

3diag - C5 - OPT Kit

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

REF TD-42567 - C5 Complement - KIT - for *Optilite*[®]

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

Test parameters

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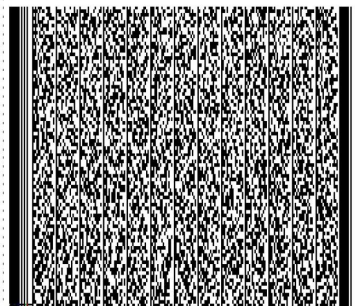
TD C5 Version number 1 . 2 Optilite 2
 s/n 864000294202

Date 30/03/2023 **User** Test designer
Time 19:03:49 **Software version:** 7.0.2

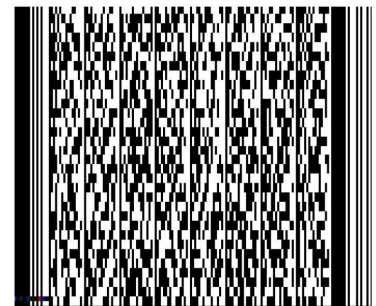
Info

Tag TD-42567
Last time changed 30/03/2023 19:01
User name Test designer
Full name C5
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 +** 13 **Dispensed volume** 150

Reagent	Reagent	Volume (µl)	Dispense with	Extra volume (µl)	Syringe speed	Replacing reagent
R C5.2		72	Extra	20	Medium	None
Barcode ID	Alarm limit (ml)	Onboard stability (days)				
987	2,0	30				

Sample	Volume (µl)	Dispense with	Extra volume (µl)	Extra wash
42		Extra	10	No

Incubate	Time (sec)	Actual time (sec)
300		297

Reagent	Reagent	Volume (µl)	Dispense with	Extra volume (µl)	Syringe speed	Replacing reagent
R C5.1		36	Extra	10	Slow	None
Barcode ID	Alarm limit (ml)	Onboard stability (days)				
988	1,0	30				

End-point blank	Blank resp. min.(A)	Blank resp. max.(A)
0		*

Incubate	Time (sec)	Actual time (sec)
300		297

End-point measurement	Main wavelength (nm)	Side wavelength (nm)	Residual net abs. (A)	Delta abs. check min. (A)
340		None	0	*

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<i>Dilution</i>		<i>Limits</i>				
		Measuring range (mg/l)		Next dilution ratio (1+)		
		Min	Max	Low	High	
Dilution with Diluent						
Primary dilution 1 +	13					
Neat sample		Primary dilution	40,00	400,00	3,0	41,0
Dispense with Extra		2nd dilution	*	*	*	*
Volume (µl) 20		3rd dilution	*	*	*	*
		4th dilution	*	*	*	*
Diluent		Test limit	15,00	1.120,00 mg/l		
Diluent ID	Diluent 1	Critical limit	*	*	mg/l	
Calibrator diluent ID	Diluent 1	Init. abs.	*	*	A	
Dispense with Extra		TVR limit (%)	*			
Volume (µl) 20						
Sample type starting dilutions						
Sample type	Dilution					
Serum	1 + 13 (Primary)					
Plasma	1 + 13 (Primary)					
Urine	1 + 13 (Primary)					
CSF	1 + 13 (Primary)					
Oral fluid	1 + 13 (Primary)					
Whole blood	1 + 13 (Primary)					
Hemol. blood	1 + 13 (Primary)					
Other	1 + 13 (Primary)					

Calibration

Calibration type Logit-Log 4 Abs. error (A) *

