



SAMPLE PROCEDURE

This “Sample Procedure” is not intended as a substitute for your facility’s Procedure Manual or reagent labeling, but rather as a model for your use in customizing for your laboratory’s needs.

Space has been provided within the document to allow you to update this template with information specific to your facility. It is suggested that a current version of the manufacturer’s directional insert be maintained as a supplement.

I. TEST NAME

OSOM[®] ImmunoDip[®] Urinary Albumin Test
CLIA Complexity: Waived

II. INTENDED USE

OSOM[®] ImmunoDip[®] Urinary Albumin tests for the presence of elevated levels of albumin in urine. Elevated urinary albumin is also known as microalbuminuria. Elevated albumin is an early sign of possible kidney damage. Identifying elevated urinary albumin can aid in the early detection and monitoring of the course of incipient nephropathy in diabetics and hypertensive patients. For *in vitro* diagnostic use.

III. SUMMARY AND EXPLANATION OF TEST

There are several kidney disease conditions that can produce high levels of albumin in urine ⁽¹⁾. Detecting albumin in urine at the low levels measured by this test will aid in early detection and treatment of patients at risk for renal (kidney) disease. Slightly elevated levels of human protein albumin in urine, >18 mg/L, is known as microalbuminuria. Levels above 18 mg/L are not normally found in healthy individuals. These low but significant levels are not detectable with older dipstick assays. The OSOM ImmunoDip Urinary Albumin Test classifies a sample as positive if it is above a level of 18 mg/L.

Conditions in which elevated levels of albumin in urine may be present include: Type 1 and Type 2 diabetes ⁽²⁻⁸⁾; hypertension ^(9, 10); and renal disease found in pregnancy ⁽¹¹⁾. There are other less common causes as well. Diabetes is the largest single cause. One study found 45% of the insulin-dependent diabetics developed serious kidney disease ⁽³⁾. Testing for elevated levels of albumin in urine helps to identify those diabetics who are prone to kidney disease. Scientific studies indicate that proper control of blood glucose (blood sugar) levels and blood pressure help slow or prevent kidney damage ^(1, 9).

IV. PRINCIPLE OF THE TEST

The OSOM ImmunoDip Urinary Albumin Test is a lateral flow immunochromatographic test strip which measures the concentration of urinary albumin. Contained in the device are labelled antibody conjugate, immobilized antigen and immobilized antibody. The albumin present in the urine binds with blue colored latex beads present in the test device. This binding is caused by monoclonal antibodies against human albumin attached to the beads. When the device is placed into urine, these beads mix with the urine sample and are carried up the test device by a wicking action. Human albumin is fixed in a band at the bottom half of the testing region. Goat anti-mouse antibodies are fixed in a band at the top half of the testing region. The test also contains buffer and stabilizing components on strip substrates.

At low levels of albumin in the sample, these blue beads bind to the band of albumin. This produces a blue colored band in the lower half of the test window. The test window has a second band that can bind the colored beads. The colored beads are bound by the second band even if they have reacted with albumin in the urine. When there is a low level of albumin in the urine, most of the beads will bind to the lower band. However, some of the beads will react with the small amount of albumin present. These beads will pass through the lower band and will be bound at the upper band. This produces a second blue band. As the amount of albumin in the urine increases, more beads pass through the lower band and are bound by the upper band. After three minutes, the darkness or intensity of the two blue bands in the test window is compared.

If the band in the upper half of the test window is lighter than or equal to the lower band, the test is negative. Negative means there is a normal level of albumin in the test urine sample. If the band in the upper half of the test window is darker than the lower band, the test is positive. Positive means there is more albumin in the test urine sample than is found in normal urine. Detailed instructions for reading the results are in the Procedure/Result Interpretation Guide section of this manual.

V. KIT CONTENTS AND STORAGE

Contents:

25 Individually packaged Test Devices
1 Package Insert

Storage Conditions:

The OSOM ImmunoDip devices are provided ready to use and are stable until the expiry date indicated on the box and device pouch. Store at 18°C/65°F - 26°C/79°F. The device is stable for four hours after being removed from the foil pouch

At this facility, kits are stored: _____.

VI. MATERIALS REQUIRED BUT NOT PROVIDED

Timer or watch.
Clean specimen collection container.
The user may wish to purchase and utilize Sekisui Diagnostics Microalbuminuria Controls (Cat. No. 791) for external quality control.

VII. WARNINGS AND PRECAUTIONS

For *in vitro* diagnostic use. Do not use beyond the stated expiry date. The OSOM ImmunoDip device must be used within four hours of removing it from the foil pouch. The instructions must be followed to obtain accurate results. The test should be performed at conventional room temperature 18°C/65°F - 26°C/79°F.

