Cat. No 9-449

DIAGNOSTIC KIT FOR DETERMINATION OF α 1-MICROGLOBULIN CONCENTRATION

OS – ALPHA 1-MICROGLOBULIN

INTRODUCTION

α 1-microglobulin (αMi) is a low molecular weight glycoprotein (24-33 kD) which was initially isolated from the urine of patients with renal tubular disorders in 1975. It is mainly synthesized in the liver and is widely distributed in various body fluids.
The measurement of αMi in serum and urine has been considered to be useful for the diagnosis of functional renal disorders, the assessment of the progress and prognosis of diseases.

METHOD PRINCIPLE

When an antigen-antibody reaction occurs between αMi in a sample and anti-αMi antibody which has been sensitized to latex particles, agglutination results. This agglutination is detected as an absorbance change (572 nm), with the magnitude of the change being proportional to the quantity of αMi in the sample. The actual concentration is then determined by interpolation from a calibration curve prepared from calibrators of know concentration.

REAGENTS

Package

1-Reagent	1 x 33.5 ml
2-Reagent	1 x 33.5 ml

The reagent is stable up to the kit expiry date printed on the package when stored at 2-10°C. The reagents are stable for 6 weeks on board the analyser at 2-10°C. Protect from light and avoid contamination!

Concentrations in the test

suspension of latex particles sensitized with (rabbit) anti-αMi antibodies	0.25 w/v%
glycine buffer solution	

Warnings and notes

- Product for in vitro diagnostic use only.
- Reagent bottles should be shaken before use by gently inverting several times.
- After measurements are taken, reagent bottles should capped and kept at 2-10°C. Care should be taken not to interchange the caps of reagent bottles.
- Reagents with different lot numbers should not be interchanged or mixed.
- The reagents contain sodium azide (< 0.1%) as a preservative. Avoid contact with skin and mucous membranes.

SPECIMEN

Serum, plasma or urine.
If the test cannot be done immediately, the sample should be placed in a tightly sealable container and stored at -20°C. Repeated freezing and thawing should be avoided.
Nevertheless, it is recommended to perform the assay with freshly collected samples!

PROCEDURE

These reagents may be used in automatic analysers Olympus AU400/AU640.
1-Reagent and 2-Reagent are ready to use.
For reagent blank 0.9% NaCl is recommended.

APPLICATION – serum

Reagent ID: **510**

Specific Test Parameters
General | LIH | ISE | Range

Test name: **AMG(S)** Type: **Serum** Operation: **Yes**

Sample: Volume **2.5** µL Dilution **0** µL Pre-Dilution Rate: **1**
Reagents: R1 Volume **150** µL Dilution **0** µL Min OD Max OD
R2 Volume **150** µL Dilution **0** µL L **-2.0000** H **2.5000**
Reagent OD Limit:
Wavelength: Pri. **570** Sec. **800** First L **-2.0000** First H **2.5000**
Method: **END** Last L **-2.0000** Last H **2.5000**
Reaction Slope: **+** Dynamic Range:
Measuring Point 1: First **0** Last **27** L H
Measuring Point 2: First **0** Last **10** Correlation Factor:
Linearity: % A **1.000** B **0.000**
No-Lag-Time: On-board Stability Period:

Specific Test Parameters
General | LIH | ISE | Range

Test name: **AMG(S)** Type: **Serum**

Value/Flag: **#** Level L: **#** Level H: **#**
Normal Ranges:

	Sex	Age L Year	Age L Month	Age H Year	Age H Month	L	H
1.	#	#	#	#	#	#	#
2.	#	#	#	#	#	#	#
3.	#	#	#	#	#	#	#
4.	#	#	#	#	#	#	#
5.	#	#	#	#	#	#	#
6.	#	#	#	#	#	#	#
7.	None Selected					#	#
8	Out of Range					#	#

	L	H		
Panic Value:	#	#	Unit: **mg/l**	Decimal Places: **2**

Calibration Specific
General | ISE

Test name: **AMG(S)** Type: **Serum**

Calibration Type: **6AB** Formula: **Spline** Counts: **1** Process: **CONC**

	Cal. No.	OD	CONC	Factor/OD-L	Factor/OD-H
Point 1:	#		**	-2.0000	2.5000
Point 2:	#		*	-2.0000	2.5000
Point 3:	#		*	-2.0000	2.5000
Point 4:	#		*	-2.0000	2.5000
Point 5:	#		*	-2.0000	2.5000
Point 6:	#		*	-2.0000	2.5000
Point 7:					

1-Point Cal.Point: with CONC-0 Slope Check: **None** Advanced Calibration: **#**
MB Type Factor: Calibration Stability Period:

