BENCE JONES PROTEIN STRIP

Competitive immunochromatographic test for the detection of free light chains κ and λ in urine

- For in vitro diagnostic use only -

Ref. C-74 **20 tests**

SUMMARY AND EXPLANATION

The presence of light-chains specific free κ/λ in urine may be an indication of a mono-or polyclonal gammapathy. This pathology, called Bences Jones Proteinuria, is characterized by the indiscriminate proliferation of B-cell lymphocytes which are detectable in the urine as free κ & λ proteins. The pathology is associated with Multiple Myeloma, Waldenström's Macroglobulinemia, monoclonal light chain amiloidosis, and light chain deposition disease.

PRINCIPLE OF METHOD

The Dipstick Bence Jones Free κ/ λ kit is a competitive, immuno-chromatographic assay, based on lateral flow nitrocellulose membrane technology. The assay has 3 reaction zones without prozone effect:

The first zone (closest to dipstick tab) represents the procedural control (CP).

2. The second zone (middle) line striped with free Lambda antigens.
3. The third zone (lowest) line striped with free Kappa antigens.

During the incubation of the dipstick device in unconcentrated, diluted urine free light chains bind to a colloidal gold conjugated antibody present in the nitrocellulose membrane resulting in the formation of an antigen-conjugate complexes in the presence of free light chain proteins.
In a lateral flow motion the sample starts to migrate to the three test zones and, if present in the sample, free light chain proteins compete for the respective available sites for binding.
The sample continues to migrate to the control zone which is specific against the capture conjugate to indicate proper test function.

KIT CONTENTS

Dipstick: 20 dipsticks and 2 desiccants
Sample Diluent: vial containing pH 9.2 buffered solution 10 mM TRIS, with surfactants and preservative Sodium Azide 0,09%.
Volume: 3 ml

MATERIALS NECESSARY BUT NOT PROVIDED

- Clean test tubes and tube rack
- Precision pipettes with disposable tips for delivering 100 and 200 µl

CONSERVATION AND STABILITY OF REAGENTS

Contents of the kit must be stored at 2 – 8 °C and used prior to the expiry date printed on the labels.
Rapidly remove the required dipsticks from their wrapping and avoid extended exposure to the ambient relative humidity.

CONSERVATION AND STABILITY OF SAMPLES

Use the first morning- urines or the 24 hours collection.
The samples must be stored at 2 – 8 °C for 2 days or at – 20 °C for 1 month, thaw only one time.

SAFETY PRECAUTIONS

1. All reagents contained in the kit are for in vitro diagnostic use.
2. At all times follow Good Laboratory Practice (GLP) guidelines.
3. Handle all test specimens with maximum care to avoid infection with potentially hazardous fluids. Avoid skin contact by wearing
4. protective disposable gloves.
5. Dispose of all used materials into appropriate bio-hazard waste containers.

TECHNICAL PRECAUTIONS

- Precisely follow instructions described in the test procedure below.
- Do not use reagents beyond the expiry date printed on each component label and do not mix reagents from different kit lots.
- Avoid all cross-contamination of samples by using disposable pipette tips.

PROCEDURE:

1. **Select the urine samples to be tested and equilibrate at room temperature.**
2. **Prepare equivalent number of sample tubes and mark them with patient ID's.**
3. **Pipette into each sample tube 100 µl of Sample Diluent.**
4. **Pipette into each sample tube 100 µl of urine.**
5. **Insert one dipstick into each sample tube.**
6. **Incubate 10 minutes (±1 min.) at room temperature.**
7. **Read and record reaction.**

Note – Do not read reaction beyond the indicated time period in the procedure.

ACCEPTABILITY CRITERIA

The red line closest to the dipstick tab, representing the procedural control, must be visible for the assay results to be considered valid.

INTERPRETATION OF RESULTS

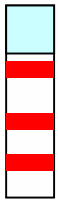
Positive K: Presence of red line in the second reaction zone of membrane (plus procedural control line).

Negative λ: Presence of red line at the second reaction zone of membrane (plus procedural control line).

Negative K: Presence of red line at third reaction zone of membrane (plus procedural control line).

Positive λ : Presence of red line at the lowest reaction zone of membrane (plus procedural control line)

Positive K e λ : Presence of red line at the first reaction zone of membrane only (procedural control line).



Negative K e λ : Presence of red lines at both reaction zones of membrane (plus procedural control line).

TEST PERFORMANCE

Sensitivity The sensitivity of the Dipstick Bence Jones assay was calculated, using a commercially available reference standard for K e λ, and serially diluted starting from 1000 mg/L to 10 mg/L resulted 30 mg/L for K and λ . These limits were confirmed using positive free light chain urine and a nephelometric methodology.

Specificity A study with 10 negative, 10 K- and 10- λ positive samples showed >99 % specificity.

Reproducibility A series of negative and positive K and λ samples were repeatedly tested and acceptable inter-and intra assay CVs were obtained.

LIMITATION OF PROCEDURE

It has been demonstrated that high levels of albumin, glucose, pH, and organic acids may interfere with the assay.

REFERENCES

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3. Rowe DS (1968) Quantitative estimation of immunoglobulins and other serum proteins by immunological methods Clin. Chem. Acta 1968 Sep, 22 (1):43.
4. Milford Ward A. (1990). Protein reference Unit Handbook of clinical Immunochemistry. 5th edition, Publ.PRU Publications, Sheffield, UK.
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GRAPHICAL SYMBOLS USED

	Storage temperature	LOT	Lot number
IVD	In vitro diagnostic device		Expiry date
REF	Catalogue number	CONT.	Contents
	Read instruction before use		Manufacturer

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