For U.S. customers, the instructions for use must be followed to maintain the waived complexity rating. If the test instructions are modified then the test will be considered highly complex and will be subject to all applicable CLIA requirements.

The “universal precautions” recommended by the Center for Disease Control should be followed whenever body fluids such as urine are handled. These precautions include wearing gloves.

RISK AND SAFETY PHRASES

S20/21: When using the device, do not eat, drink, or smoke.

S35: The device must be disposed of in a safe way. When the test is completed, the samples should be disposed of using normal laboratory practices. Disposal of used and unused devices should be made in accordance with Federal, State, or local regulations.

VIII. SPECIMEN COLLECTION & PREPARATION

This facility's procedure for patient preparation is: _____.

_____.

This facility's procedure for sample labeling is: _____.

_____.

Fresh urine at room temperature is the sample of choice. The first morning urine is recommended. The American Diabetes Association recommends that at least two of three urine collections within a 3-6 month period should show elevated levels before designating a patient as having microalbuminuria.

Do not freeze urine samples before testing and do not use urine samples containing preservatives. Fresh urine is preferred but if necessary, urine may be refrigerated up to three days. Allow urine to return to room temperature before testing. Also, fresh urine should cool to room temperature before testing.

Additional information on screening guidelines is available from the American Diabetes Association⁽¹³⁾ and the National Kidney Foundation⁽¹⁴⁾.

This facility's procedure for transporting specimens is: _____

This facility's procedure for rejected specimens is: _____

IX. QUALITY CONTROL

General Quality Control Considerations:

Prior to testing samples, check the "Expiry Date" on the box or pouch. If the product has expired, discard and do not use the device. If the samples were tested with expired devices, do not report the results. Please refer to the *Limitations* and *Kit Contents and Storage* sections of this manual.

Internal Procedural Controls:

The OSOM ImmunoDip Urinary Albumin Test contains built-in control features. During the test the device will show a visible moving front of liquid containing the blue beads. This should happen within 60 seconds of being placed into the urine sample at the proper depth.

The device must develop a blue colored band in the upper section of the window three minutes after being placed in the urine. If no upper band develops the test result is invalid.

The blue bands should be straight and reasonably uniform. Significant colored blotches or spots should not be present.

If any of the built-in control features do not function as described, the sample should be tested with another device. If the second device also fails, contact Sekisui Diagnostics Technical Assistance.

External Quality Control Testing:

External positive and negative controls are to be used to ensure that the device is performing properly. For this purpose, Microalbumin Urine Controls Cat. # SM-252 containing both positive and negative control materials are available from Sekisui Diagnostics. To test the positive and negative controls, follow the OSOM ImmunoDip Test Instructions using the controls in place of a urine specimen. The positive control should give a result with the top band darker than the bottom band. The negative control should give a result with the two bands of equal intensity or the bottom band darker. If the tests do not perform as described check the instructions and repeat. If the repeat tests do not perform properly contact Sekisui Diagnostics Technical Assistance.

For CLIA Waived Labs

Sekisui Diagnostics recommends that positive and negative external controls be run with each new lot, shipment received, and with each new untrained operator; at a minimum, external controls should be run once per month.

For CLIA Non-Waived Labs

Quality Control requirements should be established in accordance with local, state and Federal regulations or accreditation requirements. Minimally, Sekisui Diagnostics recommends that positive and negative controls be run with each new lot, shipment received and with each new untrained operator.


QC Testing Frequency and Documentation:

For this facility, External QC is run: _____

Results of External QC and action(s) taken when control results are unacceptable are documented:

X. TEST PROCEDURE

If the urine sample has been refrigerated, allow it to come to room temperature before continuing.

1. After obtaining the urine specimen, remove the OSOM ImmunoDip Device from the foil pouch.
2. Place the OSOM ImmunoDip Urinary Albumin Test device into the urine sample.
 - Do not squeeze top of housing.
 - Tap the device on bottom of urine cup to dislodge any air bubbles in plastic housing.
 - Check that urine is up to or above the  on the OSOM ImmunoDip device.
3. Wait for at least 3 minutes (but not more than 8 hours) before removing to read.

If no color develops in the top half of the test window after 3 minutes, an air bubble may have blocked fluid entrance into the test housing. Agitate the test strip to dislodge the air bubble and recheck in three more minutes.

Remove the OSOM ImmunoDip Device from the urine cup anytime after the minimum three minute time. Place on a relatively flat surface or support upright until you read the result.

4. Read results within eight (8) hours.

For this facility, used Test Devices are disposed: _____

XI. INTERPRETATION OF RESULTS

A negative test gives a result with the two bands equal or the bottom band darker.

