

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
DEVICE ONLY TEMPLATE**

A. 510(k) Number:

k032692

B. Analyte:

Beta-2-Microglobulin

C. Type of Test:

Quantitative

D. Applicant:

DakoCytomation

E. Proprietary and Established Names:

DakoCytomation Beta-2-Microglobulin kit

F. Regulatory Information:

1. Regulation section:
21 CFR §866.5630
2. Classification:
Class II
3. Product Code:
JZG
4. Panel:
Immunology 82

G. Intended Use:

1. Intended use(s)/Indication for use (s):
DakoCytomation Beta-2-Microglobulin kit is intended for quantitative determination of beta-2-Microglobulin in human serum and plasma by rate nephelometry on IMAGE[®] immunochemistry systems. Measurement of Beta-2-microglobulin aids in the diagnosis of patients with active rheumatoid arthritis and kidney disease.
Indication for use is the same as intended use.
2. Special condition for use statement(s):
The device is for prescription use only
3. Special instrument Requirements:
Beckman Coulter IMAGE[®]

H. Device Description:

The device is a microparticle immunoassay. Contains polystyrene particles of uniform size coupled with polyclonal rabbit antibody against human beta -2-microglobulin. A reaction between the immunoparticles with beta-2-microglobulin molecules in the patient specimen results in the formation of agglutinates. The instrument shows a response to this reaction. The beta-2-microglobulin concentration in the patient specimen is determined by interpolation of a calibration curve. The kit contains one 5ml of vial of polystyrene particles coupled with rabbit antibody against human beta-2-microglobulin preserved with 15 mmol/L sodium azide; calibrators 1-6 in buffer, pH 7.4 containing bovine serum albumin and preservative; high and low controls and reaction buffer. A value assignment sheet is provided. The range is established by each laboratory. The kit components should be stored at 2-8 degrees centigrade.

I. Substantial Equivalence Information:

1. Predicate device name(s):
Abbott's IMx beta -2-microglobulin assay
2. Predicate K number(s):
K890421
3. Comparison with predicate:

Similarities		
Item	Device	Predicate
	DakoCytomation's β 2 M	Abbott's IMX β 2M
Intended use/indication for use/indication for use	Quantitative measurement of β 2 M as an aid in the diagnosis of rheumatoid arthritis and kidney disease	Same
Differences		
Item	Device	Predicate
Analyzer	Beckman Coulter IMMAGE®	Abbott's IMX®
Matrix	Serum and heparinized or EDTA plasma	Serum, plasma and urine
Method	Nephelometry	MEIA
Antibody	Polyclonal	monoclonal
Lower limit of detection	0.3 mg/L	0.05 mg/L
Assay range	0.3-20 mg/L	0-40 mg/L
Reference interval	1.16-2.52 mg/L for age 20-50 1.42-3.21 mg/L for >50 years of age	< 1.9 mg/L

J. Standard/Guidance Document Referenced (if applicable):

NCCLS EP10-A2 for precision

K. Test Principle:

Nephelometry

L. Performance Characteristics (if/when applicable):1. Analytical performance:a. *Precision/Reproducibility:*

Total precision was determined using modified NCCLS EP 10-A2 (because of calibration stability claim). With the modified protocol 3 samples were mixed with repetition of the sequence to get a total of 6 determinations of each sample in each run. This was repeated 6 times with a calibration performed before each run, total of 36 determinations.

Sample	data points	mean value	Within run		Total	
			SD	CV	SD	CV
Serum level 1	36	1.77mg/L	0.084	4.7%	0.094	5.3%
Serum level 2	36	3.70 mg/L	0.094	2.5%	0.149	4.0%
Serum level 3	36	7.19 mg/L	0.194	2.7%	0.275	3.8%

b. Linearity/assay reportable range:

A serum pool was diluted with IMAGE diluent 1 to get 6 concentrations of β 2 microglobulin ranging from 1.1mg/L to 17.3mg/L. Samples were tested in quadruplicate. A linear regression plot was generated. $Y=0.996 X +0.21$; $r = 0.997$.
Measuring range = 0.5- 20mg/L.

c. *Traceability (controls, calibrators, or method):*

The assay is calibrated with an internal reference material, purified from samples obtained from patients with tubular proteinuria, in bovine serum albumin (stored frozen). For each new lot of product, the internal reference material is used for calibrator value assignment.

d. *Detection limit/functional sensitivity:*

The detection limit was estimated to be 0.3 mg/L, taking the mean beta-2-M + 3 SD of 20 replicates of a zero standard.

e. *Analytical specificity:*

Not provided

f. *Assay cut-off:*

Not provided

2. Comparison studies:a. *Method comparison with predicate device:*

Method comparison was assessed by Deming regression analysis. Samples concentrations ranged from 0.58 to 14.56 mg/L. Sixty-five serum samples were used. Five serum pools (2 different samples per pool) were prepared to provide high concentration samples. Seven samples were in-house samples of healthy adults and the remaining samples were anonymous surplus hospital samples with no patient information. It is not known whether multiple samples from the same patient are included. Serum and plasma samples were from in-house draws. Heparin and EDTA plasma samples were from 47 healthy adults.

38 paired samples were spiked with purified B2M at concentrations ranging from approximately 25 mg/L to 15 mg/L. The B2M recovery between DakoCytomation's assay and Abbott's assay is reflected in the reference intervals. The 95th percentile ranges are:

Abbott's B2M assay: <1.9 mg/L

DakoCytomation's B2M assay: 1.16-2.52 mg/L age 20-50 years
1.42-3.21 mg/L age > 50 years.

Slope = 1.17 ± 0.02 (95% CI) and intercept = 0.70 ± 0.15 (95% CI).
Mean for DakoCytomation's assay is 6.40 mg/L and for the predicate is 4.87 mg/L. Correlation coefficient $r = 0.9970$

b. Matrix comparison:

Test results of Beta 2 Microglobulin EDTA plasma (1.15 units) vs serum showed (Deming regression) $Y = 1.04 X - 0.16$; $r = 0.997$.

Sodium heparin (14 units/mL) vs serum results: $Y = 1.01 X + 0.01$; $r = 0.9968$

Lithium heparin (14 units/mL) vs serum: $y = 1.02 x - 0.07$; $r = 0.9981$.
(Serum = x and plasma = y).

3. Clinical studies:

a. Clinical sensitivity:

Not provided

b. Clinical specificity:

Not provided

c. Other clinical supportive data (when a and b are not applicable):

None

4. Clinical cut-off:

Not provided

5. Expected values/Reference range:

1.16-2.52 mg/L for 20-50 years of age

1.42-3.21 for over 50 years of age.

M. Conclusion:

DakoCytomation's Beta 2 Microglobulin assay, intended for the quantitative determination of beta-2- microglobulin in human serum and plasma by rate nephelometry on IMMAGE® immunochemistry systems and indicated as an aid in the diagnosis of patients with active rheumatoid arthritis and kidney disease, is substantially equivalent to Abbott's IMX® Beta 2 microglobulin assay with the same indication.