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3diag - C1q - TIA

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

REF TD-42551 - C1q Complement - For Turbidimetry

Optilite® is a registered trademark of *The Binding Site Group Ltd.*, Birmingham, U.K.

INFO

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

FLOW

Blank type	**Yes**	*Primary dilution 1+*	**29** (Read-only field)
		Dispensed volume	Read-only field

1st Step - Reagent

Reagent	**Select Reagent from the drop down menu - Reaction Buffer - Use** REF TD-42551-BF - **BUF C1q**
Volume (µl)	**120**
Dispense with	**Extra**
Extra volume (µl)	**10**
Syringe speed	**Medium**
Replacing Reagent	**None**

2nd Step - Reagent

Reagent	**Select Reagent from the drop down menu - Antiserum Reagent - Use** REF TD-42551-RA - **REAG Ab C1q**
Volume (µl)	**30**
Dispense with	**Extra**
Extra volume (µl)	**10**
Syringe speed	**Slow**
Replacing Reagent	**None**

3rd Step - Mix

4th Step - Incubation

Time (sec)	**54**	*Actual time (sec)*	Read-only field

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5th Step - **Sample**

Volume (µl)	**6**
Dispense with	**Extra**
Extra volume (µl)	**10**
Extra wash	**No**

6th Step - **Mix**

7th Step - **Incubation**

Time (sec)	**18**	*Actual time (sec)*	Read-only field

8th Step - **End-point (Blank)**

Blank resp. min (A)	**0** (Not used)	*Blank resp. max (A)*	* (Not used)

9th Step - **Incubation**

Time (sec)	**297**	*Actual time (sec)*	Read-only field

10th Step - **End-point (Measurement)**

Main wavelength	**600**	*Side wavelength*	**None**
Residual net abs. (A)	**0** (Not used)	*Delta abs. check min. (A)*	* (Not used)

DILUTION

Dilution with	**Diluent**
Primary dilution 1+	**29**

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 Min	Measuring range Max	Next dilution ratio 1+ Low	Next dilution ratio 1+ High
Primary dilution	See note (*1)	See note (*2)	**9**	**119**
2nd, 3rd & 4th dilution	* (Not used)	* (Not used)	* (Not used)	* (Not used)
Test limit	See note (*3)	See note (*4)		
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 (*5))	*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-42552 - **3diag - C1q - CAL**)

Nbr	Calibrator	Current Lot	Concentration	Dilution 1+
1	**Select Cal.**	Read-only value	Read-only value	**199**
2	**Select Cal.**	Read-only value	Read-only value	**119**
3	**Select Cal.**	Read-only value	Read-only value	**59**
4	**Select Cal.**	Read-only value	Read-only value	**44**
5	**Select Cal.**	Read-only value	Read-only value	**29**

NOTES

(*1) Equal to lowest calibration point (Nbr 1) concentration
(Calculated as: Cal. Concentration * (Sample Dilution / Cal Nbr 1 Dilution) = Cal. Concentration * (30 / 200))
(If **AUTOM** flag is selected, limits are defined and recalculated from the calibration)

(*2) Equal to highest calibration point (Nbr 5) concentration
(Calculated as: Cal. Concentration * (Sample Dilution / Cal Nbr 5 Dilution) = Cal. Concentration * (30 / 30))
(If **AUTOM** flag is selected, limits are defined and recalculated from the calibration)

(*3) Equal to minumum measuring range divided by the re-concentration factor of the primary dilution
(Calculated as: Min. Meas. Range / (Sample Dilution / Low Next Dil. Ratio) = Min. Meas. Range / (30 / 10) =
= Cal. Concentration * (Low Next Dil. Ratio / Cal Nbr 1 Dilution) = Cal. Concentration * (10 / 200))

(*4) Equal to maximum measuring range multiplied by the re-dilution factor of the primary dilution
(Calculated as: Max. Meas. Range * (Max Next Dil. Ratio / Sample Dilution) = Max. Meas. Range / (120 / 30) =
= Cal. Concentration * (Max Next Dil. Ratio / Cal Nbr 5 Dilution) = Cal. Concentration * (120 / 30))

(*5) 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.