BENCE JONES OUCHTERLONY

Bence Jones's proteinuria determination by double radial immunodiffusion according Ouchterlony technique

TEST SUMMARY

The antibody and the antigen dispensed into two different wells diffusing through the gel create a concentration gradient. Between the two wells, where the antibody and antigen concentration are equal there is a formation of immunoprecipitation band.

SAMPLES

Urine. Stability 7 days a 4°C o 2 months at -18°C.

REAGENTS

Plates
Agarose gel 0,9%, Tris Buffer 50 mM pH 7.4, colouring, PEG 6000 3%.

Kappa Antibody
Goat anti human kappa chains serum, Tris Buffer 50 mM pH 7.4 preservative and stabilised.

Lambda Antibody
Goat anti human Lambda chains serum, Tris Buffer 50 mM pH 7.4 preservative and stabilised.

Positive Control
Stabilised human solution with Kappa chains Lambda chains.

REAGENTS PREPARATION AND STORAGE

All reagents are ready to use.
The reagents are stable until expiration date on the label at 2-8°C.

MATERIALS REQUIRED BUT NOT SUPPLIED

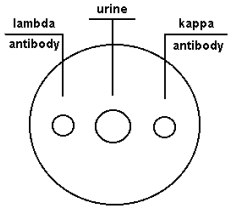
Micropipette to 10-40 µl, current laboratory instrumentation.

PRECAUTIONS

Reagent may contain some non-reactive and preservative components. It is suggested to handle carefully it, avoiding contact with skin and swallow.
Perform the test according to the general "Good Laboratory Practice" (GLP) guidelines.

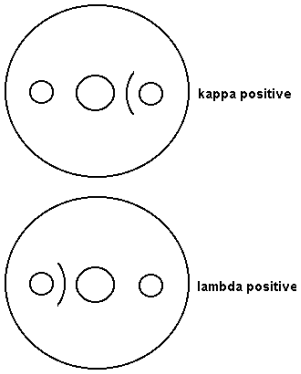
PROCEDURE

Allow all reagent and samples to come to room temperature. And mix well by gentle inversion before use. All unused reagent should be refrigerated as soon as possible after use.
Open the plate and eventually wait the evaporation of moisture present in the wells.
Properly identify the plate and lateral well (kappa well or lambda well).
Pipet 40 µl of urine into central well and 10 µl of Kappa antibody in lateral well and 10 µl Lambda antibody in other well according to the marker on the bottom.
Incubate in wet chamber at 37°C.
If the sample's concentration is high it's possible to read the results after 6-9 hours of incubation; otherwise results must be read after 9-15 hours.



RESULTS INTERPRETATION

The absence of any immunoprecipitation band means that the sample is negative for Bence Jones.
The presence of only immunoprecipitation band, Kappa or Lambda, means the presence of Bence Jones's proteinuria: A semiquantitative results can be calculated looking at the position of the band; band will be close to the sample well if the concentration is low other wise it'll be close to the antibody well.



CALIBRATION

The Kit is supplied with a Positive Control.

TEST PERFORMANCE

Precision

Intra assay (n= 60)	+	-
Bence Jones LTA	20	40
Test competitor	20	40

Sensitivity limits
The sensitivity is 5 mg/dl for Kappa chains and 5 mg/dl for Lambda chains.

WASTE DISPOSAL

This product is made to be used in professional laboratories. Please consult local regulations for a correct waste disposal.

EXPECTED VALUES

The analytes should be absent or present at a concentration lower than cut off of analysis.
If the test is performed like a preliminary screening to contrastographic assay it is generally accepted a cut off of 50 mg/dl.
However each laboratory has to determinate its cut off value.

PACKAGING

CODE UK01000	**(15 TESTS)**
Double immunodiffusion plate	15
Kappa Antibody	1 x 350 µl
Lambda Antibody	1 x 350 µl
Positive Control	1 x 100 µl

CODE UK01001	**(10 TESTS)**
Double immunodiffusion plate	10
Kappa Antibody	1 x 300 µl
Lambda Antibody	1 x 300 µl
Positive Control	1 x 100 µl

CODE UK01004	**(20 TESTS)**
Double immunodiffusion plate	20
Kappa Antibody	1 x 500 µl
Lambda Antibody	1 x 500 µl
Positive Control	1 x 100 µl

REFERENCE

OUCHTERLONY O. – Antigen-Antibody reaction in gels. Arkiv. Kemy mineral Geol. **26B** (14), 1-9 (1948).

MANUFACTURER

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SYMBOLS

IVD	Only for IVD use
LOT	Lot of manufacturing
REF	Code number
	Storage temperature interval
	Expiration date
	Warning, read enclosed documents
	Read the directions
	Biological risk

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