

## 3diag - U-A1m - TIA

### ANNEX to IFU: *Alinity c* - Application Proposal

**[REF] TD-42831 - Alpha-1 Microglobulin - Urine - for Turbidimetry**  
 using **3diag - U-A1m - CAL SET** (**[REF] TD-42832**)

*Alinity and related brand marks are registered trademarks of Abbott Laboratories, Abbott Park, Illinois, USA*

#### GENERAL TAB

##### GENERAL PARAMETERS

Assay Name	<b>UA1M</b> <sup>(*1)</sup>	Assay Type	Photometric
Assay Number	System proposes the next available one	Assay Availability	<b>Enabled</b>
Assay Version	ID of assay version	Assay Status	Primary
Date/Time	Date and time of last changes	Run Controls for Reagents by	<b>Lot</b>
Operator	User ID, who modified the definition		

##### REACTION DEFINITION

Reaction Mode	<b>End Up</b>	Main Read Time	<b>31 - 32</b>	Absorbance Range	Not Defined
Primary Wavelength	<b>604</b>	Flex Read Time	Not Defined	Sample Blank Type	<b>Self Blank</b>
Second. Wavelength	Not Defined	Blank Read Time	<b>20 - 21</b>	Blank Assay	Not Defined
Last Read Required	<b>32</b>	Color Corr. Read Time	Not Defined		

##### REAGENT

###### New Reagent flyout - for Reagents

Reagent Name	<b>R-UA1</b> <sup>(*1)</sup>
Reagent Type	<b>R1 and R2</b>
R1 bottle - Reaction Buffer - Use	<b>BUF U-A1m</b>
R2 bottle - Antiserum Reagent - Use	<b>REAG Ab U-A1m</b>
Low Alert	<b>15</b>
Number of Test	<b>75 (185 if 2 kits/cartridge are used</b> <sup>(*2)</sup> )
Onboard Stability	<b>9999</b> (Not used <sup>(*3)</sup> )

##### Reagents

Reagent Name	<b>R-UA1</b>	R1 Reagent Volume	<b>67</b>	R2 Reagent Volume	<b>65</b>
Diluent Name	<b>Saline</b>	R1 Water Volume	Not Defined	R2 Water Volume	Not Defined
Diluent Disp. Mode	<b>Type 1</b>	R1 Dispense Mode	<b>Type 1</b>	R2 Dispense Mode	<b>Type 1</b>

##### SAMPLE

Dilution Name	Sample Volume	Dil. Sample Vol.	Diluent Volume	Water Volume	Dilution Factor	Default Dilution
<b>Std 1:1</b> <sup>(*1)</sup>	<b>1.5</b>	Not Defined	Not Defined	Not Defined	1.00 (Informative)	<b>Yes</b> (Mark as Default)
<b>D1 1:8</b> <sup>(*1)</sup>	<b>15</b>	<b>1.5</b>	<b>105</b>	Not Defined	8.00 (Informative)	<b>No</b> (Not Mark as Default)
3rd Dilution Not Defined						

##### VALIDITY CHECKS

Reaction Check Type	<b>None</b>	Read Time A Range	Not Defined	Calculation Limit	Not Defined
Minimum Absorv.	Not Defined	Read Time B Range	Not Defined	Rate Linearity %	Not Defined
Maximum Absorv. Variation	Not Defined				

## 3diag - U-A1m - TIA

### ANNEX to IFU: *Alinity c* - Application Proposal

#### CALIBRATION TAB

##### CALIBRATION / VALIDITY CHECKS

<i>Calibration Method</i>	<b>Spline</b> (Recommended)	<i>Adjust Interval Hours</i>	Not Defined	<i>Adjust Level</i>	Not Defined
<i>Full Interval Hours</i>	<b>0</b> (Disabled <sup>(*4)</sup> )	<i>Adjust Type</i>	<b>None</b> <sup>(*5)</sup>	<i>Default Ordering Type</i>	Not Defined
<i>Factor</i>	Not Defined	<i>Maximum Curve Fit</i>	Not Defined	<i>Blank Absorv. Range</i>	Not Defined
<i>Use Cal Factor From</i>	Not Defined	<i>Span Blank</i>	Not Defined	<i>Span Absorv. Range</i>	Not Defined
<i>Expected Cal Factor</i>	Not Defined				
<i>Exp. Cal. F. Toler. %</i>	Not Defined				

