

REF TD-42531

## 3diag - B2m - TIA

Beta-2 Microglobulin (serum + urine) - for Turbidimetry

### ANNEX to IFU: *Optilite*<sup>®</sup> - AOR Test Parameters (URINE)

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<b>INFO</b>			
Type / Acceptace:	[Photometric] [Manual]	Result Unit / No. of Decimals:	[mg/L] [3] (min. recomm. 2)
Correction Factor/Bias:	[1] [0]	Sample Type:	[Urine]
<b>FLOW</b>			
Blank Type:	[Yes]	Primary Dilution ("1 +"):	[4]
Reagent - Name/Vol./Disp. With/Extra Vol./Syr. Speed/Repl.:	[xxx.2] [125] [Extra] [10] [Medium] [None] (Buffer)		
Reagent - Name/Vol./Disp. With/Extra Vol./Syr. Speed/Repl.:	[xxx.1] [25] [Extra] [8] [Slow] [None] (Antiserum Reagent)		
<b>Define a MIX Step</b>		Incubate - Time/Actual Time:	[54] [54]
Sample - Volume/Disp. With/Extra Vol./Extra Wash:	[10] [Extra] [10] [No]		
<b>Define a MIX Step</b>			
End-point Blank - Resp. Min/Max:	[0] [*]	Incubate - Time/Actual Time:	[297] [297]
End-point Meas. - Main WL/Side WL/Resid. Net A./Delta A. Ch.:	[600] [None] [0] [*]		
<b>DILUTION</b>			
Dilute With / Primary Dil. ("1 +"):	[Diluent] [4]	Neat Sample - Disp. With./Vol.:	[Extra] [10]
Diluent ID - Sample/Calibrator:	[Diluent 1] [Diluent 1]	Diluent - Disp. With./Volume:	[Extra] [10]
<b>LIMITS <sup>(*1)</sup></b>			
Prim. Dil. - Meas. Rg. Min./Max.:	[*] [ <sup>(*2)</sup> ]	Pr. Dil. - Next Dil. R. Low/High:	[*] [24]
2nd. Dil. - Meas. Rg. Min./Max.:	[*] [ <sup>(*3)</sup> ]	2nd. - Next Dil. R. Low/High:	[*] [119]
3rd and 4th Dilutions:	Not Defined	Test Limit:	[ <sup>(*4)</sup> ] [ <sup>(*5)</sup> ]
Critical Limit / Init Abs.:	User Defined / Not Defined	Reference Ranges / Reflex Parameters:	User Defined
<b>CALIBRATION</b>			
Type/Rep. Time/Points/Acceptance/Errors/F. Limits:	[Logit-Log4] [ <sup>(*6)</sup> ] [Duplicate] [Manual] [ <sup>(*6)</sup> ] [ <sup>(*6)</sup> ] [ <sup>(*6)</sup> ] [ <sup>(*6)</sup> ]		
Calibrator - No./Name/Lot/Conc.:	[ <sup>(*7)</sup> ]	Calibrator - Dilution ("1 +"):	[4] [4] [4] [4] [4] [4]
<b>NOTES</b>			
<p>(*1): The LIMITS proposed have only value as a recommendation, its definition is the user's responsibility.            (*2): Highest calibrator value (= Level 6 value x ( 5 / 5 ) = Level 6 value ).            (*3): Highest calibrator value x primary high dilution factor (= Level 6 value x ( 5 / 5 ) x ( 25 / 5 ) = Level 6 value x 5).            (*4): Lowest calibrator value (= Level 1 value x ( 5 / 5 ) = Level 1 value).            (*5): Highest calibrator value x 2nd high dilution factor (= Level 6 value x ( 5 / 5 ) x ( 120 / 5 ) = Level 6 value x 24).            (*6): User defined.            (*7): User Defined.            For the Lot # and concentrations see the assigned values table of the the Calibrators (REF: TD-42532 - 3diag - U-B2m - CAL SET).</p>			