

3diag - SAA - TIA

[REF] TD-42891 - Serum Amyloid A - for Turbidimetry

ANNEX to IFU: AU series analyzers

Proposal of Application - using 3diag - SAA - CAL SET ([REF] TD-42882)

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Test Name:	User Defined		
Type:	[Serum]	Operation:	[Yes]
<u>SPECIFIC TEST PARAMETERS - 1</u>			
Sample - Volume/Dilution:	[4] [0]	Pre-Dilution Rate:	[1]
Reagent R1 - Volume/Dilution:	[145] [0]	Reagent R2 - Volume/Dilution:	[45] [0]
Wavelength - Primary/Secondary:	[520] [None]	Method / Reaction Slope:	[Fixed] [+]
Measuring Point 1 - First / Last:	[12] [27]	Measuring Point 2 - First / Last:	Not Defined
Linearity / No Lag Time:	Not Defined		
Min/Max OD - L/H:	[-2.0] [2.5]	Reag. OD limit - First/Last L/H:	[-2.0] [2.5] - [-2.0] [2.5]
Correlation Factor - A/B	[1.00] [0.00]	On-board stability period:	User Defined
<u>SPECIFIC TEST PARAMETERS - 2</u>			
Value/Flag	User Defined	Level - L/H:	User Defined
Normal Ranges:	User Defined	Panic Value - L/H:	User Defined
Unit:	[mg/L]	Decimal Places:	User Defined
<u>CALIBRATION SPECIFIC</u>			
Calibration Type:	[6AB]	Formula:	[*1]
Counts:	[*2]	Process:	Not Defined
Point (1 to 5) - Cal. No./Conc.:	[*3]	Point (1 to 6) - Factor/OD-L/H:	[-2.0] [2.5]
1-Point Cal. Point:	Not Defined ^[*4]	With CONC-0:	Not Defined
MB Type Factor:	Not Defined	Calibration Stability Period:	User Defined
<u>NOTES</u>			
<p style="color: red;">(*1): User Defined, recommended [SPLINE] or [POLYGONAL].</p> <p style="color: red;">(*2): User Defined, recommended [2].</p> <p style="color: red;">(*3): For the concentrations see the table of analytical values in the IFU of the Calibrator Set (REF: TD-42882)</p> <p style="color: red;">(*4): The use of the calibration update, with only one calibrator level, is discouraged.</p>			