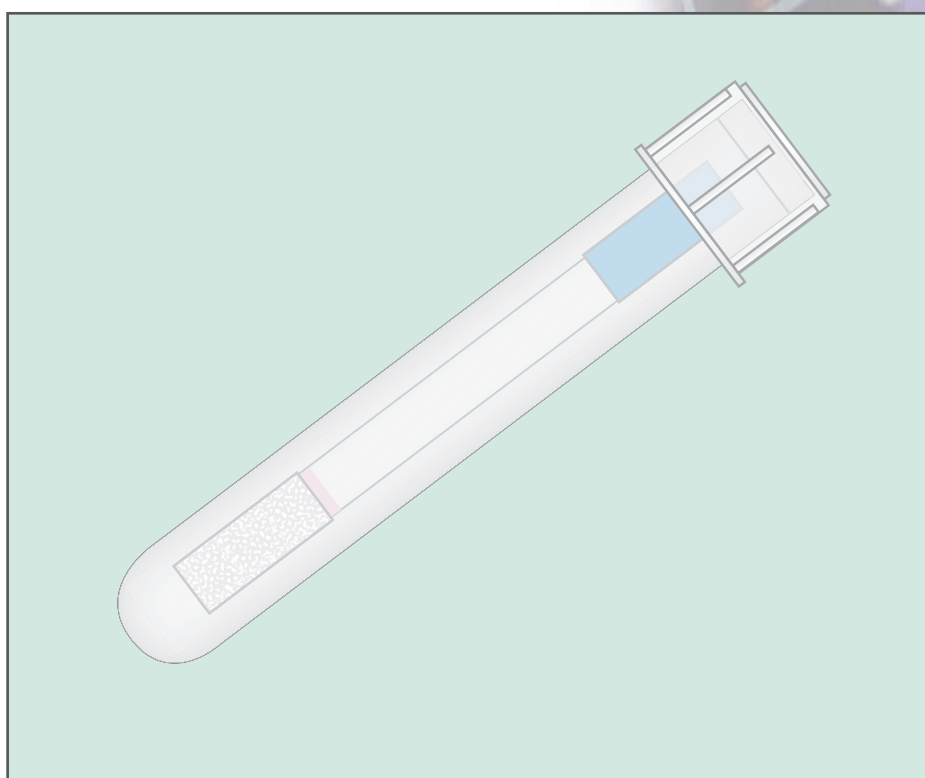


INSTRUCTION SHEET DYS052

# Bence-Jones Protein DIPSTICK **RAPYDTEST**®

A qualitative test for the determination of  
Bence-Jones Protein in Urine

**Single use device for in vitro diagnostic use only**



#### Health and Safety Benefits

- Dipstick format
- Kappa and Lambda Strips
- Qualitative Analysis
- Minimal operator time

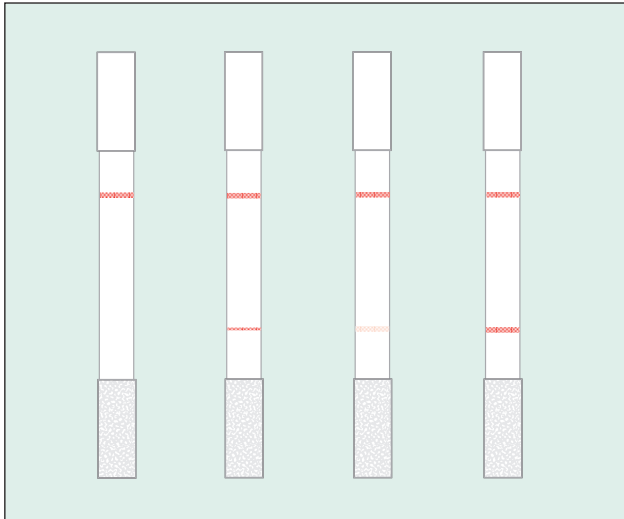
#### Performance Benefits

- Reduced processing time
- Antibody linked specificity
- High sensitivity
- All reagents supplied

# Bence-Jones Protein DIPSTICK RAPYDTEST®

## Introduction

The DiaSys Bence Jones Rapid is indicated for the detection of light chains (free & bound) in human urine. Test kits for kappa, lambda and combination kits are available.



