

## 3diag - U-A1m - TIA

Alpha-1 Microglobulin - Urine - for Turbidimetry

REF TD-42831 IVD CE

### IFU ANNEX:

### AU400 - AU480 - AU640 Application (Urine)

Specific Test Parameters										
General		LIH	ISE	Range						
Test Name:	<b>UA1M</b>	<	>	Type:	<b>Urine</b>	Operation:	<b>Yes</b>			
Sample:	Volume	<b>2.0</b>	µL	Dilution	<b>0</b>	µL	Pre-Dilution Rate:	<b>1</b>		
Reagents:	R1 Volume	<b>90</b>	µL	Dilution	<b>0</b>	µL	Min OD		Max OD	
	R2 Volume	<b>90</b>	µL	Dilution	<b>0</b>	µL	L	<b>-2.0</b>	H	<b>2.5</b>
Wavelength:	Pri.	<b>660</b>		Sec.	<b>None</b>		Reagent OD limit:			
Method:		<b>FIXED</b>					First L	<b>-2.0</b>	First H	<b>2.5</b>
Reaction slope:		<b>+</b>					Last L	<b>-2.0</b>	Last H	<b>2.5</b>
Measuring Point 1:	First	<b>12</b>		Last	<b>22</b>		Dynamic Range:			
Measuring Point 2:	First			Last			L	<b>**</b>	H	<b>**</b>
Linearity:			%				Correlation Factor:			
No Lag Time:							A	<b>1.000</b>	B	<b>0.000</b>
							On-board stability period:	<b>#</b>		

Specific Test Parameters									
General		LIH	ISE	Range					
Test Name:	<b>UA1M</b>	<	>	Type:	<b>Urine</b>				
Value/Flag:	<b>#</b>	Level L:	<b>#</b>	Level H:	<b>#</b>				
Normal Ranges:		Age L		Age H					
	Sex	Year	Month	Year	Month	L	H		
o 1.	<b>#</b>	<b>#</b>	<b>#</b>	<b>#</b>	<b>#</b>	<b>#</b>	<b>#</b>	<b>#</b>	<b>#</b>
o 2.	<b>#</b>	<b>#</b>	<b>#</b>	<b>#</b>	<b>#</b>	<b>#</b>	<b>#</b>	<b>#</b>	<b>#</b>
o 3.	<b>#</b>	<b>#</b>	<b>#</b>	<b>#</b>	<b>#</b>	<b>#</b>	<b>#</b>	<b>#</b>	<b>#</b>
o 4.	<b>#</b>	<b>#</b>	<b>#</b>	<b>#</b>	<b>#</b>	<b>#</b>	<b>#</b>	<b>#</b>	<b>#</b>
o 5.	<b>#</b>	<b>#</b>	<b>#</b>	<b>#</b>	<b>#</b>	<b>#</b>	<b>#</b>	<b>#</b>	<b>#</b>
o 6.	<b>#</b>	<b>#</b>	<b>#</b>	<b>#</b>	<b>#</b>	<b>#</b>	<b>#</b>	<b>#</b>	<b>#</b>
7. None Selected						<b>#</b>	<b>#</b>		
8. Out of Range		L		H		<b>#</b>	<b>#</b>		
Panic Value:	<b>#</b>	<b>#</b>	<b>#</b>	Unit:	<b>mg/L</b>	Decimal places:	<b>#</b>		

Calibration Specific					
General		ISE			
Test Name:	<b>UA1M</b>	<	>	Type:	<b>Urine</b>
Calibration Type:	<b>6AB</b>	Formula:	<b>See Note (1)</b>	Counts:	<b>#</b>
		Process:			
	Cal. No.	OD	CONC	Factor/OD-L	Factor/OD-H
	Point 1:	<b>1</b>	<b>**</b>	<b>-2.0</b>	<b>2.5</b>
	Point 2:	<b>2</b>	<b>**</b>	<b>-2.0</b>	<b>2.5</b>
	Point 3:	<b>3</b>	<b>**</b>	<b>-2.0</b>	<b>2.5</b>
	Point 4:	<b>4</b>	<b>**</b>	<b>-2.0</b>	<b>2.5</b>
	Point 5:	<b>5</b>	<b>**</b>	<b>-2.0</b>	<b>2.5</b>
	Point 6:	<b>6</b>	<b>**</b>	<b>-2.0</b>	<b>2.5</b>
	Point 7:				
1-Point Cal. Point:			o With CONC-0		
MB Type Factor:	<b>#</b>	Calibration Stability Period:	<b>#</b>		

# User defined  
 \*\* Lot specific, see the analytical values table of the IFU of the Calibrators  
 (1) User defined (recommended POLYGONAL)