\# User defined
* Calibrator value
** Saline should be used as calibrator 1

APPLICATION – urine

Reagent ID: **509**

Specific Test Parameters
General | LIH | ISE | Range

Test name: **AMG(U)** Type: **Urine** Operation: **Yes**

Sample: Volume **7.5** µL Dilution **0** µL Pre-Dilution Rate: **1**
Reagents: R1 Volume **150** µL Dilution **0** µL Min OD Max OD
R2 Volume **150** µL Dilution **0** µL L **-2.0000** H **2.5000**
Reagent OD Limit:
Wavelength: Pri. **570** Sec. **800** First L **-2.0000** First H **2.5000**
Method: **END** Last L **-2.0000** Last H **2.5000**
Reaction Slope: **+** Dynamic Range:
Measuring Point 1: First **0** Last **27** L H
Measuring Point 2: First **0** Last **10** Correlation Factor:
Linearity: % A **1.000** B **0.000**
No-Lag-Time: On-board Stability Period:

Specific Test Parameters

General | LIH | ISE | Range

Test name: **AMG(U)** Type: **Urine**

Value/Flag: # Level L: # Level H: #

Normal Ranges:

	Sex	Age L Year	Age L Month	Age H Year	Age H Month	L	H
1.	#	#	#	#	#	#	#
2.	#	#	#	#	#	#	#
3.	#	#	#	#	#	#	#
4.	#	#	#	#	#	#	#
5.	#	#	#	#	#	#	#
6.	#	#	#	#	#	#	#
7. None Selected						#	#
8 Out of Range						#	#

	L	H		
Panic Value:	#	#	Unit: **mg/l**	Decimal Places: **2**

Calibration Specific

General | ISE

Test name: **AMG(U)** Type: **Urine**

Calibration Type: **5AB** Formula: **Spline** Counts: **1** Process: **CONC**

	Cal. No.	OD	CONC	Factor/OD-L	Factor/OD-H
Point 1:	#		**	**-2.0000**	**2.5000**
Point 2:	#		*	**-2.0000**	**2.5000**
Point 3:	#		*	**-2.0000**	**2.5000**
Point 4:	#		*	**-2.0000**	**2.5000**
Point 5:	#		*	**-2.0000**	**2.5000**
Point 6:					
Point 7:					

1-Point Cal.Point: [ ] [ ] with CONC-0 Slope Check: **None** Advanced Calibration: #

MB Type Factor: Calibration Stability Period:

\# User defined
* Calibrator value
** Saline should be used as calibrator 1

REFERENCE VALUES [3]

serum, plasma	10.0 – 30.0 mg/l
urine	1.0 – 5.0 mg/l

It is recommended for each laboratory to establish its own reference ranges for local population. Diagnosis should only be made after taking clinical symptoms and the results of other tests into consideration.

QUALITY CONTROL

For internal quality control it is recommended to use control serum for determination of αMi with each batch of samples, eg.: ROCHE or BIORAD.

For the calibration of automatic analysers systems the CORMAY ALPHA 1-MGLOB CALIBRATORS (S) (Cat. No 4-286) for serum samples and the CORMAY ALPHA 1-MGLOB CALIBRATORS (U) (Cat. No 4-285) for urine samples is recommended.

The calibration curve should be prepared every time the test is performed, with every change of reagent lot number or as required e.g. quality control findings outside the specified range.

PERFORMANCE CHARACTERISTICS

These metrological characteristics have been obtained using the automatic analyser HITACHI 917. Results may vary if a different instrument is used.

- **Analytical range:** 1.5 – 200 mg/l (serum).
  0.3 – 50.0 mg/l (urine).
  For higher concentration dilute the sample with 0.9% NaCl and repeat the assay. Multiply the result by dilution factor.

- **Specificity / Interferences**
  Haemoglobin up to 0.5 g/dl, NH_4Cl do 400 mg/dl, bilirubin up to 31 mg/dl do not interfere with the test in urine.

- **Precision**

Repeatability (run to run) n = 20	Mean [mg/l]	SD [mg/l]	CV [%]
level 1	0.5	0.0	3.97
level 2	1.6	0.0	1.81
level 3	13.9	0.1	0.42

- **Method comparison**

A comparison between CORMAY reagent (y) and another commercially available assay (x) using 55 serum samples gave following results:
y = 1.00 x + 2.83 mg/l;
R = 1.00 (R – correlation coefficient)

A comparison between CORMAY reagent (y) and another commercially available assay (x) using 55 urine samples gave following results:
y = 1.00 x - 0.52 mg/l;
R = 1.00 (R – correlation coefficient)

WASTE MANAGEMENT

Please refer to local legal requirements.

LITERATURE

1. Galvin J. P. et al.: Particle enhanced photometric immunoassay systems., Clin. Lab. Assays (Pap. Annu. Clin. Lab. Assays Conf.), 4th, 73 (1983).
2. Singer J. M. et al.: The latex fixation test. I. Application to the serologic diagnosis of rheumatoid arthritis, Amer. J. Med., 21, 888 (1956).
3. Yoshihisa Ito: a1-microglobulin (protein HC), Nippon Rinsho, 47, 176 (1989)

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