## Hazards and Cautions

This test contains material of human origin. Although the material has been tested for HIV and Hepatitis surface antigen, the assays should be treated with the same care as other human material.

On completion of the test, the Duo Dipsticks should be disposed of in accordance with hospital regimes.

## Principle

The assay uses competitive immunochemistry in a lateral flow device. When urine is introduced into the Duo tube it flows by capillary action along the device.

At the capture zone the urine is exposed to a coloured capture antibody conjugate, which will complex in the presence of light chains. Independent of a reaction the fluid will continue to migrate to the test zone, where any uncomplexed capture antibody will bind to the membrane, and will be observed as a red line.

## When to use the test

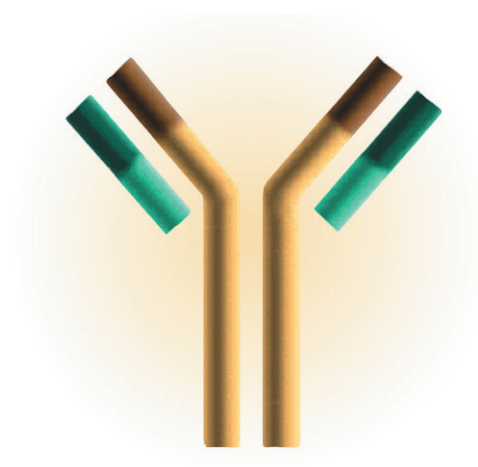
The test may be used as a general screen of all potential myeloma samples, or as a more general screen for all senior population and renal referral urines.

It may also be used after electrophoresis, where the presence of a band in the gamma/beta region is not easily discernible.

The test should not be used for samples with high total protein (>1g/L), and all samples in this range should be evaluated by electrophoresis.

Following a positive result the sample should be further investigated for full characterisation by immunoelectrophoresis or immunofixation electrophoresis.

The sample will continue to migrate to a control zone, where both free and complexed capture antibody will bind to the membrane, indicating that the test has functioned correctly.



# Bence-Jones Protein DIPSTICK RAPYDTEST<sup>®</sup>



## Procedure

1. Remove the reaction device from the a tube.
2. Add 300 microlitres (0.3ml) urine to the tube.
3. Replace the reaction device, ensuring that the conjugate pad (slight purple colour is at the base and that the absorbent pad (Blue for kappa, white for Lambda) is at the top.
4. Allow the urine to migrate through the device.
5. After 5-10 minutes read the result - the assay is complete where there is clear banding without background colouration on the strip.

## Results

**Kappa** - The strip has a blue pad at the top.

**Lambda** - Strip has a white top.

This is a competitive assay - the absence of a Band in the test zone indicates a positive sample.

The control zone should always have a line in the completed assay - if no control line is present the test should be repeated. If the banding is not clear please use the following chart for interpretation:

**NOTE:** At very low BJP titres a faint (ghost) line may be observed - under these circumstances the sample should be concentrated prior to immunofixation.

