

3diag - FB - OPT Kit

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

REF TD-42717 - Factor B (C3 Proactivator) - KIT - for *Optilite*[®]

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Test parameters

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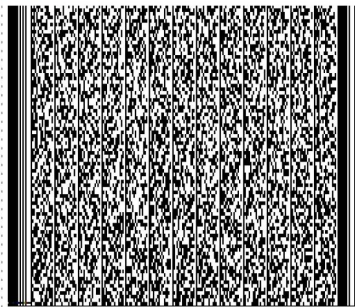
TD FB Version number 1.2 Optilite 2
 s/n 864000294202

Date 30/03/2023 **User** Test designer
Time 19:17:35 **Software version:** 7.0.2

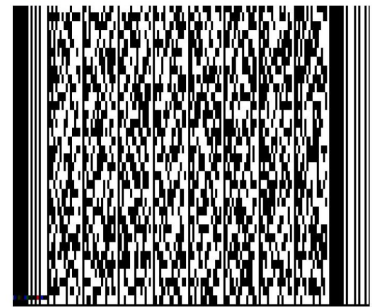
Info

Tag TD-42717
 Last time changed 30/03/2023 19:16
 User name Test designer
 Full name Factor B (C3Pa)
 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 + 19 Dispensed volume 145

Reagent	Reagent	Volume (µl)	Dispense with	Extra volume (µl)	Syringe speed	Replacing reagent
R FB.2		65	Extra	20	Medium	None
Barcode ID	Alarm limit (ml)	Onboard stability (days)				
669	2,0	30				
Sample	Volume (µl)	Dispense with	Extra volume (µl)	Extra wash		
40		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 FB.1		40	Extra	10	Normal	None
Barcode ID	Alarm limit (ml)	Onboard stability (days)				
670	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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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 FB Cal	Default	*	4
2	TD FB Cal	Default	*	5
3	TD FB Cal	Default	*	6
4	TD FB Cal	Default	*	8
5	TD FB Cal	Default	*	10
6	TD FB Cal	Default	*	15
7	TD FB Cal	Default	*	24
8	TD FB Cal	Default	*	49

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 FB HQC				1
Kit QC	TD FB LQC				1

Procedure	Nbr of controls	SD multiplier
Kit QC	1	2