TRIMERO DIAGNOSTICS

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3diag - SAA - TIA

ANNEX to IFU: *Architect c* - Application Proposal

REF TD-42891 -   Serum Amyloid A - for Turbidimetry

using **3diag - SAA - CAL SET** (REF TD-42882)

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GENERAL

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Assay	**SAA** (*1)	*Assay Type*	**Photometric**
Assay Availability	**Enabled**	*Run Controls for R. by*	**Kit** (Recommended)

REACTION DEFINITION

Reaction Mode	**End Up**	*Primary Wavelength*	**524**	*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	**42891**	*R1 Reagent Volume*	**126**	*R2 Reagent Volume*	**38**
Diluent Name	User Defined (*1)	*R1 Water Volume*	Not Defined	*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 (*2)	**3.5**	Not Defined	Not Defined	Not Defined	1.00 (Informative)	**Yes** (Mark as Default)
D1 1:5 (*2)	**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*	**SAA CAL** (*2)	*Replicates*	**2** (Recommended)

NOTE: The Concentration of the calibrator level **SAA 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:	**SAA CAL 1**	**1.5**	**3.5**	**300**	Not Defined	201.00 (Informative)
Cal 1:	**SAA CAL 2**	**3.5**	Not Defined	Not Defined	Not Defined	1.00 (Informative)
Cal 2:	**SAA CAL 3**	**3.5**	Not Defined	Not Defined	Not Defined	1.00 (Informative)
Cal 3:	**SAA CAL 4**	**3.5**	Not Defined	Not Defined	Not Defined	1.00 (Informative)
Cal 4:	**SAA CAL 5**	**3.5**	Not Defined	Not Defined	Not Defined	1.00 (Informative)
Cal 5:	**SAA CAL 6**	**3.5**	Not Defined	Not Defined	Not Defined	1.00 (Informative)

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INTERVALS

Full Interval (hours)	Not Defined [*3])	*Adjust Interval (hours)*	Not Defined		
Adjust Type	**None** [*4]	*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 [*5]	*High Linearity*	User Defined [*5] [*6]
Gender and Age Spec. Ranges	User Defined		
Name, Range & Rev. Required	User Defined		
Result Units	**mg/L**	*Decimal Places*	**2** (Recommended)
Correlation Factor	**1.0000**	*Intercept*	**0.0000**

NOTES

(*1)   User Defined Sample Diluent.   Define and use   **DIL | SAA**   as specific diluent for the assay (samples and calibrators).
Refer to the sections *"Configure a user-defined sample diluent"* for c4000 and c8000 Systems and to *"Configure a reagent kit for a user-defined sample diluent"* for the c16000.

(*2)   Proposal, User defined field.

(*3)   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.

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

(*5)   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 (fixed value), and
- High Linearity Limit equal to Cal Set (REF: TD-42882) Level-6 value.

(*6)   If defined, High Linearity Limit should be adjusted to the new calibrator values whenever a new lot of Cal Set (REF: TD-42882) with different values is used.

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

(*8)   **DISCLAIMER:**
The definition of these parameters is based on the *Abbbott*'s document *"ARCHITECT c System Assay Applications Guide"* (Doc: 96322-103 - February, 2011). For any doubt or further information, please refer to this document.
Application validation is the sole responsability of the user. Methods and terminology for validation procedures vary by country and area. For the requirements and recommended procedures for your area, please refer to your specific acreditation guidelines.