MICROALBUMIN

Cat. No.	Pack Name	Packaging (Content)
XSYS0083	MAL	R1: 2 x 30 ml Buffer, R2: 1 x 10 ml Antiserum

EN

CE IVD

INTENDED USE
Diagnostic reagent for quantitative *in vitro* determination of microalbumin in urine.

CLINICAL SIGNIFICANCE
Diabetic nephropathy, which is accompanied by irreversible kidney damage and persistent proteinuria, is a major cause of death in persons with insulin-dependent diabetes mellitus. An early sign of diabetic nephropathy are small Albumin secretions in urine, i.e. Microalbuminuria. Therefore, detection of kidney (glomerular) damage that is minimal and reversible is important.

METHODOLOGY
Measurement of antigen-antibody reaction by the end-point method.

REAGENT COMPOSITION
R1 (Buffer)
Saline (0.9%)
Accelerator
Sodium azide (0.09 %)
R2 (Antiserum)
Phosphate buffered saline
Polyclonal goat anti-human Albumin (variable).
Sodium azide (0.09 %).

REAGENT PREPARATION
Reagents are liquid, ready to use.

STABILITY AND STORAGE
The reagents are stable until expiry date when kept at 2–8°C. Stability in the instrument is at least 4 weeks if contamination is avoided. Do not freeze.

SAMPLE COLLECTION
Collect urine during 24 hours or as a random midstream sample. If the test can not be carried out on the same day, the urine may be stored at 2–8°C for 48 hours. If stored for a longer period, the sample should be frozen. The use of centrifuged urine is recommended.

MATERIALS REQUIRED BUT NOT PROVIDED
- Any instrument with temperature control of 37 ± 0.5 °C that is capable of reading absorbance accurately at 340 nm may be used.
- Analyser specific consumables such as sample cups.
- Controls.
- Saline (9 g/l NaCl)

ASSAY PROCEDURE
Refer to the assay parameters for details.

CALIBRATION
Blank: Saline

Cat. No.	Product Name	Pack Name	Content
BLT20032	MAL CALIBRATOR	MAL CAL	1 x 1 ml

Calibraton curve: generate a 6 point calibration curve by diluting the calibrator 1:32, 1:16, 1:8, 1:4, 1:2 and undiluted in saline.

Calibration frequency
Calibration verification: Not necessary.

QUALITY CONTROL
For quality control use

Cat. No.	Product Name	Pack Name	Content
BLT20033	MAL CONTROL	MAL CON	1 x 1 ml

CALCULATION
Results are calculated automatically by the instrument.

EXPECTED VALUES
0 – 25 mg/l (IFCC)
This range is given for orientation only. Each laboratory should establish its own reference values.

PERFORMANCE DATA
Data contained within this section is representative of performance on ERBA XL systems. Data obtained in your laboratory may differ from these values.

Detection limit: 0.57 mg/l
Measuring Range: 0.57 – 550 mg/l
Hook Effect: > 6000 mg/l

PRECISION

Intra-assay precision Within run	Mean (mg/l)	SD (mg/l)	CV (%)
Sample 1	171	2.50	1.46
Sample 2	68.5	1.59	2.32

Inter-assay precision Run to run	Mean (mg/l)	SD (mg/l)	CV (%)
Sample 1	133.0	3.70	2.78
Sample 2	29.75	1.24	4.16

COMPARISON
A comparison between XL-Systems MAL (y) and a commercially available test (x) using 40 samples gave following results:
y = 0.984 x - 0.19 mg/l
r = 0.998

Specificity: Monospecific
Interferences: No interference for: Heparin (50 mg/dl), Na-citrate (1000 mg/dl), Hemoglobin (1000 mg/dl), Bilirubin (>15 mg/dl), Triglyceride (2500 mg/dl), EDTA (5 mg/dl), Turbidity (>0.63%) interfere with the test.
Limitations: None
Stability at 4°C: At least 3 years after production

WARNING AND PRECAUTIONS
1. For *in vitro* diagnostic use. To be handled by entitled and professionally educated person.
2. Sodium azide has been reported to form lead or copper azide in laboratory plumbing which may explode on percussion. Flush drains with water thoroughly after disposing of fluids containing sodium azide.
3. Each donor unit used in the preparation of the standards and controls was found to be negative for the presence of HIV1 and HIV2 antibodies, as well as for the hepatitis B surface antigen and anti-hepatitis C antibodies, using a method approved by the FDA.

WASTE MANAGEMENT
Please refer to local legal requirements.

