DADE BEHRING

N Latex ßTP

For the determination of ß-trace protein in human body fluids

Principle of the Method

Polystyrene particles coated with antibodies to human ß-trace protein are agglutinated when mixed with samples containing ß-trace protein. The intensity of the scattered light in the nephelometer depends on the concentration of the analyte in the sample and consequently its concentration can be determined by comparison with dilutions of a standard of known concentration.

Reagents

Materials provided

N Latex ßTP test kit (for the determination of ß-trace protein), Code No. NCWO 11

3 x for 2.0 ml of N ßTP Reagent

3 x 0.6 ml of N ßTP Supplementary Reagent

Composition

N ßTP Reagent consists of lyophilized polystyrene particles coated with rabbit antibodies to ß-trace protein. After reconstitution as instructed, the concentration of suspended polystyrene particles is optimal for agglutination measurement by immunonephelometry using the BN systems.

N ßTP Supplementary Reagent contains rabbit immunoglobulin in buffered solution. It is used to suppress interference by rheumatoid factors.

Preservative:

Reagent after reconstitution:	Sodium azide < 1g/l
N ßTP Supplementary Reagent:	Sodium azide < 1g/l

Warnings and Precautions

1. For research purposes only. Not for diagnostic use.
2. Reagents containing sodium azide must be handled with due caution:
   Do not ingest or allow to contact skin or mucous membranes!
   Sodium azide can form explosive azides when contacting heavy metals such as copper or lead.

Preparation of the Reagents

N ßTP Reagent: Resuspend the lyophilized contents of a vial with the labelled volume of distilled water. The reagent can be used 30 min after reconstitution. It must be gently shaken each day before use.

N ßTP Supplementary Reagent is supplied ready-for-use.

Storage and Stability

Stored at +2 to +8 °C, all the components of the test kit can be used by the labelled expiry date. The reconstituted N ßTP Reagent and the N ßTP Supplementary Reagent can be used within 4 weeks if stored tightly closed at +2 to +8 °C after use. Freezing can lead to a loss of function and must therefore be avoided.

Materials required but not provided

BN System (BNA, BN 100 or BN II)

N Protein Standard UY, Code No. OQLV

N/T Protein Control LC, Code No. OQLW

N Diluent, 1.5 l or 5 l, Code No. OUMT

Additional materials as described in the instruction manual for the BN systems.

Specimens

Suitable assay specimens are human serum, plasma (heparinized), CSF, nasal or oral secretion samples, either as fresh as possible (stored for max at 14 days at +2 to +8 °C) or deep-frozen. Samples deep-frozen within 24 hours after collection can be used within 4 months of storage at -20 °C if repeated thawing and freezing is avoided.

The serum samples must have completely coagulated and, after centrifugation, must not contain any particles or traces of fibrin.

Lipaemic samples or turbid frozen samples (i.e. turbid when thawed) must be clarified by centrifugation (10 min at approx.15 000 x g) before the assay.

CSF, nasal and oral secretions must always be centrifuged before use.

The assay protocol specifies a sample dilution of 1:100 and a minimum dilution of 1:1. However, a sample dilution of < 1:100 (1:20, 1:5 or 1:1) should only be used if a final dilution of 1:100 is achieved by pretreatment or manual predilution.

Method

Procedure

Notes:

1. For detailed instructions, consult the instruction manual for the BN systems.
2. The reagents must not be used beyond the expiry date
3. Components from other kits can be used in the test only if they are from the same lot number.
4. The lyophilized reagent must not be used until properly reconstituted, i.e. not until at least 30 min. after addition of distilled water.
5. The reagents should have reached a temperature of +15 to +25 °C before assay on the BNA and BN 100. The BN II, however, permits direct use of reagents stored at +2 to +8 °C.
6. On the BNA and BN 100, samples must be run at approximately the same ambient temperature (max. 2 °C deviation) as the measurements used for recording the reference curve.

All the steps necessary for preparing the run and for performing the measurements are performed automatically by the instrument.

Establishing the reference curve

The ß-trace protein concentration of the N Protein Standard UY is given in the table of analytical values. The necessary dilutions of the standard are prepared automatically with N Diluent by the BN system. The standard dilutions must then be used within 3 hours.

The reference curve is valid for 4 weeks. If a different lot of reagent is used, a new reference curve must be recorded.

Measuring the patient samples

The samples are automatically diluted 1:100 with N Diluent. The diluted samples must then be used with 3 hours.

Note:

Some samples may yield measurement signals beyond the range of the reference curve. In these cases, if further quantification is required, repeat the determination using a higher or lower dilution.

Internal Quality Control

Control of the accuracy and precision of the ß-trace protein assay on the BN systems should be carried out by running the N/T Protein Control LC with each series of samples. The control is assayed and evaluated in the same way as for the patient samples.

The assigned value of the control and its confidence interval are given in the package insert (accuracy control).

Calculation of the Analytical Results

The result of the measurement is calculated automatically using a logit-log function.

Limitations and Interferences

Interferences by rheumatoid factors are generally suppressed by the use of the N ßTP Supplementary Reagent.

Turbidity, cells and particles in the samples can interfere with the determination. For this reason, cells and particles which have formed in incompletely coagulated samples or due to protein denaturation, must be removed by centrifugation prior to the assay.

Highly lipaemic samples which cannot be clarified by centrifugation (10 min at approx. 15,000 x g) must be excluded from the assay.

Observe the following guidelines for the BNA/BN 100:

To assure reliable results, samples found to have a ß-trace protein content of > 1 mg/l (1:100 sample dilution) must be retested. The lowest ß-trace protein result is to be considered correct.

Specific Performance Characteristics

Measuring Range and Sensitivity

The N ßTP assay covers a range of approx. 0.25 to 15.8 mg/l for a sample dilution of 1:100.

The sensitivity of the test is determined by the lower limit of the reference curve and thus depends on the concentration of the analyte in the standard. A typical limit of detection is 0.25 mg/l for samples diluted 1:100.

Specificity

The assay is specific for human ß-trace protein.

Manufacturer: Dade Behring Marburg GmbH
Emil-von-Behring-Str. 76
D-35041 Marburg/Germany

USA Distributor: Dade Behring Inc.
Newark, DE 19714 U.S.A.

Edition March 2000