

3diag - RBP - OPT Kit

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

REF TD-42667 - Retinol Binding Protein - Serum - KIT - for *Optilite*[®]

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

Test parameters

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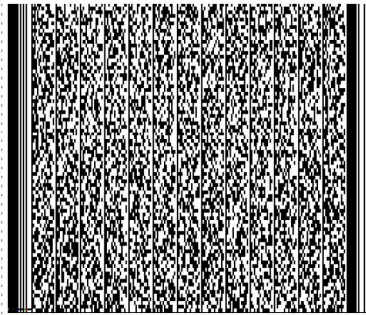
TD RBP Version number 1 . 2 Optilite 4
 s/n 864000295027

Date 21/11/2023 **User** Test designer
Time 19:26:09 **Software version:** 7.0.2

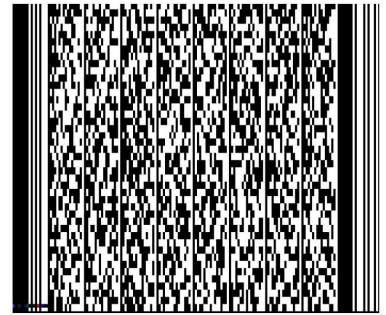
Info

Tag TD-42667
 Last time changed 21/11/2023 18:59
 User name Test designer
 Full name RBP Serum
 In use Yes
 Type Photometric
 Online name
 Acceptance Automatic
 Result unit mg/l
 Number of decimals 2
 Correction factor 1
 Correction bias 0
 Sample type Serum

Barcode 1



Barcode 2



Flow

Blank type Yes Primary dilution 1 + 29 Dispensed volume 150

Reagent	Reagent	Volume (µl)	Dispense with	Extra volume (µl)	Syringe speed	Replacing reagent
R RBP.2		120	Extra	20	Medium	None
Barcode ID	Alarm limit (ml)		Onboard stability (days)			
982	2,0		30			
Reagent	Reagent	Volume (µl)	Dispense with	Extra volume (µl)	Syringe speed	Replacing reagent
R RBP.1		20	Extra	10	Slow	None
Barcode ID	Alarm limit (ml)		Onboard stability (days)			
983	1,0		30			
Incubate	Time (sec)	Actual time (sec)				
	300	297				
Sample	Volume (µl)	Dispense with	Extra volume (µl)	Extra wash		
	10	Extra	10	No		
Incubate	Time (sec)	Actual time (sec)				
	18	18				
End-point blank	Blank resp. min.(A)	Blank resp. max.(A)				
	*	*				
Incubate	Time (sec)	Actual time (sec)				
	300	297				

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TD RBP		Version number 1 . 2		Optilite 4		
				s/n 864000295027		
Date	21/11/2023	User	Test designer			
Time	19:26:09	Software version: 7.0.2				
End-point measurement	Main wavelength (nm)	Side wavelength (nm)	Residual net abs. (A)	Delta abs. check min. (A)		
	600	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				Primary dilution	6,000 140,000	9,0 119,0
Dispense with		Extra		2nd dilution	* *	* *
Volume (µl)		10		3rd dilution	* *	* *
Diluent				4th dilution	* *	* *
Diluent ID		Diluent 1		Test limit	2,500 560,000 mg/l	
Calibrator diluent ID		Diluent 1		Critical limit	* * mg/l	
Dispense with		Extra		Init. abs.	* * A	
Volume (µl)		20		TVR limit (%)	*	
Sample type starting dilutions						
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	21/11/2023	User	Test designer		
Time	19:26:09	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 RBP Cal	Default	*	4	
2	TD RBP Cal	Default	*	5	
3	TD RBP Cal	Default	*	6	
4	TD RBP Cal	Default	*	8	
5	TD RBP Cal	Default	*	12	
6	TD RBP Cal	Default	*	19	
7	TD RBP Cal	Default	*	39	
8	TD RBP Cal	Default	*	119	
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 RBP HQC				1
Kit QC	TD RBP LQC				1
Procedure	Nbr of controls	SD multiplier			
Kit QC	1	2			