REFERENCES
1. Mount, J.n., J.Clin. Pathology, 22,12 (1986)
2. Schmidtz, A., et al., Diabetic Medicine, 5, 126 (1998)

QUALITY SYSTEM CERTIFIED
ISO 9001 ISO 13485

Erba Lachema s.r.o., Karásek 2219/1d, 621 00 Brno, CZ
e-mail: diagnostics@erbamannheim.com, www.erbamannheim.com

12000156
N/121/17/C/INT
Date of revision: 14.2. 2017

ASSAY PARAMETERS (conventional units)

Instrument	XL-100 EM-100	XL-200 EM-200	XL-300/600 EM-360	XL-640	XL-1000	XL-180
Test Details						
Test	MAL	MAL	MAL	MAL	MAL	MAL
Test Code	75	75	75	75	75	75
Report Name	Microalbumin	Microalbumin	Microalbumin	Microalbumin	Microalbumin	Microalbumin
Unit	mg/dl	mg/dl	mg/dl	mg/dl	mg/dl	mg/dl
Decimal Places	2	2	2	2	2	2
Wavelength-Primary	340	340	340	340	340	340
Wavelength-Secondary	0	0	0	0	0	0
Assay type	2-Point	2-Point	2-Point	2-Point	2-Point	2-Point
Curve type	Cubic Spline	Cubic Spline	Cubic Spline	Cubic Spline	Cubic Spline	Cubic Spline
M1 Start	16	16	12	24	10	16
M1 End	16	16	12	24	10	16
M2 Start	34	36	51	62	31	34
M2 End	34	36	51	62	31	34
Sample replicates	1	1	1	1	1	1
Standard replicates	3	3	3	3	3	3
Control replicates	1	1	1	1	1	1
Control interval	0	0	0	0	0	0
Reaction Direction	Increasing	Increasing	Increasing	Increasing	Increasing	Increasing
React. Abs. Limit	NA	NA	NA	NA	NA	NA
Prozone Limit %	0	0	0	0	0	0
Prozone Check	Lower	Lower	Lower	Lower	Lower	Lower
Linearity Limit %	0	0	0	0	0	0
Delta Abs/Min	0	0	0	0	0	0
Technical Minimum	NA	NA	NA	NA	NA	NA
Technical Maximum	NA	NA	NA	NA	NA	NA
Y=aX+b						
a=	1	1	1	1	1	1
b=	0	0	0	0	0	0
Reagent Abs Min	NA	NA	NA	NA	NA	NA
Reagent Abs Max	0	0	0	0	0	0
Auto Rerun	No	No	No	No	No	No
Total Reagents	2	2	2	2	2	2
Reagent R1	MAL R1	MAL R1	MAL R1	MAL R1	MAL R1	MAL R1
Reagent R2	MAL R2	MAL R2	MAL R2	MAL R2	MAL R2	MAL R2
Reagent R3	NA	NA	NA	NA	NA	NA
Test Volumes						
Test	MAL	MAL	MAL	MAL	MAL	MAL
Sample Type	URINE	URINE	URINE	URINE	URINE	URINE
Sample Volumes						
Normal	12	12	13.4	12	10	12
Dilution Ratio	1	1	1	1	1	1
Increase	24	24	26.8	24	10	24
Dilution Ratio	1	1	1	1	1	1
Decrease	6	6	6.7	6	5	6
Dilution Ratio	1	1	1	1	1	1
Standard volume	12	12	13.4	12	10	12
Reagent Volumes and Stirrer speed						
RGT-1 Volume	180	180	200	180	160	180
R1 Stirrer Speed	High	High	NA	High	High	High
RGT-2 Volume	30	30	33	30	27	30
R2 Stirrer Speed	High	High	NA	High	High	High
RGT-3 Volume	0	0	0	0	0	0
R3 Stirrer Speed	NA	NA	NA	NA	NA	NA
Reference Ranges						
Test	MAL	MAL	MAL	MAL	MAL	MAL
Sample Type	URINE	URINE	URINE	URINE	URINE	URINE
Reference Range	Default	Default	Default	Default	Default	Default
Category Male						
Normal-Lower Limit	0	0	0	0	0	0
Normal-Upper Limit	2.5	2.5	2.5	2.5	2.5	2.5
Panic-Lower Limit	NA	NA	NA	NA	NA	NA
Panic-Upper Limit	NA	NA	NA	NA	NA	NA
Category Female						
Normal-Lower Limit	0	0	0	0	0	0
Normal-Upper Limit	2.5	2.5	2.5	2.5	2.5	2.5
Panic-Lower Limit	NA	NA	NA	NA	NA	NA
Panic-Upper Limit	NA	NA	NA	NA	NA	NA
Revision Number						
Revision	<A-100-MAL-1 01.08.2014>	<A-200-MAL-1 01.08.2014>	<A-300/600-MAL-2 03.12.2014>	<A-640-MAL-1 01.08.2014>	<A-1000-MAL-1 01.08.2014>	<A-180-MAL-1 01.08.2014>

ASSAY PARAMETERS (SI units)

