

Detect Kidney Disease Before it Results in Irreversible Damage

Microalbuminuria is the first clinically identifiable indicator of diabetic nephropathy and systemic microvascular permeability.

Current Definitions of Abnormalities in Albumin Excretion

Category	24-hour Collection (mg/24h) ¹	Timed Collection (µg/min) ¹	Spot Collection Alb/Cr Ratio (µg Alb/mg Cr) ¹	Spot Collection Alb Concentration (mg/L) ^{2,3,4}
Normal	<30	<20	<30	<20
Microalbuminuria	30-299	20-199	30-299	20-199
Clinical Albuminuria	≥300	≥200	≥300	≥200

1. *Diabetes Care* 2001; 24: (Suppl. 1): S69-S72.

2. *Diabetes Care* 1995; 18: No. 4: 572-581.

3. *The Practitioner* 1995; 239: 343-345.

4. *Diabetes Care* 1997; 20: No. 4: 516-519.

For More Information or To Place an Order

In the USA: 800-325-2436

In Canada: 800-565-0265

Product Descriptions

Cat. No.	790-25	ImmunoDip Urinary Albumin 25 Tests/Box – CLIA Waived 790-25 Billable under CPT Code 83518QW
	700-25	ImmunoDip Stick for Microalbuminuria 25 Tests/Box – CLIA Moderate 700-25 Billable under CPT Code 82044
	SM-252	Microalbumin Urine Controls (2 Vials High / 2 Vials Low)



ImmunoDip is a Registered Trademark of Diagnostic Chemicals Limited. U.S. Patent Nos. 5,656,502 and 6,001,658. Other patents pending.



Diagnostic Chemicals Limited

800-565-0265 (Canada) - Charlottetown, PE, Canada C1E 2A6, 902-566-1396 ♦ Fax 902-566-2498

800-325-2436 (USA) - Oxford, Connecticut, USA 06478, 203-881-2020 ♦ Fax 203-888-1143

www.dclchem.com ♦ e-mail: sales@dclchem.com

Represented By:

Introducing a revolutionary new test for Microalbumin



ImmunoDip[®]
Microalbumin Urine Dipstick Test
from Diagnostic Chemicals Limited

Microalbumin Urine Testing Has Never Been So Easy!

Simple ...

Walk-Away Convenience

Simply place the ImmunoDip into the urine sample and ... walk away. The patented housing will draw the precise amount of sample needed for an accurate test.

Self-Timing

The ImmunoDip test will run to completion in 3 minutes. Because the resulting color bands remain stable, even if left in the urine sample, the test results can be read at your convenience ... a vital feature for today's busy office staff.

Built-In Internal Control

Provides you with absolute confidence in every test result.

Room Temperature Storage

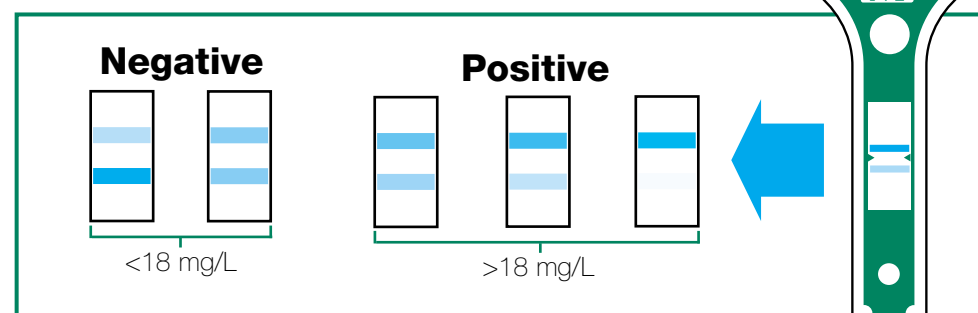
The individually foil wrapped ImmunoDip can be stored at room temperature for 18 months from date of manufacture, ensuring a fresh, reliable test every time.

CLIA Waived and Cost Effective

ImmunoDip (Cat. No. 790-25), which is now CLIA Waived and billable under CPT Code 83518QW, can produce additional office revenue while providing immediate test results.

Accurate ...

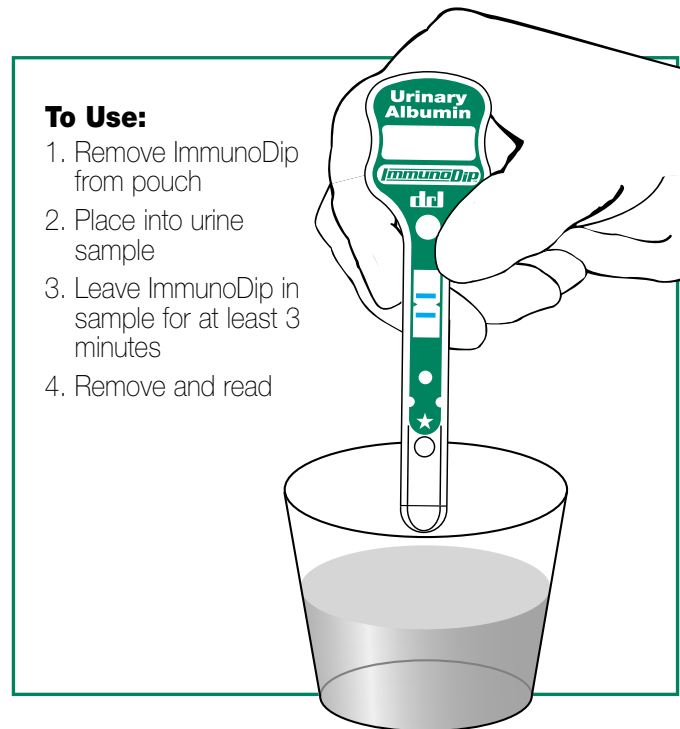
ImmunoDip measures the concentration of urinary albumin in a lateral flow membrane containing specific monoclonal antibodies against Human Serum Albumin. This unique immunometric strip uses these antibodies conjugated to blue latex particles to develop an easy to read signal consisting of two bands. The relative darkness or intensity of the color of these bands when compared one to the other enables an accurate determination of micro-concentrations of albumin in the urine sample.



