

IT'S ALL ABOUT THE RIGHT CHEMISTRY

GENERAL | SPECIAL | VETERINARY | POINT-OF-CARE | IMMUNO



IMMUNODIP[®] RAPID TEST FOR THE DETECTION OF MICROALBUMIN IN URINE

INTRODUCTION

Almost half of all insulin dependent diabetics develop a diabetic nephropathy (DNP), with protein in the urine and a decline in the filtration rate, during the course of their disease. If a DNP remains undetected, it can lead to irreversible kidney failure, necessitating dialysis treatment or kidney transplant. Additionally, high blood pressure, through atherosclerotic changes in the blood vessels that supply the kidneys, can lead to inadequate blood supply and to nephropathy. Microalbuminuria, is defined as a slight increase in urinary albumin (20 – 200 mg/L), caused by a disturbance in the glomerular filtration barrier. Microalbuminuria may have various causes; it may be the concomitant product of profound physical stress, fever, cardiac insufficiency or poor regulation of hypertension. After the elimination of the causative factors, the levels can return to normal. However, a constant, detectable, prolonged microalbuminuria suggests damage to the glomerular filter. The risk of progression to kidney damage can be greatly reduced by means of metabolic adjustment, blood pressure control and early pharmaceutical intervention. The increased risk of cardiovascular disease that accompanies a nephropathy can, at the same time, also be reduced.

TEST PRINCIPLE

The ImmunoDip[®] Microalbumin rapid test measures the concentration of urinary Albumin by utilization of a self-contained, immunochromatographic, lateral flow membrane test strip containing specific monoclonal antibody against human albumin. The test strip contains

labeled antibody conjugate, immobilized antigen and immobilized antibody. When Albumin present in the urine binds with antibody coated latex beads on the test strip, a maximum of two blue colored bands are formed. The resulting intensity of these bands corresponds to the concentration of Albumin in the urine sample.

KEY FEATURES & BENEFITS

- **Simple & Fast** -- An easy five (5) step testing procedure allows you to obtain test results in only three (3) minutes.
- **Cost Effective** – Generate accurate, reliable test results without the need for expensive reagents, calibrators and instrumentation.
- **Testing Versatility** – Able to use in virtually any clinical setting . . . 24 hours a day, 7 days a week.
- **Minimal Interferences** – No significant cross-reactivity with common medications and other human proteins.
- **Stable Results** – Able to obtain either qualitative or semi-quantitative test results eight (8) hours after testing.
- **Built-In Testing Control** – Provides utmost confidence in test results.
- **Convenient Storage & Shelf-Life** – Able to store at either refrigerated or ambient temperatures for eighteen (18) months after date of manufacture.
- **Proven Performance** – A documented and published history of testing in some of the most demanding clinical environments world-wide.

TESTING & INTERPRETATION

To perform the test:

- Remove test device from pouch.
- Place into urine sample, preferably using a first morning void.
- Check that urine sample is up to, or above, vent hole.
- Let sit in sample a minimum of three (3) minutes.
- Read the result within eight (8) hours after placing the strip in the urine sample.

To read the test, compare the relative intensity of the two bands. The top band also functions as a built in control:

- If the bottom band is darker than the top band, the result is *NEGATIVE* (<12 mg/L).
- If the bottom band and top band are of equal color intensity, the result is *NEGATIVE* (12-18 mg/L).
- If the bottom band is lighter than the top band, the result is *POSITIVE* (>18 mg/L).
- If only a top band is present, the result is *POSITIVE* (>18 mg/L).



ORDERING INFORMATION

PRODUCT	CATALOGUE NUMBER	PACKAGE CONFIGURATION
ImmunoDip Qualitative Test (Complexity Rating: CLIA Waived)	790-25	25 Test Strips/Kit
ImmunoDip Semi-Quantitative Test (Complexity Rating: Moderate)	700-25	25 Test Strips/Kit
Two-Level Microalbumin Urine Quality Control Materials	SM-252	4 x 8 mL

REFERENCES

1. Mogensen, CE, et al. Prevention of Diabetic Renal Disease with Special Reference to Microalbuminuria. *Lancet* 346: 1080-1084 (1995).
2. Tobe, SW, et al. Microalbumin in Diabetes Mellitus. *CMAJ* 167: 499-503 (2002).
3. National Kidney Foundation. K/DOQI Clinical Practice Guidelines for Chronic Kidney Disease: Evaluation, Classification and Stratification. *Kidney Disease Outcome Quality Initiative. Am J Kidney Dis* 39: (2 Suppl 1): 1-246 (2002).
4. American Diabetes Association, Inc. (ADA). Position Statement: *Nephropathy in Diabetes. Diabetes Care* 27:S79-83, 2004.

REFER TO PACKAGE INSERT AND/OR MSDS FOR ADDITIONAL TECHNICAL INFORMATION

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