A positive test gives a result with the top band darker.

The absence of the top or both bands should be reported as invalid.

No color in the bottom band indicates a very high albumin level (at least 160 mg/L). Levels this high are rarely found in individuals who are unaware of an albuminuria condition.

In the case of an invalid result, repeat the test with a new device. If the problem persists, contact Sekisui Diagnostics Technical Assistance.

The OSOM ImmunoDip Urinary Albumin Test device is intended to identify elevated urinary albumin levels. In most cases, positive results would be subject to further medical interpretation and/or further diagnostic testing.

In the event this test becomes inoperable, this facility's course of action for patient samples is: _____

XII. LIMITATIONS

The amount of albumin excreted in the urine can vary for several reasons in healthy individuals. Changes in posture, strenuous physical activity, elevated blood pressure, and pregnancy may all influence the albumin level in urine. The OSOM ImmunoDip Urinary Albumin Test can help to detect these conditions but can not differentiate among them. The test will detect elevated albumin in urine. This is only part of the medical diagnosis of any of the conditions that can produce such elevated urinary albumin.

Urinary Albumin fluctuates day-to-day; therefore, testing two separate samples over a three to six month period may increase the predictive value, where two positive samples are predictive of incipient nephropathy. Quantitative procedures may be indicated for such follow up testing.

Before running the test, carefully review the chart below for potential sources of error.

Potential sources of error	Consequence or Effect	Corrective Action
Patient is/has: Any acute illness Fever Urinary tract infection Currently menstruating Pregnant Undergone physical exercise or other extraordinary physical efforts the evening prior to the test	Under these conditions albumin levels in the urine may be elevated regardless of diabetes or hypertension-related kidney damage.	Postpone the test.
Uncontrolled diabetes	If diabetes is not well controlled, albumin levels in the urine may be elevated regardless of diabetes or hypertension-related kidney damage.	Retest when diabetes is under better control.

If the test zone is devoid of color after three minutes despite correct immersion depth and the absence of an air bubble, verify that the OSOM ImmunoDip devices are not past the "Expiry Date". Determine if devices may have been exposed to extreme heat or cold. If either of these conditions occurred, suspend testing with these devices. Open a new box of test devices that has not reached its expiry date and retest.

XIII. EXPECTED VALUES AND ASSAY RANGE

The OSOM ImmunoDip Urinary Albumin Test functions over a range of urinary albumin concentrations from 1 to >2500 mg/L. The albumin concentration of an average urine specimen from a healthy individual should not exceed 18 mg/L (7). Except for the limitations stated previously, healthy individuals will show a negative result. A negative Urinary Albumin Test is a result in which the bottom blue band is either darker than or equal to the upper blue band. A single negative result (≤ 18 mg /L) does not rule out all renal disease⁽¹⁾.

A positive Urinary Albumin Test is a result in which the upper blue band is darker than the lower blue band. A single positive result (> 18 mg/L) may be an early indicator of kidney disease and indicates that further testing is warranted. Clinical diabetic nephropathy is indicated when microalbuminuria (> 18 mg/L) is present in at least two of three morning urine specimens⁽¹¹⁾.

XIV. CROSS REACTIVITY

Potential cross-reactivity with common medications and various human proteins has been determined. OSOM ImmunoDip devices were tested with common medications and certain human proteins at normal and abnormal levels using two urine samples with negative and positive levels of microalbuminuria. No cross-reactivity or interference has been found with:

(Tested at 20 mg/dL) Acetaminophen, Ascorbic Acid, Caffeine, Gentisic Acid, Ampicillin, Tetracycline, (at 2 g/dL) D-glucose; (at 1 mg/dL) Hemoglobin; (at 100 mg/dL) oxytetracycline; (at 0.2 mg/dL) α -1-acid Glycoprotein; (at 0.22 g/dL) β -hydroxybutyric acid; (at 0.1 g/dL) uric acid; (at 10 g/dL) urea; (at 75 mg/dL) acetone; (at 4000 U/L) α -amylase; (at 0.012 g/L) α -1-antitrypsin; (at 10 mg/dL) holo-Transferrin; (at 100 mg/dL) Calcium; (at 400 mg/dL) Salicylic acid, Acetylsalicylic Acid and (at 0.43 mg/dL and 0.86 mg/dL) Pyridium.

XV. PERFORMANCE CHARACTERISTICS & POL STUDIES

Refer to directional insert – OSOM[®] ImmunoDip[®] Urinary Albumin Test

XVI. REFERENCES

Refer to directional insert – OSOM[®] ImmunoDip[®] Urinary Albumin Test

XVII. ASSISTANCE

For assistance contact Sekisui Diagnostics Technical Assistance at (800) 332-1042.