

3diag - C1q - OPT Kit

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

REF TD-42547 - C1q Complement - KIT - for *Optilite*[®]

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

Test parameters

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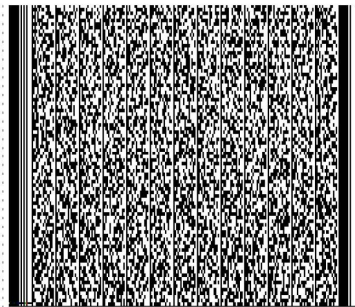
TD C1q Version number 1 . 2 Optilite 2
 s/n 864000294202

Date 30/03/2023 **User** Test designer
Time 18:35:16 **Software version: 7.0.2**

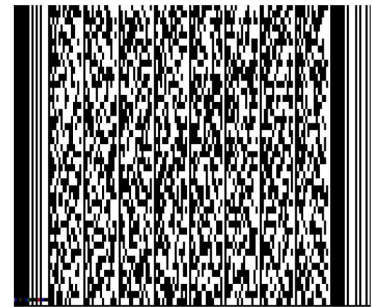
Info

Tag TD-42547
Last time changed 30/03/2023 18:29
User name Test designer
Full name C1q
In use Yes
Type Photometric
Online name
Acceptance Automatic
Result unit mg/l
Number of decimals 1
Correction factor 1
Correction bias 0
Sample type Serum

Barcode 1



Barcode 2



Flow

Blank type Yes **Primary dilution 1 +** 29 **Dispensed volume** 156

Reagent	Reagent	Volume (µl)	Dispense with	Extra volume (µl)	Syringe speed	Replacing reagent
R C1q.2		115	Extra	20	Medium	None
Barcode ID	Alarm limit (ml)	Onboard stability (days)				
996	2,0	30				
Reagent	Reagent	Volume (µl)	Dispense with	Extra volume (µl)	Syringe speed	Replacing reagent
R C1q.1		35	Extra	10	Slow	None
Barcode ID	Alarm limit (ml)	Onboard stability (days)				
997	1,0	30				
Incubate	Time (sec)	Actual time (sec)				
	300	297				
Sample	Volume (µl)	Dispense with	Extra volume (µl)	Extra wash		
	6	Extra	10	No		
Incubate	Time (sec)	Actual time (sec)				
	18	18				
End-point blank	Blank resp. min.(A)	Blank resp. max.(A)				
	0	*				
Incubate	Time (sec)	Actual time (sec)				
	300	297				

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TD C1q		Version number 1 . 2		Optilite 2		
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Date	30/03/2023	User	Test designer			
Time	18:35:16	Software version: 7.0.2				
End-point measurement	Main wavelength (nm)	Side wavelength (nm)	Residual net abs. (A)	Delta abs. check min. (A)		
	575	None	0	*		
Dilution		Limits				
Dilution with		Diluent		Measuring range (mg/l)		Next dilution ratio (1+)
Primary dilution 1 +		29		Min	Max	Low High
Neat sample	Dispense with	Extra		Primary dilution	40,00	370,00 7,0 119,0
	Volume (µl)	10		2nd dilution	*	* * *
Diluent	Dilution with	Extra		3rd dilution	*	* * *
	Volume (µl)	20		4th dilution	*	* * *
	Diluent ID	Diluent 1		Test limit	15,00	1.480,00 mg/l
	Calibrator diluent ID	Diluent 1		Critical limit	*	* mg/l
Sample type starting dilutions	Dispense with	Extra		Init. abs.	*	* A
	Volume (µl)	20		TVR limit (%)	*	
Sample type		Dilution				
Serum		1 + 29 (Primary)				
Plasma		1 + 29 (Primary)				
Urine		1 + 29 (Primary)				
CSF		1 + 29 (Primary)				
Oral fluid		1 + 29 (Primary)				
Whole blood		1 + 29 (Primary)				
Hemol. blood		1 + 29 (Primary)				
Other		1 + 29 (Primary)				
Calibration						
Calibration type	Logit-Log 4		Abs. error (A)		*	

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Date	30/03/2023	User	Test designer			
Time	18:35:16	Software version: 7.0.2				
Repeat time (days)	180	Rel. error (%)	*			
Points/calibrator	Single	Factor limit min.	*			
Acceptance	Manual	Factor limit max.	*			
Nbr	Calibrator	Current lot	Concentration	Dilution 1 +		
1	TD C1q Cal	Default	*	2		
2	TD C1q Cal	Default	*	3		
3	TD C1q Cal	Default	*	4		
4	TD C1q Cal	Default	*	5		
5	TD C1q Cal	Default	*	7		
6	TD C1q Cal	Default	*	10		
7	TD C1q Cal	Default	*	17		
8	TD C1q Cal	Default	*	29		
QC						
Procedure	Kit QC	QC profile	Kit QC			
Interval type		In use	Yes			
Requests		Acceptance	Manual			
Time (hh:mm)	0:00	Trigger	Manual,Calibration			
Procedure	Control	Current Lot	Conc.	SD	Req. count	
Kit QC	TD C1q HQC				1	
Kit QC	TD C1q LQC				1	
Procedure	Nbr of controls	SD multiplier				
Kit QC	1	2				