quantex B-2-MICROGLOBULIN (B2M)

Kit Configuration

P/N 3000-2307	1 x 40 mL β_2m R1
	4 x 3 mL β_2m R2

Reagent Preparation

P/N 3000-2307 β_2m R1: Ready to use
β_2m R2: Ready to use.
Place the bottles into reagent tray.

In Use Stability

For optimal stability remove reagents from the system and store them at 2-8°C in the original vial securely closed.
On board: 28 days

Specimen

Serum.

Calibration

Use quantex β2-microglubulin standard Cat. No 3000-2192.See vial label for lot specific concentration. A reagent blank should be run daily before sample analysis. Recalibrate every 30 days or when a new lot of reagent is used.

Quality Control

Use quantex Proteins Control I/II Cat. No. 3000-2122.

Calculation of Analytical Results

The results concentration is automatically calculated by the instrument against the Calibration curve. For detailed description, refer to the Instrument settings and to the ILab 600/650 Operator's Manual.

Reference Interval

Serum ß2m concentrations have been reported to be independent of body mass and sex but to be slightly increased in elderly persons. In the serum or plasma of apparently healthy persons the normal range is approximately 0.97 to 2.64 mg/L by a RIA technique. Concentrations of ß2m in urine from healthy subjects averaged 0.098 mg/L with an upper normal limit of 0.32 mg/L.

References / Literatur / Bibliografía / Bibliographie / Bibliografia /

See package insert enclosed in the kit

Performance Characteristics

Limitation/Interfering Substances

No significant interference from lipemia up to a sample absorbance of 4.3/cm at 660 nm, bilirubin up to concentrations of 25 mg/dL (425 µmol/L), hemoglobin up to concentrations of 400 mg/dL (0.24 mmol/L) and rheumatoid factor up to 750 IU/mL.
For a comprehensive review of interfering substances, refer to the publication by Young *et al.*[1]

Precision

Serum	Samples/Runs	Mean (mg/L)	CV(%)	Mean (mg/L)	CV(%)
Within run	4/10	0.77	2.0	6.02	2.7
Total	4/10	0.77	2.9	6.02	3.7

Method Comparison

	Serum	Urine
Comparison method	same reagent	same reagent
Comparison instrument (x)	ILab 900/1800	ILab 900/1800
Slope	0.959	0.817
y intercept	0.053	0.003
Range (mg/L)	0.20 - 109.85	0.01 – 67.50
Mean X (mg/L)	7.75	10.02
Mean Y (mg/L)	7.48	8.19
r	0.997	0.992
Syx	1.04	1.75
n	62	40

Linearity

no rerun 0.5 - 16 mg/L ; with rerun 0.05 - 96 mg/L

Note:
High sensitivity application for urine samples:
Very low concentrations of ß2m can be quantified in urine samples using the rerun capability of the instrument, when possible.
Another option is using the "high sensitivity application" but only with those urine samples reporting LESS THAN 1 mg/l with the regular application, otherwise false low reported results due to prozone effect may be obtained.

Instrument Settings

Instrumentation Laboratory
Instrumentation Laboratory SpA – V.le Monza 338 – 20128 Milano (Italy))
Instrumentation Laboratory Company - Lexington, MA 02421-3125 (USA)

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CE

Photometric Test Parameters		***Serum***	***Urine High Sensitivity***
Test No.		**	**
Test Name, Test Code		B2M, B2M	B2MHS, B2MHS
Sample Type		Serum/Plasma/Urine	Urine <1 mg/L
Reporting Unit, Decimal Points		mg/L, 2	mg/L, 2
Reation Cycle		Standard	Standard
Twin Analysis		OFF	OFF
Methodology Type, Measuring Point		End Point, 20/33	End Point, 20/33
Photometric Methodology		1 Wavelength	1 Wavelength
Primary/Secondary Wavelenght		570	570
Sampling Conditions			
Sampling 1	Sample Vol.	3	30
	Sample/Diluent Vol.	0/0	0/0
Sampling 2	Sample Vol.	3	***
	Sample/Diluent Vol.	30/150	***
Sampling 3	Sample Vol.	30	***
	Sample/Diluent Vol.	0/0	***
Sampling 4		***	***
Diluent Code		Saline	Saline
Diluent Warning Limit		***	***
First Run		Sampling 1	Sampling 1
Below/Above Normal Range		***	***
Panic L		Sampling 3	***
Panic H		Sampling 2	***
Noise		***	***
Prozone		N/A	N/A
High!, ABS!		Sampling 2	***
Sample Volume Reduction		**	**
Reagent Volumes			
R1	Code	01821	01821
	Rgt/Dil. Vol. Stirring	150/0, ON	150/0, ON
	Low Vol. Warning Limit	***	***
	Stability (days)	28	**
R2	Code	01822	01822
	Rgt/Dil. Vol. Stirring	120/20, ON	120/20, ON
	Low Vol. Warning Limit	***	***
	Stability (days)	28	**

Ranges and Evaluation Criteria	***Serum***	***Urine High Sensitivity***
Normal Range-Male	**	**
Normal Range-Female	**	**
Normal Range-Other	**	**
Valid Range	0.50 - 16.00	0.05 - 1.60
Hemolysis/Icterus/Lipemia Limit	***	***
Reaction Slope	Positive	Positive
Absorbance Limit	Above, 3200	Above, 3200
Prozone Limit	N/A	N/A
Non Linear Limit	N/A	N/A
Slope/Intercept Correction	1/0	1/0
Qualitative Report	OFF	OFF
Calibration Conditions		
Calibration	1 Point, Linear, 3 Reps	1 Point, Linear, 3 Reps
Stability (days)	30	**
Calibrator, Concentration	Std β2m *	Std β2m *
R-Blank Limit (mAbs)	1000	1000
Cal. Reps Range (%)	***	***
Min Cal. Response (mAbs)	***	***
Cal. Factor Change (%)	***	***
M-Point Curve Fit (%)	N/A	N/A
Reagent Blank	ON	ON
Auto R-Blank by Bottle	ON	ON

* Lot dependent
** operator definable
*** optional
N/A not applicable to this test

Note: for urine High Sensitivity application the Calibrator has to be dilute 1:10 (1+9) with Saline. The Calibrator concentration is calculated dividing Calubrator value by 10.

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