QDx Instacheck™ Microalbumin

INTENDED USE

QDx Instacheck™ Microalbumin along with **QDx Instacheck™ Reader** is a fluorescence immunoassay for quantitative determination of albumin in human urine. The test is used for assessing microalbuminuria for early detection of kidney damage most commonly associated with diabetes.

INTRODUCTION

A microalbumin test (often called MAU test) evaluates urine for the presence of albumin[1]. Albumin is the most abundant protein in human blood. It is filtered by kidney glomeruli but undergoes selective reabsorption[2]. When the kidneys are working normally, albumin is not present in the urine. However, when the kidneys are damaged/diseased, small amounts of albumin leak into the urine. This condition is called microalbuminuria[1-4]. Microalbuminuria is most commonly caused by kidney damage resulting from diabetes. However, many other clinical conditions such as classical hypertension, heart failure, liver cirrhosis, and systemic lupus erythematosus (SLE) may also lead to kidney damage. If early kidney damage is not treated, larger amounts of albumin and other proteins may leak into the urine[5-6]. This condition is called macroalbuminuria or proteinuria which indicates serious kidney damage leading to chronic kidney disease. The microalbumin test is normally performed on a routine urine sample collected randomly but it can also be performed on the first-voided sample (sample collected when the patient urinates for the first time in the morning) as well as the timed samples (samples collected after specific time intervals over a 24-hour period)[7].

PRINCIPLE

QDx Instacheck™ Microalbumin is an immunoassay system based on antigen-antibody reaction and fluorescence technology.

When a human urine sample is processed with the detection buffer in the detection buffer tube, the fluorochrome-labeled detector antibodies (anti-albumin) in the detection buffer binds with albumin in the urine sample.

When the processed urine sample is loaded into the sample well on the test cartridge as per the prescribed test procedure, it migrates through the nitrocellulose matrix of the test strip.

The fluorochrome-labeled detector antibody-analyte (urine albumin) complexes get captured on to the capture antibodies (anti-albumin) which have been immobilized at the test line on the test strip.

As a result, the complexes of the capture antibody-analyte (urine albumin)-detector antibody get accumulated at the test line on test cartridge membrane.

Thus, more the albumin in the urine sample, more the complexes that get accumulated at the test line on the test cartridge membrane.

Upon inserting the sample-loaded test cartridge in the **QDx Instacheck™ Reader**, the laser light illuminates the test cartridge membrane thereby triggering fluorescence from the fluorochrome-labeled complexes of albumin.

Intensity of the fluorescence is scanned and converted into an electric signal. The on-board microprocessor computes the microalbumin concentration based on a pre-programmed calibration.

The computed and converted result is displayed by the **QDx Instacheck™ Reader** quantitatively in terms of mg/L.

COMPONENTS AND REAGENTS

QDx Instacheck™ Microalbumin is consists of a 'Test Cartridge', an 'ID Chip' and a 'Detection Buffer Tube'.

- The test cartridge contains a test strip; on the membrane of which, murine antibodies against human albumin and rabbit immunoglobulin-G have been immobilized at the test line and the control line respectively.
- Each test cartridge is individually sealed in an aluminum foil pouch containing a desiccant. 25 sealed test cartridges are packed in a box which also contains an ID chip.
- The detection buffer pre-dispensed in a plastic tube contains fluorochrome-labeled anti-albumin antibodies, fluorochrome-labeled anti-rabbit immunoglobulin-G, bovine serum albumin (BSA) as a stabilizer and sodium azide in phosphate buffered saline (PBS) as a preservative.
- The detection buffer is dispensed in each detection buffer tube. 25 detection buffer tubes are packed in a separate box which is further packed in a Styrofoam box provided with ice packs for the purpose of shipment.

