

3diag - C5 - TIA

ANNEX to IFU: *Optilite*[®] - AOR Test Parameters - Proposal of Application

REF TD-42571 - C5 Complement - For Turbidimetry

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INFO

<i>Name</i>	User Defined		
<i>Tag</i>	Read-only field		
<i>Version number</i>	Updated when new settings are saved		
<i>Full name</i>	User Defined		
<i>Online name</i>	User Defined		
<i>Type</i>	Photometric	<i>Number of decimals</i>	2 (minimum recommended 1)
<i>In use</i>	Yes	<i>Correction factor</i>	1.000
<i>Acceptance</i>	Manual	<i>Correction bias</i>	0.000
<i>Result Unit</i>	mg/dl		
<i>Sample Type</i>	Serum		
<i>Test version ID</i>	Read-only field		
<i>Last time changed</i>	Date and time of last changes		
<i>User name</i>	User ID, who modified the definition		

FLOW

<i>Blank type</i>	Yes	<i>Primary dilution 1+</i>	9 (Read-only field)
		<i>Dispensed volume</i>	Read-only field

1st Step - **Reagent**

<i>Reagent</i>	Select Reagent from the drop down menu - Reaction Buffer - Use REF TD-42571-BF - BUF C5		
<i>Volume (µl)</i>	77		
<i>Dispense with</i>	Extra		
<i>Extra volume (µl)</i>	10		
<i>Syringe speed</i>	Medium		
<i>Replacing Reagent</i>	None		

2nd Step - **Sample**

<i>Volume (µl)</i>	27		
<i>Dispense with</i>	Extra		
<i>Extra volume (µl)</i>	10		
<i>Extra wash</i>	No		

3rd Step - **Mix**

4th Step - **Incubation**

<i>Time (sec)</i>	54	<i>Actual time (sec)</i>	Read-only field
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5th Step - Reagent

Reagent	Select Reagent from the drop down menu - Antiserum Reagent - Use <input type="text" value="REF"/> TD-42571-RA - <input type="text" value="REAG"/> <input type="text" value="Ab"/> <input type="text" value="C5"/>		
Volume (µl)	33		
Dispense with	Extra		
Extra volume (µl)	10		
Syringe speed	Slow		
Replacing Reagent	None		

6th Step - End-point (Blank)

Blank resp. min (A)	0 (Not used)	Blank resp. max (A)	* (Not used)
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7th Step - Incubation

Time (sec)	297	Actual time (sec)	Read-only field
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8th Step - End-point (Measurement)

Main wavelength	340	Side wavelength	None
Residual net abs. (A)	0 (Not used)	Delta abs. check min. (A)	* (Not used)

DILUTION

Dilution with	Diluent
Primary dilution 1+	9

Neat sample

Dispense with	Extra
Volume (µl)	10

Diluent

Sample diluent ID	Diluent 1
Calibrator diluent ID	Diluent 1
Dispense with	Extra
Volume (µl)	10

LIMITS (User defined, the proposed parameters have only value as a recommendation)

	Measuring range		Next dilution ratio 1+	
	Min	Max	Low	High
Primary dilution	* (Not used)	See note (*1)	* (Not used)	49
2nd, 3rd & 4th dilution	* (Not used)	* (Not used)	* (Not used)	* (Not used)
Test limit	See note (*2)	See note (*3)		
Critical limit	* (Not used)	* (Not used)		
Init. abs.	* (Not used)	* (Not used)		
Reference ranges	User Defined			

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CALIBRATION

Calibration type	Logit-Log4	Abs. error (A)	* (Not used)
Repeat time (days)	0 (Not used, see note (*4))	Rel. error (%)	* (Not used)
Points / calibrator	Duplicate	Factor limit min.	* (Not used)
Acceptance	Manual	Factor limit max.	* (Not used)
Concentration axis	Linear	Bias limit min.	* (Not used)
Response axis	Linear	Bias limit max.	* (Not used)

Calibrators (User-defined Calibrators are defined in "F4 > Cal/Ctrl definition" - as Calibrator, use REF TD-42578 - **3diag - C5 - CAL-L**)

Nbr	Calibrator	Current Lot	Concentration	Dilution 1+
1	Select Cal.	Read-only value	Read-only value	95
2	Select Cal.	Read-only value	Read-only value	23
3	Select Cal.	Read-only value	Read-only value	11
4	Select Cal.	Read-only value	Read-only value	5
5	Select Cal.	Read-only value	Read-only value	3
6	Select Cal.	Read-only value	Read-only value	2

NOTES

- (*1) Equal to highest calibration point (Nbr 6) concentration
 (Calculated as: $\text{Cal. Concentration} * (\text{Sample Dilution} / \text{Cal Nbr 6 Dilution}) = \text{Cal. Concentration} * (10 / 3)$)
 (Limits should be adjusted to the new calibrator values whenever a new lot of Calibrator (REF: TD-42578) with different value is used)
 (If **AUTOM** flag is selected, limits are recalculated from the calibration)
- (*2) Equal to lowest calibration point (Nbr 1) concentration
 (Calculated as: $\text{Cal. Concentration} * (\text{Sample Dilution} / \text{Cal Nbr 1 Dilution}) = \text{Cal. Concentration} * (10 / 96)$)
- (*3) Equal to maximum measuring range multiplied by the re-dilution factor of the primary dilution
 (Calculated as: $\text{Max. Meas. Range} * (\text{Max Next Dil. Ratio} / \text{Sample Dilution}) = \text{Max. Meas. Range} / (50 / 10) =$
 $= \text{Cal. Concentration} * (\text{Max Next Dil. Ratio} / \text{Cal Nbr 6 Dilution}) = \text{Cal. Concentration} * (50 / 3)$)
- (*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. Nevertheless, if desired, the user can always define a calibration repeat time in order to be notified of a due calibration when the defined time is elapsed.
- (*5) The definition of these parameters is based on the *Binding Site's* document "*Optilite - Available on Request (AOR) Tests - Reference Guide*" (Doc. Code: AP DOC 49A - Version 131115). For any doubt or further information, please refer to this document.