

## 3diag - sTfR - OPT Kit

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

**REF** TD-42687 - Soluble Transferrin Receptor - 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

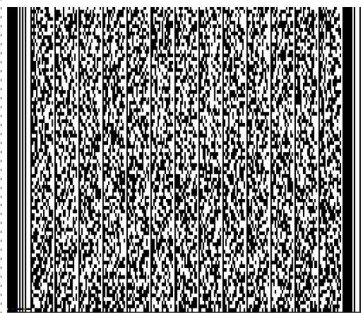
TD sTfR Version number 1.2 Optilite 4  
 s/n 864000295027

**Date** 12/02/2024 **User** Test designer  
**Time** 9:20:49 **Software version:** 7.0.2

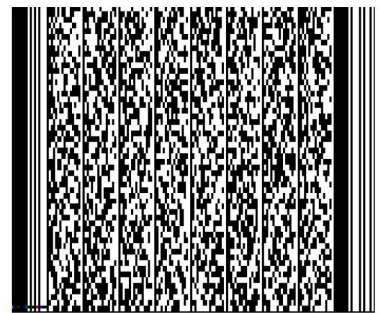
#### Info

Tag TD-42687  
 Last time changed 12/02/2024 09:15  
 User name Test designer  
 Full name Soluble Transferrin Recept ..  
 In use Yes  
 Type Photometric  
 Online name  
 Acceptance Manual  
 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 + 23 Dispensed volume 153

Reagent	Reagent	Volume (µl)	Dispense with	Extra volume (µl)	Syringe speed	Replacing reagent
R sTfR.2		105	Extra	20	Medium	None
Barcode ID	Alarm limit (ml)	Onboard stability (days)				
899	2,0	30				
Reagent	Reagent	Volume (µl)	Dispense with	Extra volume (µl)	Syringe speed	Replacing reagent
R sTfR.1		22	Extra	10	Slow	None
Barcode ID	Alarm limit (ml)	Onboard stability (days)				
900	1,0	30				
Incubate	Time (sec)	Actual time (sec)				
	300	297				
Sample	Volume (µl)	Dispense with	Extra volume (µl)	Extra wash		
	26	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)				
	600	594				

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Test parameters					Page	2 / 3
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<b>Date</b>	12/02/2024		<b>User</b>	Test designer		
<b>Time</b>	9:20:49		<b>Software version: 7.0.2</b>			
End-point measurement	Main wavelength (nm)	Side wavelength (nm)	Residual net abs. (A)	Delta abs. check min. (A)		
	600	None	0	*		
<b>Dilution</b>						
	Dilution with		Diluent		Limits	
	Primary dilution 1 +		23		Measuring range (mg/l)	
					Next dilution ratio (1+)	
					Min	Max
Neat sample					Low	High
	Dispense with		Extra		Primary dilution	0,452
	Volume (µl)		10		2nd dilution	* 4,520
					3rd dilution	* 22,600
					4th dilution	* *
Diluent					Test limit	0,150 113,000 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			
<b>Sample type starting dilutions</b>						
	Sample type		Dilution			
	Serum		1 + 23 (Primary)			
	Plasma		1 + 23 (Primary)			
	Urine		1 + 23 (Primary)			
	CSF		1 + 23 (Primary)			
	Oral fluid		1 + 23 (Primary)			
	Whole blood		1 + 23 (Primary)			
	Hemol. blood		1 + 23 (Primary)			
	Other		1 + 23 (Primary)			
<b>Calibration</b>						
Calibration type	Logit-Log 4		Abs. error (A)		*	

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<b>Time</b>	9:20:49	<b>Software version: 7.0.2</b>				
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 sTfR Cal	Default	*	5		
2	TD sTfR Cal	Default	*	6		
3	TD sTfR Cal	Default	*	8		
4	TD sTfR Cal	Default	*	11		
5	TD sTfR Cal	Default	*	16		
6	TD sTfR Cal	Default	*	24		
7	TD sTfR Cal	Default	*	37		
8	TD sTfR Cal	Default	*	59		
<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 sTfR HQC				1	
Kit QC	TD sTfR LQC				1	
Procedure	Nbr of controls	SD multiplier				
Kit QC	1	2				