

K955594

OCT -3 1996

Attachment 1

**510(k) Summary of Safety and Effectiveness for
N Latex B2-Microglobulin Reagent**

1. Manufactures Name, Address, Telephone, and contact person, date of preparation:

Manufacturer	Behringwerke AG Postfach 1140 35001 Marburg Germany
Distributor	Behring Diagnostics Inc. 151 University Avenue Westwood, MA 02090 617-320-3000 Attn: Kathleen Dray-Lyons

Preparation date: July 16, 1996

2. Device Name/ Classification:

N Latex B2-Microglobulin Reagent: reagent for the quantitative determination of B2-Microglobulin
Classification Number: class II (866.5630)

3. Identification of the legally marketed device:

Abbott IMx B2 Microglobulin

4. Proposed Device Description:

The N Latex Microglobulin Reagent is a reagent intended to be used together with the Behring Nephelometer Systems in the quantitative determination of B2-microglobulin in serum. Polystyrene latex particles coated with specific antibodies to human B2-microglobulin are agglutinated when mixed with samples containing B2-microglobulin. The intensity of the resulting scattered light measured by the nephelometer is dependent upon the B2-microglobulin content of the sample which is determined by reference to standards of known concentrations.

5. Proposed Device Intended Use:

N Latex B2-Microglobulin Reagent is an *in vitro* diagnostic reagent for the quantitative determination of human B2-microglobulin in serum by means of particle-enhanced nephelometry. Measurement of B2 -microglobulin aids in the diagnosis of active rheumatoid arthritis and kidney disease.

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6. Medical device to which equivalence is claimed and comparison information:

The B₂-Microglobulin assay using the proposed product is substantially equivalent in intended use and results obtained to the Abbott IMx B₂ Microglobulin. The Abbott IMx B₂ Microglobulin like the proposed product, depends upon assaying standards of known B₂-microglobulin content to convert the measured signal to concentrations. Both tests utilize specific antibody to B₂-microglobulin for capture of the B₂-microglobulin present in sample.

The N Latex B₂-Microglobulin Reagent differs from the Abbott IMx B₂ Microglobulin in that the Abbott IMx B₂ Microglobulin assay is a sequential binding assay which consists of an antibody-antigen complex that is transferred to a glass fiber and measured using a fluorometer; while the N Latex B₂-Microglobulin Reagent contains antibody that is affixed to a polystyrene particle which binds the B₂-microglobulin in the patient sample. The polystyrene particles agglutinate, increasing the amount of light a given concentration of B₂-microglobulin can scatter, effectively amplifying the signal when measure by a nephelometer.

7. Proposed Device Performance Characteristics:

Assay range and sensitivity

The N Latex B₂-Microglobulin Reagent is designed to measure B₂-microglobulin concentrations within an assay range of approx. 0.62 to 20 mg/l for a sample dilution of 1:100. If a sample dilution of 1:400 is used the assay range is extended to approx. 80 mg/l.

The sensitivity is given by the lower limit of the reference curve and thus depends on the B₂-microglobulin concentration of the standard.

Precision and reproducibility

Intra-assay precision was determined by assaying three B₂-microglobulin concentrations (approx. 1.2, 1.5 and 6.0 mg/l) in replicates of twenty (20), the coefficient of variation ranged from 2.5 to 3.3 %.

Inter-assay precision was determined by assaying three B₂-microglobulin concentrations (approx. 1.0, 1.4, and 5.8 mg/l) for a total of eight (8) replicates, the coefficient of variation ranged from 2.1 to 3.0%.

Method comparison (accuracy)

Results of comparative studies using the N Latex B₂-Microglobulin Reagent and a commercially available enzyme immunoassay for 84 serum samples gave a correlation coefficient of 0.987, a y-intercept of 0.215, and a slope of 0.967.