##### CALIBRATORS

<b>New Cal Set flyout</b>	
<i>Calibrator Set Name</i>	<b>UA1 CAL</b> <sup>(*1)</sup>
<i>Calibrator Set Levels</i>	<b>6</b>

##### Calibrators

<i>Calibrator Set Name</i>	<b>Select from menu</b>	<i>Replicates</i>	<b>2</b> (Recommended)
<u>Cal Level</u>	<u>Sample Volume</u> <u>Dil. Sample Vol.</u>	<u>Diluent Volume</u>	<u>Water Volume</u> <u>Dilution Factor</u>
Blank: <b>UA1 CAL 1</b>	<b>1.5</b> Not Defined	Not Defined	Not Defined    1.00 (Informative)
Cal 1: <b>UA1 CAL 2</b>	<b>1.5</b> Not Defined	Not Defined	Not Defined    1.00 (Informative)
Cal 2: <b>UA1 CAL 3</b>	<b>1.5</b> Not Defined	Not Defined	Not Defined    1.00 (Informative)
Cal 3: <b>UA1 CAL 4</b>	<b>1.5</b> Not Defined	Not Defined	Not Defined    1.00 (Informative)
Cal 4: <b>UA1 CAL 5</b>	<b>1.5</b> Not Defined	Not Defined	Not Defined    1.00 (Informative)
Cal 5: <b>UA1 CAL 6</b>	<b>1.5</b> Not Defined	Not Defined	Not Defined    1.00 (Informative)

#### RESULT TAB

##### RESULT UNITS

<i>Result Units</i>	<b>mg/l</b>	<i>Decimal Places</i>	<b>2</b> (Recommended)	<i>Result Unit UCUM</i>	<b>mg/l</b>
<i>Correlation Factor</i>	<b>1.0000</b>	<i>Intercept</i>	<b>0.0000</b>		

##### RESULT PARAMETERS

<i>Low Linearity</i>	<b>User Defined</b> <sup>(*6)</sup>	<i>High Linearity</i>	<b>User Defined</b> <sup>(*6) (*7)</sup>
<i>Gender and Age Spec. Ranges</i>	<b>User Defined</b>		

##### INTERPRETATION PARAMETERS

*Name, Range & Rev. Required* **User Defined**

## 3diag - U-A1m - TIA

### ANNEX to IFU: *Alinity c* - Application Proposal

#### **RETEST RULES TAB** ( User defined, the proposed parameters have only value as a recommendation )

##### 1st - Retest Rule

Retest Rule Name	UA1 DIL1 <sup>(*1)</sup>	Result Indicator	Select Result Range
Result Range	Set as Cal Set (REF: TD-42832) Level-6 value <sup>(*7)</sup>		
To	Not Defined		
Original Dilution	Std 1:1 (Default Dilution)		
<u>Selected Retest Assay</u>	<u>Retest Dilution</u>	<u>Replicates</u>	
<b>UA1M</b>	<b>D1 1:8</b>	<b>1</b>	

#### **NOTES**

- (\*1) Proposal, User defined field.
- (\*2) The number of test per kit can be optimized if 2 kits are transferred into a single container.
- (\*3) We recommend to disable the Onboard Stability check, and re-calibrate when the QC established procedures do not give the expected results. If, after re-calibration, QC established procedures still not giving the expected results then discard the reagents.
- (\*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.
- (\*5) The use of the calibration adjustment, with only one or two calibrator levels, is discouraged.
- (\*6) We recommend to define the Linearity Limits as:
  - Low Linearity Limit equal to 0.1 (fixed value), and
  - High Linearity Limit equal to Cal Set (REF: TD-42832) Level-6 value.
- (\*7) High Linearity Limit and Result Ranges for the retest rules should be adjusted to the new calibrator values whenever a new lot of Cal Set (REF: TD-42832) with different values is used.