WARNINGS AND PRECAUTIONS

- For *in vitro* diagnostic use only.
- Carefully follow the instructions and procedures described in this insert as well as the **QDx Instacheck™ Reader** operation manual.
- Lot numbers of all the test components (test cartridge, ID chip and detection buffer tube) must match with each other.
- Neither interchanges the test components form different lots nor use the test components beyond expiration date.
- Test performed by using any test component of mismatching lot number or that beyond the expiration date may yield misleading test result(s).
- **QDx Instacheck™ Microalbumin** is compatible only with **QDx Instacheck™ Reader**.
- The test cartridge should remain sealed in its original pouch until just prior to use. Do not use the test cartridge should it be damaged or the pouch found already opened.
- Allow a minimum of 30 minutes for the test cartridge (if stored in a refrigerator) and the detection buffer tube to attain room temperature prior to performing the test.
- Unpreserved urine sample(s) stored for longer periods at room temperature is susceptible to microbial proliferation with resultant degradation of albumin. Hence the patient should be asked to submit a freshly collected random**/**routine urine sample in a suitable container to the laboratory for testing. Avoid direct exposure of the urine sample to sunlight. If absolutely necessary, the patient should store the urine sample in a refrigerator (2-8°C) for a short period. Proper instructions must be given to the patient in this regard.
- **QDx Instacheck™ Microalbumin** as well as the **QDx Instacheck™ Reader** should be used away from vibration and/or magnetic field. During normal usage, **QDx Instacheck™ Reader** may produce minor vibrations which should be regarded as normal.
- A detection buffer tube should be used for processing one urine sample only. Similarly a test cartridge should be used for testing one processed urine sample only. Both the detection buffer tube as well as the test cartridge should be discarded after single use.
- Being potentially infectious, used test cartridge(s) and detection

buffer tube(s) should be handled carefully and disposed of by appropriate method in accordance with relevant local regulations.

- Sodium azide is not likely to be a human health hazard in the quantity present in the detection buffer. Generally, exposure to larger quantities of sodium azide may cause certain health issues like convulsions, low blood pressure and heart rate, loss of consciousness, lung injury and respiratory failure.

STORAGE AND STABILITY

- The test cartridge is stable for 20 months (while sealed in the aluminum foil pouch) if stored at 4~30°C.
- The detection buffer dispensed in the detection buffer tube is stable for 20 months if stored at 2~8°C.
- Allow a minimum of 30 minutes for the test cartridge (if stored in a refrigerator) and the detection buffer tube to attain room temperature prior to performing the test.
- Do not remove the test cartridge from the aluminum foil pouch until just prior to use.
- After the test cartridge pouch and the detection buffer tube are opened, the test should be performed within 30 minutes.

LIMITATIONS OF THE TEST SYSTEM

QDx Instacheck™ Microalbumin provides accurate and reliable test results subject to the following constraints:

- **QDx Instacheck™ Microalbumin** should be used only in conjunction with **QDx Instacheck™ Reader**.
- The test should always be performed as soon as possible after collection and processing of the urine sample(s). If testing cannot be performed within two hours after collecting the urine sample, it should be immediately stored in a refrigerator (2~8°C).
- Though unpreserved urine sample(s) stored at 2~8°C have been reportedly stable for one week without significant effect on its stability, it should be tested as soon as possible. Refrigerated sample(s) should be allowed to attain room temperature before testing.
- Effectiveness of the test is highly dependent on storage of test components and urine samples at prescribed optimal conditions.
- The test may yield false positive result(s) due to cross-reactions of some components of urine with the capture/detector antibodies and/or non-specific adhesion of certain components having similar epitopes to bind with the antibodies.
- The test may also yield false negative results; the most common factor being non-responsiveness of the antigen to the antibodies due to its epitopes being masked by some unknown components such that the antigen cannot be detected or captured by the antibodies.
- Concurrent treatment of the patient with certain drugs may affect composition of urine and thereby the test result.
- Contamination of urine sample with residues of soaps, detergents, antiseptics etc. possibly present in the sample container may also affect the test result.
- Any clinical diagnosis based on the test result must be supported by a comprehensive judgment of the concerned physician including clinical symptoms and other relevant test results.

SAMPLE COLLECTION AND PROCESSING

The test can be performed on human urine.

- It is recommended to test the sample within 24 hours after collection.
- Samples may be stored for up to two days at 2-8 °C prior to being tested. If testing will be delayed more than two days, samples should be frozen at -20 °C.
- Samples stored frozen at -20 °C for 3 months showed no performance difference.
- Once the sample was frozen, it should be used one time only for test, because repeated freezing and thawing can result in the change of test values.

