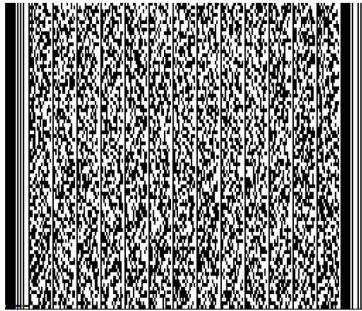
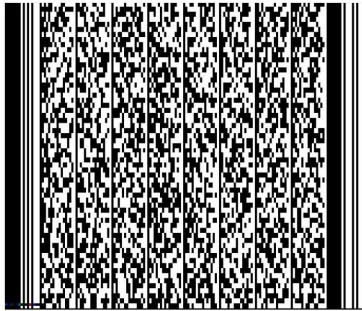


## 3diag - U-RBP - OPT Kit

### ANNEX to IFU: *Optilite*<sup>®</sup> - Proposal of Application

**REF** TD-42677 - Retinol Binding Protein - Urine - KIT - for *Optilite*<sup>®</sup>

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

Test parameters		Page 1 / 3	
TD RBP U		Version number 1 . 2	Optilite 4 s/n 864000295027
<b>Date</b>	28/11/2023	<b>User</b>	Test designer
<b>Time</b>	17:51:36	<b>Software version:</b>	7.0.2
<b>Info</b>			
Tag	TD-42677	<b>Barcode 1</b>	<b>Barcode 2</b>
Last time changed	28/11/2023 17:50		
User name	Test designer		
Full name	RBP urine		
In use	Yes		
Type	Photometric		
Online name			
Acceptance	Manual		
Result unit	mg/l		
Number of decimals	3		
Correction factor	1		
Correction bias	0		
Sample type	Urine		
<b>Flow</b>			
Blank type	Yes	Primary dilution 1 +	0
		Dispensed volume	160
<b>Reagent 1</b>			
Reagent	Reagent	Volume (µl)	Dispense with
	R RBP U.2	132	Extra
	Barcode ID	Alarm limit (ml)	Onboard stability (days)
	908	2,0	30
<b>Reagent 2</b>			
Reagent	Reagent	Volume (µl)	Dispense with
	R RBP U.1	20	Extra
	Barcode ID	Alarm limit (ml)	Onboard stability (days)
	909	1,0	30
<b>Incubate</b>			
Time (sec)	Actual time (sec)		
300	297		
<b>Sample</b>			
Volume (µl)	Dispense with	Extra volume (µl)	Extra wash
8	Extra	10	Yes
Washing solution	Wash target	Wash sequence	
Water	Sample probe	Before dispense	
<b>Incubate</b>			
Time (sec)	Actual time (sec)		
18	18		
<b>End-point blank</b>			
Blank resp. min.(A)	Blank resp. max.(A)		
0	*		
<b>Incubate</b>			
Time (sec)	Actual time (sec)		

## 3diag - U-RBP - OPT Kit

### ANNEX to IFU: *Optilite*<sup>®</sup> - Proposal of Application

Test parameters				Page	2 / 3
		TD RBP U	Version number 1 . 2	Optilite 4	
				s/n 864000295027	
<b>Date</b>	28/11/2023	<b>User</b>	Test designer		
<b>Time</b>	17:51:36	<b>Software version:</b>	7.0.2		
	300		297		
<b>End-point measurement</b>	Main wavelength (nm)	Side wavelength (nm)	Residual net abs. (A)	Delta abs. check min. (A)	
	600	None	0	*	
<b>Dilution</b>			<b>Limits</b>		
	Dilution with	Diluent	Measuring range (mg/l)		Next dilution ratio (1+)
	Primary dilution 1 +	0	Min	Max	Low High
<b>Neat sample</b>			Primary dilution	*	1,0000 * 7,0
	Dispense with	Extra	2nd dilution	*	8,0000 * 63,0
	Volume (µl)	10	3rd dilution	*	64,0000 * 499,0
			4th dilution	*	* *
<b>Diluent</b>			Test limit	0,0080	500,0000mg/l
	Diluent ID	TD RBP U DIL	Critical limit	*	* mg/l
	Calibrator diluent ID	TD RBP U DIL	Init. abs.	*	* A
	Dispense with	Extra	TVR limit (%)	*	
	Volume (µl)	20			
<b>Sample type starting dilutions</b>					
	Sample type	Dilution			
	Serum	1 + 0 (Primary)			
	Plasma	1 + 0 (Primary)			
	Urine	1 + 0 (Primary)			
	CSF	1 + 0 (Primary)			
	Oral fluid	1 + 0 (Primary)			
	Whole blood	1 + 0 (Primary)			
	Hemol. blood	1 + 0 (Primary)			
	Other	1 + 0 (Primary)			
<b>Calibration</b>					
<b>Calibration type</b>	Logit-Log 4		Abs. error (A)		*

## 3diag - U-RBP - OPT Kit

### ANNEX to IFU: *Optilite*<sup>®</sup> - Proposal of Application

<b>Test parameters</b>				Page	3 / 3
TD RBP U		Version number 1 . 2		Optilite 4	
				s/n 864000295027	
<b>Date</b>	28/11/2023	<b>User</b>	Test designer		
<b>Time</b>	17:51:36	<b>Software version: 7.0.2</b>			
Repeat time (days)	180	Rel. error (%)		*	
Points/calibrator	Single	Factor limit min.		*	
Acceptance	Manual	Factor limit max.		*	
<b>Nbr</b>	<b>Calibrator</b>	<b>Current lot</b>	<b>Concentration</b>	<b>Dilution 1 +</b>	
1	TD RBP U Cal	Default	*	2	
2	TD RBP U Cal	Default	*	3	
3	TD RBP U Cal	Default	*	4	
4	TD RBP U Cal	Default	*	6	
5	TD RBP U Cal	Default	*	10	
6	TD RBP U Cal	Default	*	19	
7	TD RBP U Cal	Default	*	39	
8	TD RBP U Cal	Default	*	399	
<b>QC</b>					
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 U HQC				1
Kit QC	TD RBP U LQC				1
		Procedure	Nbr of controls	SD multiplier	
		Kit QC	1	2	