

## 3diag - HPX - TIA

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

#### **REF** TD-42635 - Hemopexin - KIT - For Turbidimetry

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#### INFO

Name	User Defined		
Tag	Read-only field		
Version number	Updated when new settings are saved		
Full name	User Defined		
Online name	User Defined		
Type	<b>Photometric</b>	Number of decimals	<b>1</b> (minimum recommended 1)
In use	<b>Yes</b>	Correction factor	<b>1.000</b>
Acceptance	<b>Manual</b>	Correction bias	<b>0.000</b>
Result Unit	<b>mg/dl</b>		
Sample Type	<b>Serum</b>		
Test version ID	Read-only field		
Last time changed	Date and time of last changes		
User name	User ID, who modified the definition		

#### FLOW

Blank type	<b>Yes</b>	Primary dilution 1+	<b>9</b> (Read-only field)
		Dispensed volume	Read-only field

#### 1st Step - **Reagent**

Reagent	Select Reagent from the drop down menu - Reaction Buffer - Use <b>REF</b> TD-42631-BF - <b>BUF</b> <b>HPX</b>		
Volume (µl)	<b>108</b>		
Dispense with	<b>Extra</b>		
Extra volume (µl)	<b>10</b>		
Syringe speed	<b>Medium</b>		
Replacing Reagent	<b>None</b>		

#### 2nd Step - **Sample**

Volume (µl)	<b>6</b>		
Dispense with	<b>Extra</b>		
Extra volume (µl)	<b>10</b>		
Extra wash	<b>No</b>		

#### 3rd Step - **Mix**

#### 4th Step - **Incubation**

Time (sec)	<b>297</b>	Actual time (sec)	Read-only field
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#### 5th Step - Reagent

Reagent	Select Reagent from the drop down menu - Antiserum Reagent - Use <input type="text" value="REF"/> TD-42631-RA - <input type="text" value="REAG"/> <input type="text" value="Ab"/> <input type="text" value="HPX"/>		
Volume (µl)	<b>36</b>		
Dispense with	<b>Extra</b>		
Extra volume (µl)	<b>10</b>		
Syringe speed	<b>Slow</b>		
Replacing Reagent	<b>None</b>		

#### 6th Step - End-point (Blank)

Blank resp. min (A)	<b>0</b> (Not used)	Blank resp. max (A)	* (Not used)
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#### 7th Step - Incubation

Time (sec)	<b>297</b>	Actual time (sec)	Read-only field
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#### 8th Step - End-point (Measurement)

Main wavelength	<b>340</b>	Side wavelength	<b>None</b>
Residual net abs. (A)	<b>0</b> (Not used)	Delta abs. check min. (A)	* (Not used)

### DILUTION

Dilution with	<b>Diluent</b>
Primary dilution 1+	<b>9</b>

#### Neat sample

Dispense with	<b>Extra</b>
Volume (µl)	<b>10</b>

#### Diluent

Sample diluent ID	<b>Diluent 1</b>
Calibrator diluent ID	<b>Diluent 1</b>
Dispense with	<b>Extra</b>
Volume (µl)	<b>10</b>

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

	Measuring range		Next dilution ratio 1+	
	Min	Max	Low	High
Primary dilution	* (Not used)	<b>See note (*1)</b>	* (Not used)	<b>49</b>
2nd, 3rd & 4th dilution	* (Not used)	* (Not used)	* (Not used)	* (Not used)
Test limit	<b>See note (*2)</b>	<b>See note (*3)</b>		
Critical limit	* (Not used)	* (Not used)		
Init. abs.	* (Not used)	* (Not used)		
Reference ranges	<b>User Defined</b>			

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#### CALIBRATION

Calibration type	<b>Logit-Log4</b>	Abs. error (A)	* (Not used)
Repeat time (days)	<b>0</b> (Not used, see note (*4))	Rel. error (%)	* (Not used)
Points / calibrator	<b>Duplicate</b>	Factor limit min.	* (Not used)
Acceptance	<b>Manual</b>	Factor limit max.	* (Not used)
Concentration axis	<b>Linear</b>	Bias limit min.	* (Not used)
Response axis	<b>Linear</b>	Bias limit max.	* (Not used)

**Calibrators** ( User-defined Calibrators are defined in "F4 > Cal/Ctrl definition" - as **Calibrator**, use REF TD-42622 - **3diag - HPX - CAL SET** )

Nbr	Calibrator	Current Lot	Concentration	Dilution 1+
1	Select Cal.	Read-only value	Read-only value	<b>9</b>
2	Select Cal.	Read-only value	Read-only value	<b>9</b>
3	Select Cal.	Read-only value	Read-only value	<b>9</b>
4	Select Cal.	Read-only value	Read-only value	<b>9</b>
5	Select Cal.	Read-only value	Read-only value	<b>9</b>
6	Select Cal.	Read-only value	Read-only value	<b>9</b>

#### NOTES

- (\*1) Equal to highest calibration point (REF: TD-42622-6) concentration  
 ( Limits should be adjusted to the new calibrator values whenever a new lot of Calibrators with different values is used )  
 ( If **AUTOM** flag is selected, limits are recalculated from the calibration )
- (\*2) Equal to lowest calibration point (REF: TD-42622-1) concentration
- (\*3) Equal to highest calibration point (REF: TD-42622-6) concentration, **multiplied by 5**
- (\*4) 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.
- (\*5) The definition of these parameters is based on the *Binding Site's* document "*Optilite - Available on Request (AOR) Tests - Reference Guide*" (Doc. Code: AP DOC 49A - Version 131115). For any doubt or further information, please refer to this document.