

REF TD-42531-U - Beta-2 Microglobulin - Urine - for Turbidimetry
3diag - U-B2m - TIA - ANNEX to IFU: Alinity c
Application Proposal (Urine) - using 3diag - U-B2m - CAL SET (REF TD-42532)

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GENERAL + REACTION DEFINITION			
Assay Type - Availability:	[Photometric] [Enabled]	Run Controls by:	[Lot] or [Kit] (User Selected)
Reaction Mode:	[End Up]	Wavelength (Prim./Sec.):	[600] [None]
Read Times (Main) - Last Req. T.:	[37] [38] - [38]	Abs. Range - Color Correction:	Not Defined
Sample Blank Type:	[Self]	Blank Read Time:	[20] [21]
REAGENT / SAMPLE + VALIDITY CHECKS			
Reagent Name:	User Defined	Diluent/Disp. Mode:	[Saline] [Type 1]
R1 - Volume/Water/Disp. Mode:	[100] [---] [Type 1]	R2 - Volume/Water/Disp. Mode:	[20] [---] [Type 1]
Reagent Definition	option 1 (2 kits x cartridge) ^(*1) :	[R1+R2] [15] [120] [720]	Fill R1 bottle with Buffer and R2 with Latex
Type/Low Alert/No.Test/Onboard Stab.:	option 2 (3 kits x cartridge) ^(*2) :	[R1+R2] [15] [225] [720]	Fill R1 bottle with Buffer and R2 with Latex
Dilution - Name/Sample/Dil. S./Diluent/Water/Default:	[STD-1:5]	[20] [8] [80] [---] [Default]	Dil. Factor = 1:5
Dilution - Name/Sample/Dil. S./Diluent/Water/Default:	[D-1:30]	[4] [8] [116] [---] [---]	Dil. Factor = 1:30
Dilution - Name/Sample/Dil. S./Diluent/Water/Default:	[D-1:181]	[1.5] [8] [270] [---] [---]	Dil. Factor = 1:181
Reaction Check:	[None]	Maximum Absorbance Variation:	Not Defined
CALIBRATION PARAMETERS			
Calibration Method:	[Spline] or [Logit-4]	Full Calibration Interval:	[0] (not tracked, recommended)
Adjust Type:	[None] ^(*3)	Calibrator Set Name:	User Defined
Levels:	[6]	Replicates:	[2] (minimum recommended 2)
Cal. Level (Blank) - Conc./Sample/Dil. S./Diluent/Water:	[Water] [0]	[8] [---] [---] [---]	Dil. Factor = 1:1
Cal. Level (1 to 6) - Conc./Sample/Dil. S./Diluent/Water:	[Cal 1..6] ^(*4)	[20] [8] [80] [---]	Dil. Factor = 1:5
Blank Absorbance Range:	Not Defined	Span - Span Absorbance Range:	Not Defined
Expected Cal Factor - ECF % Tol.:	Not Defined	Max. Curve Fit (Logit-4 Method only):	Not Defined
RESULTS			
Result Units:	[mg/l] or [IU/ml] (User Def.)	Decimal Places:	User Defined
Correl factor - Intercept:	[1.0000] [0.0000]	Low/High Linearity:	[^(*5)] [^(*5)]
Gender and Age Specific Ranges:	User Defined	Assay Retest Rules:	User Defined ^(*6)
NOTES			
<p>(*1): At least 2 kits have to be transferred to a single container. (*2): The number of test per kit can be optimized if 3 kits are transferred into a single container. (*3): The use of the calibration adjustment, with only one or two calibrator levels, is discouraged. (*4): User Defined, for the concentrations see the values table of the IFU of the Calibrators (REF: TD-42532). (*5): Lot Specific, equal to Cal 1 and Cal 6 values (recommended). (*6): User Defined, it is recommended to retest samples higher than the upper limit of the assay range at 1:30 dilution.</p>			