

3diag - RBP - TIA

ANNEX to IFU: *Optilite*[®] - AOR Test Parameters - Proposal of Application (URINE)

REF TD-42671 - Retinol Binding Protein - For Turbidimetry

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INFO

<i>Name</i>	User Defined		
<i>Tag</i>	Read-only field		
<i>Version number</i>	Updated when new settings are saved		
<i>Full name</i>	User Defined		
<i>Online name</i>	User Defined		
<i>Type</i>	Photometric	<i>Number of decimals</i>	3 (minimum recommended 2)
<i>In use</i>	Yes	<i>Correction factor</i>	1.000
<i>Acceptance</i>	Manual	<i>Correction bias</i>	0.000
<i>Result Unit</i>	mg/dl		
<i>Sample Type</i>	Urine		
<i>Test version ID</i>	Read-only field		
<i>Last time changed</i>	Date and time of last changes		
<i>User name</i>	User ID, who modified the definition		

FLOW

<i>Blank type</i>	Yes	<i>Primary dilution 1+</i>	4 (Read-only field)
		<i>Dispensed volume</i>	Read-only field

1st Step - Reagent

<i>Reagent</i>	Select Reagent from the drop down menu - Reaction Buffer - Use REF TD-42671-BF - BUF RBP		
<i>Volume (μl)</i>	120		
<i>Dispense with</i>	Extra		
<i>Extra volume (μl)</i>	10		
<i>Syringe speed</i>	Medium		
<i>Replacing Reagent</i>	None		

2nd Step - Sample

<i>Volume (μl)</i>	10
<i>Dispense with</i>	Extra
<i>Extra volume (μl)</i>	10
<i>Extra wash</i>	No

3rd Step - Incubation

<i>Time (sec)</i>	180	<i>Actual time (sec)</i>	Read-only field
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4th Step - Reagent

Reagent	Select Reagent from the drop down menu - Antiserum Reagent - Use REF TD-42671-RA - REAG Ab RBP		
Volume (µl)	20		
Dispense with	Extra		
Extra volume (µl)	10		
Syringe speed	Slow		
Replacing Reagent	None		

5th Step - End-point (Blank)

Blank resp. min (A)	0 (Not used)	Blank resp. max (A)	* (Not used)
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6th Step - Incubation

Time (sec)	297	Actual time (sec)	Read-only field
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7th Step - End-point (Measurement)

Main wavelength	600	Side wavelength	None
Residual net abs. (A)	0 (Not used)	Delta abs. check min. (A)	* (Not used)

DILUTION

Dilution with	Diluent
Primary dilution 1+	4

Neat sample	
Dispense with	Extra
Volume (µl)	10

Diluent	
Sample diluent ID	Diluent 1
Calibrator diluent ID	Diluent 1
Dispense with	Extra
Volume (µl)	10

LIMITS (User defined, the proposed parameters have only value as a recommendation)

	Measuring range		Next dilution ratio 1+	
	Min	Max	Low	High
Primary dilution	See note (*1)	See note (*2)	See note (*1)	29
2nd dilution	* (Not used)	See note (*3)	* (Not used)	119
3rd & 4th dilution	* (Not used)	* (Not used)	* (Not used)	* (Not used)
Test limit	See note (*4)	See note (*5)		
Critical limit	* (Not used)	* (Not used)		
Init. abs.	* (Not used)	* (Not used)		
Reference ranges	User Defined			

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CALIBRATION

Calibration type	Logit-Log5	Abs. error (A)	* (Not used)
Repeat time (days)	0 (Not used, see note (*6))	Rel. error (%)	* (Not used)
Points / calibrator	Duplicate	Factor limit min.	* (Not used)
Acceptance	Manual	Factor limit max.	* (Not used)
Concentration axis	Linear	Bias limit min.	* (Not used)
Response axis	Linear	Bias limit max.	* (Not used)

Calibrators (User-defined Calibrators are defined in "F4 > Cal/Ctrl definition" - as Calibrator, use REF TD-42672 - **3diag - RBP - CAL**)

Nbr	Calibrator	Current Lot	Concentration	Dilution 1+
1	Select Cal.	Read-only value	Read-only value	699
2	Select Cal.	Read-only value	Read-only value	119
3	Select Cal.	Read-only value	Read-only value	39
4	Select Cal.	Read-only value	Read-only value	19
5	Select Cal.	Read-only value	Read-only value	9
6	Select Cal.	Read-only value	Read-only value	4

NOTES

- (*1) Not Used or, if a measurement is desired on samples with values below the measurement limit, define:
 Measuring range / Min **0.02** Next dilution ratio 1+ / Low **0**
- (*2) Equal to highest calibration point (Nbr 6) concentration
 (If **AUTOM** flag is selected, limits are recalculated from the calibration)
- (*3) Equal to highest calibration point (Nbr 6) concentration, **multiplied by 6**
- (*4) Equal to lowest calibration point (Nbr 1) concentration or, if a measurement is defined on samples with values below the measurement limit, equal to lowest calibration point (Nbr 1) concentration, **divided by 5**
- (*5) Equal to highest calibration point (Nbr 6) concentration, **multiplied by 24**
- (*6) We recommend to disable the automatic control of the calibration interval, and re-calibrate when a new batch of reagents is used, or when the QC established procedures do not give the expected results. Nevertheless, if desired, the user can always define a calibration repeat time in order to be notified of a due calibration when the defined time is elapsed.

WARNING

Parameters valid only for Reagents, Calibrators and Controls of lots:

- **3diag - RBP - TIA** REF.: TD-42671 LOT: **671-20** and subsequent
- **3diag - RBP - CAL** REF.: TD-42672 LOT: **672-20** and subsequent
- **3diag - RBP - CONTROL** REF.: TD-42663 LOT: **663-20** and subsequent