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AZIENDA CERTIFICATA
UNI EN ISO 9001:2008
UNI EN ISO 13485:2004
CERTIFIED COMPANY

ALBUMIN

Colorimetric method (BCG)

IVD CE In conformity with Directive 98/79 CE

000271 Rev. 4 del 04/02/10

REF	ASR01280/B	4 x 100 ml + CAL
	ASR01280/2	2 x 100 ml + CAL
	ASKIT2702	15 x 4 ml

• Principle

In acid conditions buffered at p.H 3.8, the albumin is bound by the green dyed BCG to produce an increase in the blue green colour.
The colour increase is proportional to the concentration of albumin present in the sample.
Albumin determination is useful in diagnoses of hepatic and renal pathologies.

• Sample

Not hemolyzed fresh serum, plasma with heparin.
Albumin in serum or plasma is reported stable for one week at room temperature (15 – 25°C), and approximately one year when stored in the refrigerator at -20°C and protected against evaporation.
Centrifugate those specimens which present fibrin particles.
Shake and bring the samples at room temperature (15 – 25°C) before using.

• Expected value

SERUM	3.5 – 5.3 g/dl

Consider the above mentioned values as a reference.
It is strongly recommended that each laboratory establishes its own normal range according to its geographic area.

• Kit composition and possible risk classification

REAGENT (A)	
Buffer pH 3.8	100 mmol/l
BCG	7 mmol/l
CALIBRATOR (B)	
Bovine Albumin	3 g/dl

Avoid pipetting with mouth.
The kit doesn't contain substance or prepared classified as dangerous according to the currently legislation.

• Package: collection and storage

Store in refrigerator (2 – 8°C).
Stable until the expiration date reported on the package.
After unsealing, it is advised to close up the bottle immediately in order to avoid evaporation, direct light exposure and bacteric contamination.

• Reagent preparation and stability

Liquid reagent ready to use, must be at room temperature (15 – 25°C) before using.
The Reagent is limpid and yellow-green.

• Precautions and warning

Whenever agents infettantis, chemical reagents, reagents of human/animal origin, blood or other biological liquids are manipulated, it is advisable to follow the most common recommendations and take all the necessary hygienic precautions as the monouse gloves.

• Waste disposal

Please consult local regulations for a correct waste disposal.

• Operative method

Wavelength:	628nm (620-640)
Reading in bio chromatism	P620nm/S690/700nm
Cuvette:	1 cm
Temperature:	+25/30/37°C
Zero operation:	Against blank reagent
Assay type:	End Point
Sample/Reagent ratio:	1/150

	WHITE	SAMPLE	CALIBRATOR
Reagent (A)	1500 µl	1500 µl	1500 µl
Distilled water	10 µl		
Sample		10 µl	
Calibrator (B)			10 µl

Mix, incubate for 1' at room temperature (15 – 25°C) and read as fast as possible of the sample and calibrator extinction.
Volumes can be proportionally modified.
This methodology describes the manual procedure to use the kit.

• Calculation

Serum: Albumin g/dl = $\frac{\text{E Sample}}{\text{E Calibrator}}$ x 3 (Calibrator Value)

Conversion Factor from g/dl x 144.9 = µmol/l

• Performance

A. METHOD PERFORMANCE

Measure interval/linearity:	0.11 – 10 g/dl
Detection limit (2DS):	0.11 g/dl
Sensitivity:	1 g/dl = 0.0922a a 650nm

B. INTRA-ASSAY PRECISION: n=20

	Mean	C.V.(%)
Low control	M = 1.73 g/dl	1.88 %
Medium control	M = 3.77 g/dl	1.78 %
High control	M = 6.62 g/dl	1.36 %

C. INTER-ASSAY PRECISION: n=20

	Mean	C.V.(%)
Low control	M = 1.72 g/dl	0.57 %
Medium control	M = 3.80 g/dl	0.79 %
High control	M = 6.52 g/dl	1.52 %

D. CORRELATION BETWEEN METHODS
This method compared with a correspondent one from the competition, has given the following results:
N = 60 r= 0.989 y = 0.9873 x + 0.089

E. INTERFERENCE (in accordance with recommendations SFBC)
1. Bilirubine does not interfere up to 30 mg/dl
2. Triglicerides > 300 mg/dl increases the measurement
3. Hemoglobin > 0.3 mg/dl increases the measurement
For a thorough evaluation of the interfering substances, consult: Young, D.S.,et al.,Clin.Chem. 21:1D (1975).

• Limitations

Avoid excessive hemolysis since every 100 mg/dl of hemoglobin corresponds to about 100 mg/dl of albumin.
Severely lipemic serum, should have a serum blank with physiologic solution.
Ampicillin has been found to seriously interfere with BCG methods.
For concentration higher than 10 g/dl, repeat the measure on sample diluted 1:2 with saline solution and multiply the results by 2.

• Quality Control

It is recommended to execute the quality control at every kit utilization to verify that values are within the reference range indicated by the methodology.
For this purpose the use of test serum REF. ASR02010 (Normal level) and REF. ASR02020 (Pathologic level) is suggested.

• Bibliography

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