Instrument	XL-100 EM-100	XL-200 EM-200	XL-300/600 EM-360	XL-640	XL-1000	XL-180
Test Details						
Test	MAL	MAL	MAL	MAL	MAL	MAL
Test Code	75	75	75	75	75	75
Report Name	Microalbumin	Microalbumin	Microalbumin	Microalbumin	Microalbumin	Microalbumin
Unit	mg/l	mg/l	mg/l	mg/l	mg/l	mg/l
Decimal Places	1	1	1	1	1	1
Wavelength-Primary	340	340	340	340	340	340
Wavelength-Secondary	0	0	0	0	0	0
Assay type	2-Point	2-Point	2-Point	2-Point	2-Point	2-Point
Curve type	Cubic Spline	Cubic Spline	Cubic Spline	Cubic Spline	Cubic Spline	Cubic Spline
M1 Start	16	16	12	24	10	16
M1 End	16	16	12	24	10	16
M2 Start	34	36	51	62	31	34
M2 End	34	36	51	62	31	34
Sample replicates	1	1	1	1	1	1
Standard replicates	3	3	3	3	3	3
Control replicates	1	1	1	1	1	1
Control interval	0	0	0	0	0	0
Reaction Direction	Increasing	Increasing	Increasing	Increasing	Increasing	Increasing
React. Abs. Limit	NA	NA	NA	NA	NA	NA
Prozone Limit %	0	0	0	0	0	0
Prozone Check	Lower	Lower	Lower	Lower	Lower	Lower
Linearity Limit %	0	0	0	0	0	0
Delta Abs/Min	0	0	0	0	0	0
Technical Minimum	NA	NA	NA	NA	NA	NA
Technical Maximum	NA	NA	NA	NA	NA	NA
Y=aX+b						
a=	1	1	1	1	1	1
b=	0	0	0	0	0	0
Reagent Abs Min	NA	NA	NA	NA	NA	NA
Reagent Abs Max	0	0	0	0	0	0
Auto Rerun	No	No	No	No	No	No
Total Reagents	2	2	2	2	2	2
Reagent R1	MAL R1	MAL R1	MAL R1	MAL R1	MAL R1	MAL R1
Reagent R2	MAL R2	MAL R2	MAL R2	MAL R2	MAL R2	MAL R2
Reagent R3	NA	NA	NA	NA	NA	NA
Test Volumes						
Test	MAL	MAL	MAL	MAL	MAL	MAL
Sample Type	URINE	URINE	URINE	URINE	URINE	URINE
Sample Volumes						
Normal	12	12	13.4	12	10	12
Dilution Ratio	1	1	1	1	1	1
Increase	24	24	26.8	24	10	24
Dilution Ratio	1	1	1	1	1	1
Decrease	6	6	6.7	6	5	6
Dilution Ratio	1	1	1	1	1	1
Standard volume	12	12	13.4	12	10	12
Reagent Volumes and Stirrer speed						
RGT-1 Volume	180	180	200	180	160	180
R1 Stirrer Speed	High	High	NA	High	High	High
RGT-2 Volume	30	30	33	30	27	30
R2 Stirrer Speed	High	High	NA	High	High	High
RGT-3 Volume	0	0	0	0	0	0
R3 Stirrer Speed	NA	NA	NA	NA	NA	NA
Reference Ranges						
Test	MAL	MAL	MAL	MAL	MAL	MAL
Sample Type	URINE	URINE	URINE	URINE	URINE	URINE
Reference Range	Default	Default	Default	Default	Default	Default
Category Male						
Normal-Lower Limit	0	0	0	0	0	0
Normal-Upper Limit	25	25	25	25	25	25
Panic-Lower Limit	NA	NA	NA	NA	NA	NA
Panic-Upper Limit	NA	NA	NA	NA	NA	NA
Category Female						
Normal-Lower Limit	0	0	0	0	0	0
Normal-Upper Limit	25	25	25	25	25	25
Panic-Lower Limit	NA	NA	NA	NA	NA	NA
Panic-Upper Limit	NA	NA	NA	NA	NA	NA
Revision Number						
Revision	<ASI-100-MAL-1 01.08.2014>	<ASI-200-MAL-1 01.08.2014>	<ASI-300/600-MAL-2 03.12.2014>	<ASI-640-MAL-1 01.08.2014>	<ASI-1000-MAL-1 01.08.2014>	<ASI-180-MAL-1 01.08.2014>

Erba Mannheim

XL SysPack

USED SYMBOLS

- REF — Catalogue Number
- LOT — Lot Number
- Expiry Date
- Manufacturer
- CE Mark - Device comply with the Directive 98/79/EC
- IVD — In Vitro Diagnostics
- See Instruction for Use
- Storage Temperature
- CONT — Content

12000156