## The Assay

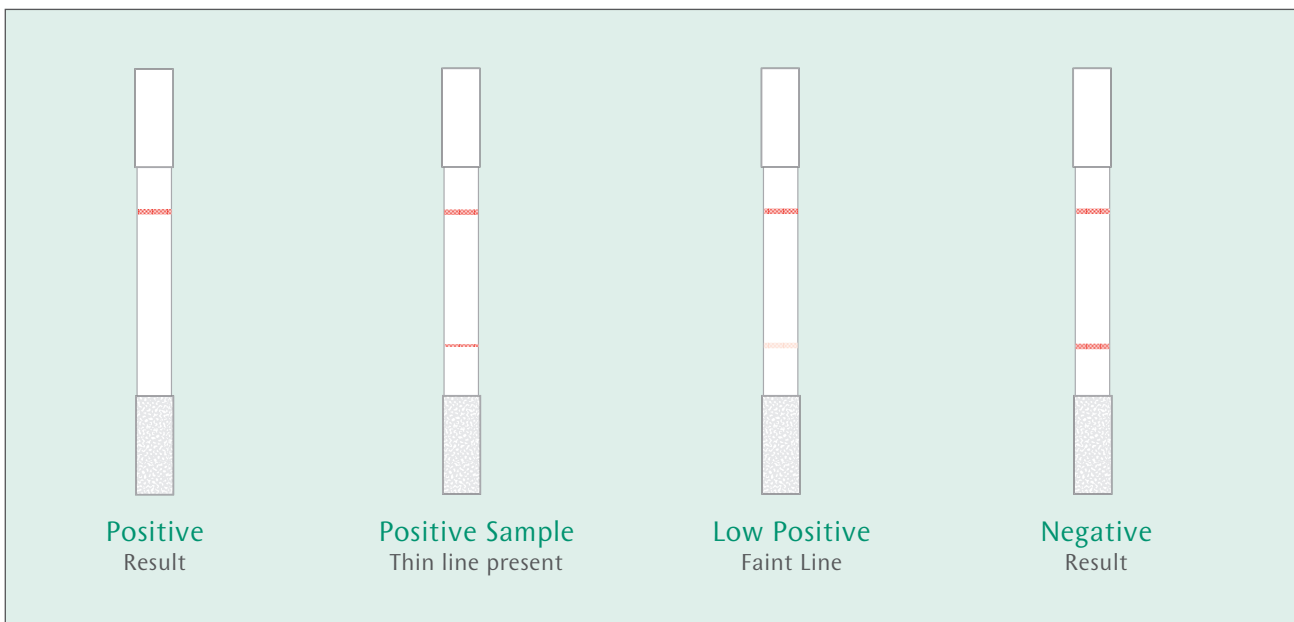
The DiaSys goal was to develop an assay that requires little technical expertise is rapid, sensitive and may be used either as a screen, or as a confirmatory step prior to immunoelectrophoresis, or immunofixation electrophoresis.

The assay is a competitive chromatographic immunoassay based on lateral flow technology. An unconcentrated sample is introduced into the assay, where both free and bound light chains bind to a migratable conjugated monoclonal antibody cocktail. Assuming the formation of an antigen-conjugate complex the sample will migrate to a membrane bound test zone of free light chains - the complex will not bind here, and the absence of a clear line in the test zone indicates the presence in the urine of <10mg/l immunochemical.

The sample will continue to migrate to a membrane bound control zone specific against the capture conjugate to indicate correct test function. The entire process requires no pre-treatment of the urine sample, and results are read in 5 minutes.

## Characterisation of the Assay

The assay is demonstrated to have no cross-reaction with other urinary factors, including pH, glucose, ketones, osmolarity, albumin and organic acids. There is no cross-reaction between light chain species.



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## Characterisation of the Assay cont.

The assay is specific for free and bound light chains, and will detect light chain when complexed to heavy chains or polymerised with other light chain units. The monoclonal cocktail nature of the capture antibody allows for a multi-epitope target, whilst retaining the specificity.

The assay cannot determine the monoclonal nature of the light chains, and where an equivalent concentration of polyclonal light chain is present the assay will indicate a positive result. However, any sample with super-physiological levels of light chain should be referred to electrophoretic analysis. The monoclonal nature of the immunochemical will be determined by electrophoretic migration rate. The assays are presented as strips in a resealable tube, into which urine should be directly introduced.

## Results

Test sensitivity ~10mg/L Urinary free light chain

<b>Sensitivity</b>	<b>Specificity</b>
88%*	100%

Assay shows no cross reactivity between light chains, with pH, Sg, Albumin or any other physiological factors.

\*Samples demonstrated to have low levels of polyclonal (para) protein.

## Recommended Procedure

This assay provides a rapid method of detecting low levels of BJP in urine, which might be missed on routine electrophoresis. The test may be employed at several stages in the urinalysis regime.

The test may be used as a screen prior to electrophoresis for myeloma or senior population referral samples, with the result considered with respect to the total protein. With the indication of a positive result, or atypical total protein the sample should be referred to immunofixation electrophoresis.

If electrophoresis is used as the initial screen, the assay may be used as a check where banding is inconclusive (typically for protein concentration <100mg/L).

## Ordering Information

Product	Pack Size	Ordering Codes
Kappa Rapydtest Dipstick	40	53000
Lambda Rapydtest Dipstick	40	53001
Kappa/Lambda Rapydtest Dipstick	40	53002

## Order product direct from DiaSys or appointed distributor



DiaSys updates its home pages on the Internet regularly with new product announcements, applications and company news. Visit our web page for all the latest information: <http://www.diasys.com> or e-mail on: [sales@diasys.co.uk](mailto:sales@diasys.co.uk)



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