MATERIALS SUPPLIED

REF **IFPC-2**

Components of QDx Instacheck™ Microalbumin

- **Test Cartridge Box:**
  - Test Cartridges 25
  - ID Chip 1
  - Package Insert 1
- **Detection Buffer Box*:**
  Detection Buffer Tubes 25

MATERIALS REQUIRED BUT SUPPLIED ON DEMAND

Following items can be purchased separately from **QDx Instacheck™ Ferritin**. Please contact our sales division for more information.

- **QDx Instacheck™ Reader** REF FPRR010
- Transfer Pipette (10 µL and 75 µL)
- Thermal Printer

TEST SETUP

1. Check the following components of **QDx Instacheck™ Microalbumin**: Sealed Test Cartridge(s), ID Chip and Detection Buffer Tube(s)
2. Ensure that the lot number of the test cartridge matches with that of the ID chip as well as the detection buffer tube.
3. Keep test cartridge and detection buffer tube at room temperature for at least 30 minutes just prior to performing the test. Place the test cartridge on a clean, dust-free and flat surface.
4. Turn on power supply of the **QDx Instacheck™ Reader**.
5. Insert the ID chip into the 'ID Chip Port' of the **QDx Instacheck™ Reader**.
6. Press 'Select' button on the **QDx Instacheck™ Reader**.
   (*Please refer to* the '***QDx Instacheck™ Reader** Operation Manual' for complete information and operating instructions*.)

TEST PROCEDURE

[Single mode]

1. Transfer 10 µL of the urine sample to the detection buffer tube using a transfer pipette. If a quality control test is to be performed, pipette out 10 µL of the control reagent instead of the urine sample and transfer it to the detection buffer tube.
2. Mix the sample gently and thoroughly with the detection buffer by pipetting the mixture up and down 10 times in the detection buffer tube. Alternatively, mixing may also be effected by shaking and/or inverting the detection buffer tube many times.
3. Pipette out 75 µL of the above sample mixture and dispense it into the sample well on the test cartridge.
4. For scanning the sample-loaded test cartridge, insert it into the test cartridge holder of the **QDx Instacheck™ Reader**. Ensure proper orientation of the test cartridge before pushing it all the way inside the test cartridge holder. An arrow has been marked on the test cartridge especially for this purpose.
5. Press 'Select' button on the **QDx Instacheck™ Reader** to start the scanning process.

6. **QDx Instacheck™ Reader** will start scanning the sample-loaded test cartridge after 12min.
7. Read the test result on the display screen of the **QDx Instacheck™ Reader**.

[Multi mode]

1. Transfer 10 µL of the urine sample to the detection buffer tube using a transfer pipette. If a quality control test is to be performed, pipette out 10 µL of the control reagent instead of the urine sample and transfer it to the detection buffer tube.
2. Mix the sample gently and thoroughly with the detection buffer by pipetting the mixture up and down 10 times in the detection buffer tube. Alternatively, mixing may also be effected by shaking and/or inverting the detection buffer tube many times.
3. Pipette out 75 µL of the above sample mixture and dispense it into the sample well on the test cartridge.
4. Leave the sample-loaded test cartridge at room temperature for 12 minutes.
5. For scanning the sample-loaded test cartridge, insert it into the test cartridge holder of the **QDx Instacheck™ Reader**. Ensure proper orientation of the test cartridge before pushing it all the way inside the test cartridge holder. An arrow has been marked on the test cartridge especially for this purpose.
6. Press 'Select' button on the **QDx Instacheck™ Reader** to start the scanning process.
7. **QDx Instacheck™ Reader** will start scanning the sample-loaded test cartridge immediately.
8. Read the test result on the display screen of the **QDx Instacheck™ Reader**.

