

3diag - SAA - TIA

ANNEX to IFU: *Alinity c* - Application Proposal

REF TD-42891 - Serum Amyloid A - for Turbidimetry
 using 3diag - SAA - CAL SET (**REF** TD-42882)

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GENERAL TAB

GENERAL PARAMETERS

Assay Name	SAA ^(*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	548	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-SAA ^(*1)
Reagent Type	R1 and R2
R1 bottle - Reaction Buffer - Use	BUF SAA
R2 bottle - Antiserum Reagent - Use	REAG Ab SAA
Low Alert	15
Number of Test	86 (249 if 2 kits/cartridge are used ^(*2))
Onboard Stability	9999 (Not used ^(*3))

New Reagent flyout - for Diluent

Reagent Name	D-SAA ^(*1)
Reagent Type	Diluent
R1 bottle - SAA Diluent - Use	DIL SAA
R2 bottle - Not Used	
Low Alert	15
Number of Test	Not Applicable
Onboard Stability	9999 (Not used ^(*3))

Reagents

Reagent Name	R-SAA	R1 Reagent Volume	80	R2 Reagent Volume	25
Diluent Name	D-SAA	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)	2.3	Not Defined	Not Defined	Not Defined	1.00 (Informative)	Yes (Mark as Default)
D1 1:5 ^(*1)	20	2.3	80	Not Defined	5.00 (Informative)	No (Not Mark as Default)
D2 1:25 ^(*1)	5.0	2.3	120	Not Defined	25.00 (Informative)	No (Not Mark as Default)

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

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

CALIBRATORS

New Cal Set flyout

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

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

Calibrators

<i>Calibrator Set Name</i>	<i>Select from menu</i>		<i>Replicates</i> 2 (Recommended)		
<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: SAA CAL 1	1.5	2.3	300	Not Defined	201.00 (Informative)
Cal 1: SAA CAL 2	2.3	Not Defined	Not Defined	Not Defined	1.00 (Informative)
Cal 2: SAA CAL 3	2.3	Not Defined	Not Defined	Not Defined	1.00 (Informative)
Cal 3: SAA CAL 4	2.3	Not Defined	Not Defined	Not Defined	1.00 (Informative)
Cal 4: SAA CAL 5	2.3	Not Defined	Not Defined	Not Defined	1.00 (Informative)
Cal 5: SAA CAL 6	2.3	Not Defined	Not Defined	Not Defined	1.00 (Informative)

RESULT TAB

RESULT UNITS

<i>Result Units</i>	mg/l	<i>Decimal Places</i>	2 (Recommended)	<i>Result Unit UCUM</i>	mg/l
<i>Correlation Factor</i>	1.0000	<i>Intercept</i>	0.0000		

RESULT PARAMETERS

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

<i>Retest Rule Name</i>	SAA DIL1 ^(*1)	<i>Result Indicator</i>	Select Result Range
<i>Result Range</i>	Set as Cal Set (REF: TD-42882) Level-6 value (equal to SAA CAL 6 value) ^(*7)		
<i>To</i>	Not Defined		
<i>Original Dilution</i>	Std 1:1 (Default Dilution)		
<u><i>Selected Retest Assay</i></u>	<u><i>Retest Dilution</i></u>	<u><i>Replicates</i></u>	
SAA	D1 1:5	1	

2nd - Retest Rule

<i>Retest Rule Name</i>	SAA DIL2 ^(*1)	<i>Result Indicator</i>	Select Result Range
<i>Result Range</i>	Set as Cal Set (REF: TD-42882) Level-6 value (equal to SAA CAL 6 value), <u>multiplied by 5</u> ^(*7)		
<i>To</i>	Not Defined		
<i>Original Dilution</i>	D1 1:5		
<u><i>Selected Retest Assay</i></u>	<u><i>Retest Dilution</i></u>	<u><i>Replicates</i></u>	
SAA	D2 1:25	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.
- (*7) Result Ranges for the retest rules should be adjusted to the new calibrator values whenever a new lot with different values is used.

The definition of these parameters is based on the *Abbott's* document "*Alinity c Assay Applications Guide*"
 (Doc. control number: ADD-00063141 - March 2018)
 For any doubt or further information, please refer to this document.