mALB

infinosis™

Microalbuminuria (FIA)

REF: IN067703 Σ 25

Intended use
The infinosis™ mALB is a fluorescence immunoassay for the in vitro quantitative determination of Microalbumin (mAlb) in Human urine. For professional use only.

Summary
References[1-4]
The level of albumin protein produced by microalbuminuria can be detected by special albumin-specific urine dipsticks, which have a lower detection threshold than standard urine dipsticks. A microalbumin urine test determines the presence of the albumin in urine. In a properly functioning body, albumin is not normally present in urine because it is retained in the bloodstream by the kidneys.
Microalbuminuria can be diagnosed from a 24-hour urine collection (between 30–300 mg/24 hours) or, more commonly, from elevated concentration in a spot sample (20 to 200 mg/l). Both must be measured on at least two of three measurements over a two- to three-month period.
An albumin level above the upper limit values is called "macroalbuminuria", or sometimes just albuminuria. Sometimes, the upper limit value is given as one less (such as 300 being given as 299) to mark that the higher value (here 300) is defined as macroalbuminuria.

Test principle
Sandwich principle. Total duration of assay: **15 minutes**
Sample is added to the sample well of the test, then the fluorescence-labeled detector anti-mALB antibody binds to mALB antigen in specimen. As the sample mixture migrates on the nitrocellulose matrix of test strip by capillary action, the complexes of detector antibody and mALB are captured to anti-mALB antibody that has been immobilized on test strip.
The more mALB antigen is in specimen, the more complexes are accumulated on test strip. Signal intensity of fluorescence of detector antibody reflects amount of mALB captured and instrument for infinosis™ tests shows mALB concentrations in specimen.

Reagents
Materials provided
- **Test Cartridge**, 25 pcs, individually packaged
- **ID Chip**, 1 pcs
- **Sample Buffer,** 25 tubes
- **IFU**, 1 copy

Materials required (but not provided)
- mAlb control (DiaSino control is recommended)
- Infinosis™ 2020 FIA analyzer
- Transfer pipette set (100 µL size)
- Timer

Precautions and warnings
- For in vitro diagnostic use only.
- Carefully follow the instructions and procedures described in this instructions before testing.
- The Test Cartridge should remain in its original sealed pouch until ready to use. Do not use it if the pouch is damaged or the seal is broken.
- Do not use reagents beyond the labeled expiry date.
- Do not mix or use components from kits with different Lots.
- Don't use Test Cartridge if its Lot does not match with ID Chip that is inserted onto the instrument.
- The Infinosis™ mALB assay should be used only in conjunction with the instrument for infinosis™ tests.
- The tests should be applied by professionally trained staff working in certified laboratories at some remove from the patient and clinic at which the sample is taken by qualified medical personnel.
- Infinosis™ mALB assay is single use only. Do not re-use it.
- The Test Cartridge and Analyzer should be used away from vibration and magnetic field. During normal usage, the Test Cartridge may introduce minute vibration, which should be regarded as normal.
- Use separate clean pipette tips and detector buffer vials for different specimens. The pipette tips and detector buffer vials should be used for one specimen only.
- Do not smoke, eat, or drink in areas in which specimens or kit reagents are handled.
- Specimens, used Test Cartridges, pipette tips and detector buffer vials are potentially infectious. Proper laboratory safety techniques, handing and disposal methods should be followed in accordance with standard procedures and relevant regulations observed by microbiological hazard materials.
- The results should be interpreted by the physician along with clinical findings and other laboratory test results.

Incident report
Any suspected serious incidents related to this assay shall be immediately reported to DiaSino, DiaSino's Authorized Representative in the EU, and the national competent authorities of the Member States where the users and/or patients are located.

Storage and stability
- Store the test kit at 2-30℃, the stability is up to the expiration date printed on package.
- Test cartridge and sample buffer should be used within 1 hour after opening the pack.

Specimen collection and preparation
- The test can be performed urine. Collect the urine sample in the urine container.
- Test should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Specimens may be stored at 2-8℃ for up to 3 days. For long-term storage, specimens should be kept below -20℃.

Quality control
- Quality control tests are a part of the good testing practice to confirm the expected results and validity of the assay and should be performed at regular intervals.
- The control tests should be performed immediately after opening a new test lot to ensure the test performance is not altered.
- Quality control tests should also be performed whenever there is any question concerning the validity of the test results.
- Control materials are provided on demand with infinosis™ tests. For more information regarding obtaining the control materials, contact DiaSino Laboratories Co., Ltd for assistance.