INTERPRETATION OF TEST RESULT

- **QDx Instacheck™ Reader** calculates the test result automatically and displays microalbumin concentration of the urine sample in terms of mg/L.
- Cut-off (reference value) of **QDx Instacheck™ Microalbumin** is 20 mg/L.
- If the test result is above 20 mg/L, consult the physician for diagnosis and/or further investigation.
- Working range of **QDx Instacheck™ Microalbumin** is 2-300 mg/L.
- **QDx Instacheck™ Microalbumin** test should be considered as a screening tool only. In case of a positive result (above 20 mg/L), consult the physician to discuss the test result. The physician may decide further course of action.

QUALITY CONTROL

- Quality control tests should be performed as a part of the good testing practice to confirm the expected quality control results and validity of the assay as well as to ensure accuracy of the test results with clinical samples.
- A quality control test should be performed at regular intervals. Before testing a clinical sample using a new test lot, control reagents should be tested to confirm the test procedure, and to verify whether the test produces the expected quality control results. Quality control tests should also be performed whenever there is any question concerning the validity of the test results.
- Control reagents are not provided with **QDx Instacheck™ Microalbumin**. For more information regarding obtaining the control reagents, contact the technical section at **Diasys Diagnostics India Private Limited.**
- **Internal Control**: **QDx Instacheck™ Microalbumin** test has an in-built quality control indicator that satisfies the routine quality control requirements. This internal control test is performed automatically each time a clinical sample is tested. An invalid result from the internal control leads to display an error message on the **QDx Instacheck™ Reader** indicating that the test should be repeated.

PERFORMANCE CHARACTERISTICS

1. **Specificity/Interference:** Biomolecules such as Hemoglobin (Hb), Carcinoembryonic antigen (CEA), Prostate-specific antigen (PSA), α-Fetoprotein (AFP), Alkaline phosphatase (ALP), C-reactive protein (CRP) , Troponin-I, and Myoglobin were added to the test samples at concentrations much higher than their normal physiological levels. **QDx Instacheck™ Microalbumin** test results showed neither any significant interference from these biomolecules nor any significant cross-reactivity with the same.

2. **Precision**: For testing intra-assay precision, one person tested three lots of **QDx Instacheck™ Microalbumin** times at each concentration of the control reagent. For testing inter-assay precision under the same conditions, three persons tested three different lots of **QDx Instacheck™ Microalbumin** three times at each concentration of the control reagent.

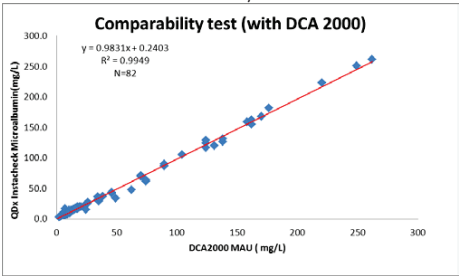
Precision Testing of QDx Instacheck™ Microalbumin

Microalbumin Concentration (mg/L)	Intra-assay Precision			Inter-assay Precision		
	Mean	SD	CV(%)	Mean	SD	CV(%)
25	24.3	1.0	4.32	24.5	1.5	6.6
100	100.2	5.5	5.48	100.7	7.6	7.6
200	200.6	6.5	3.25	200.0	13.8	6.9

(SD = Standard Deviation, CV = Coefficient of Variation)

3. **Comparability (Correlation):** Microalbumin concentrations of 82 clinical samples were quantified independently by **QDx Instacheck™ Microalbumin** and Bayer/Siemens DCA 2000 Analyzer (now upgraded DCA Vantage Analyzer of Siemens Healthcare Diagnostics Inc., USA). Results of both the test methods were analyzed and their compatibility was investigated with linear regression and coefficient of correlation (*R*). The coefficient of correlation between the two methods was found to be 0.997(R^2=0.9949).

Comparison between QDx Instacheck™ Microalbumin and DCA 2000 Analyzer.



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Note: Please refer to the table below to identify various symbols.

	Sufficient for <n> tests
	Read instruction for use
	Use by Date
LOT	Batch code
REF	Catalog number
	Caution
	Manufacturer
EC REP	Authorized representative of the European Community
IVD	In vitro diagnostic medical device
	Temperature limit
	Do not reuse
CE	This product fulfills the requirements of the Directive 98/79/EC on in vitro diagnostic medical devices

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