	Not Defined	5.00 (Informative)
Cal 2: IGD CAL 3	20	3.6	80	Not Defined	5.00 (Informative)
Cal 3: IGD CAL 4	20	3.6	80	Not Defined	5.00 (Informative)
Cal 4: IGD CAL 5	20	3.6	80	Not Defined	5.00 (Informative)
Cal 5: IGD CAL 6	20	3.6	80	Not Defined	5.00 (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 0.05 (fixed value), and
 - High Linearity Limit equal to Cal Set (REF: TD-42642) Level-6 value, **divided by 5** (the calibration dilution).
- (*5) High Linearity Limit should be adjusted to the new calibrator values whenever a new lot of Cal Set (REF: TD-42642) 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 1:80 dilution.