Test setup
- Ensure that the lot number of the cartridge matches that of the sample buffer, and the ID Chip.
- If the sealed cartridge and sample buffer have been stored in refrigerator, place them at room temperature (18-25 ℃) at least 30 minutes before measurement.
- Turn on the instrument for infinosis™ tests.
  Refer to the *'instrument for infinosis™ tests Operation Manual'* for the complete information and operating instructions.

Test procedure
1. Insert ID Chip into the instrument for infinosis™ tests and read ID chip information.
2. Using a pipette to transfer **20 µL** of sample (Human urine) to the **sample buffer tube** provided in the kit.
3. Close the lid of the sample mixing tube and mix the sample thoroughly for **5-10 seconds** by tapping or inverting the tube.
4. Pipette out **100 µL** of **sample mixture** and load it onto the sample well on the cartridge.
5. Leave the sample-loaded cartridge at room temperature for **15 minutes.**
6. Insert the sample-loaded cartridge into the cartridge holder of instrument for infinosis™ tests.
   Ensure proper orientation of the cartridge before pushing it all the way inside the cartridge holder.
7. Press **"Test"** button on the instrument for infinosis™ tests.
8. Instrument for infinosis™ tests will start scanning the sample-loaded cartridge immediately.
9. Read the test result on the display screen of the instrument for infinosis™ tests.
10. Print out the testing results when press **"Print"** button on the instrument for infinosis™ tests.

Limitations - interference
- This test has been developed for testing human urine specimen only.
- The results of infinosis™ mALB should be evaluated with all clinical and laboratory data available. If mALB test results do not agree with the clinical evaluation, additional tests should be performed.

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- The false positive results may come from cross-reactions with some similar antibodies in sample.
- The false negative results may from some unknown substance blocking epitope adhering antibodies, unstable or degenerated mALB that cannot be identified due to prolonged time and temperature and storage condition of sample and reagent.
- Other factors may interfere with infinosis™ mALB and may cause erroneous results. These include technical or procedural errors, as well as additional substances in specimens.
- For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.

Measuring range
5.0-300 mg/L (defined by the lower detection limit and the maximum of the master curve). Values below the lower detection limit are reported as < 5.0 mg/L. Values above the measuring range are reported as > 300 mg/L.

Lower detection limit
5.0 mg/L
The detection limit represents the lowest analyte level that can be distinguished from zero. It is calculated as the value lying two standard deviations above that of the lowest standard (master calibrator, standard 1+2 SD, repeatability study, n = 21).

Expected values
0- 20 mg/L
Expected values may vary with age, sex, diet and geographical location. Each laboratory should determine its own expected values as dictated by good laboratory practice.

Specific performance data
Representative performance data are given below. Results obtained in individual laboratories may differ.

Precision
Intra-assay
Determined by by using 10 replicates from same batch to test with 20 mg/L mALB control. CV ≤ 10%.

Inter-assay
Determined by using 3 replicates from random 3 continuous batches to test with 20 mg/L MALB control CV ≤ 15%.

Linearity
A serial concentration of MALB controls at 10 ng/mL, 20 mg/L, 50 mg/L, 100 mg/L, 150 mg/L and 200 mg/L were tested, the Correlation Coefficient is r ≥ 0.9950.

Method comparison
A comparison of the Infinosis™ mALB assay (y) with the Roche Micral-Test mALB assay (x) using 97 clinical samples gave the correlation: r=0.9820

Analytical specificity
The following cross-reactivities were not found

Cross-reactant	Concentration
Human Albumin	≤ 110 mg/mL
Bilirubin	≤ 6 mg/mL
Hemoglobin	≤ 10 mg/mL
Creatinine	≤ 4 mg/mL

Functional sensitivity
5.12 mg/L
The functional sensitivity is the lowest analyte concentration that can be reproducibly measured with an intermediate precision CV of ≤ 20 %.

References

1. "Person—microalbumin level (measured), total micrograms per minute N[NNN].N".
2. Mary Lee (2009-02-26). Basic Skills in Interpreting Laboratory Data. ASHP. pp. 291–. ISBN 978-1-58528-274-6.PMID 10982534.

Symbols

IVD In vitro diagnostic medical device	Temperature limit	Consult instructions for use	REF Catalog number
LOT Batch code	Date of manufacture	Use-by date	Σ Contains sufficient for <n> tests
Manufacturer	Do not re-use	Do not use if package is damaged and consult instructions for use	
CE European Conformity	EC REP Authorized representative in the European Community		

diasino

DiaSino Laboratories Co., Ltd
No.68 Jingnansi Road National Eco & Tech Development Area
Zhengzhou 450000, P.R. China. info@diasino.com

EC REP **CMC Medical Devices & Drugs S.L**
C/Horacio Lengo Nº 18, CP 29006 Málaga, Spain. Tel: +34 9512 14054

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