(Note: Representation of CLIA Waived product Cat. No. 790-25)

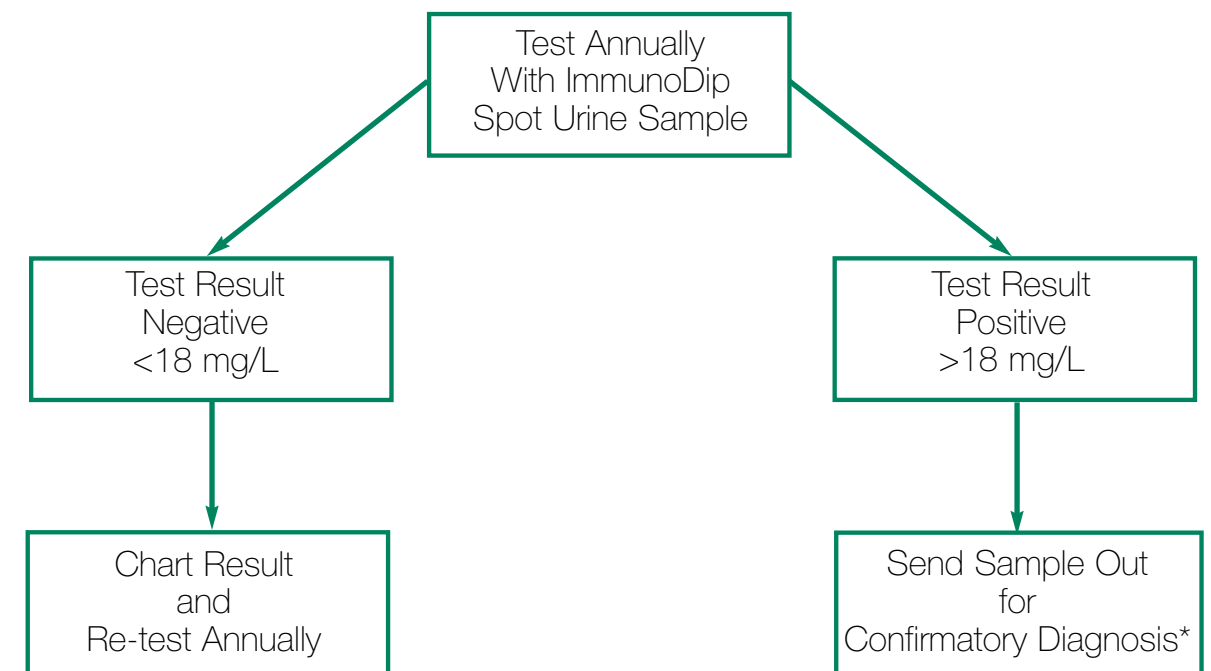
To Use:

1. Remove ImmunoDip from pouch
2. Place into urine sample
3. Leave ImmunoDip in sample for at least 3 minutes
4. Remove and read



Early Detection of Kidney Disease

The American Diabetes Association (ADA), the National Kidney Foundation (NKF) and the National Committee for Quality Assurance (NCQA) recommend that patients at risk for kidney disease and those with diabetes be screened annually by testing for microalbuminuria. ImmunoDip is an excellent "rule-out" test for diabetic nephropathy and chronic kidney disease and provides the sensitivity and accuracy to meet ADA, NKF and NCQA recommendations when following the algorithm below.^(1,2)



(*Quantitative albumin/creatinine ratio or 24-hour urine. Two out of three positives in a 3-6 month period to confirm microalbuminuria.)

Negative Predictive Value: 100%
Sensitivity: 100%

Positive Predictive Value: 94%
Specificity: 97%

Reference: American Association of Clinical Chemistry, 1998 Oak Ridge Conference, Raleigh, NC

Early detection of low levels of urinary albumin allows early intervention in cases of sub-clinical nephropathy in diabetes^(3,4) and hypertension. Microalbuminuria is now accepted as highly predictive of cardiovascular risk in hypertensive individuals.^(5,6) Increased cardiovascular risk can be detected among patients with hyperlipidemia, gestational diabetes and women taking oral contraceptives or receiving hormone replacement therapy.^(7,8) The prevalence of pre-term delivery in diabetic pregnancy is considerably increased in women with microalbuminuria.⁽⁹⁾

1. *Diabetes Care* 2001; 24: (Suppl. 1): S69-S72. 2. *Am J Kidney Dis* 2002; 39: (Suppl. 1): S17-S31. 3. Viberti et al *Lancet* 1982; i: 1430-1432.
4. Mogensen et al *N Engl J Med* 1984; 311: 89-93. 5. Agrawal et al *Journal of Hypertension* 1996; 14: 223-228.
6. Bigazzi et al *Journal of Hypertension* 1998; 16: 1325-1333. 7. Roest et al *Circulation* 2001; 103: 3057-3061.
8. Go et al *Diabetes Care* 2001; 24: 1764-1769. 9. Ekblom et al *Diabetes Care* 2001; 24: 1739-1744.