Meril
Diagnostics

For *in vitro* diagnostic use
Read this pack insert thoroughly before use

Albumin Kit
CliniQuant - FSR
BCG Dye Method, End Point

REF	Pack Size	R1 Albumin Reagent	R2 Albumin Standard
ALBFSR-01	4 x 50ml	4 x 50ml	1 x 5ml
ALBFSR-02	2 x 500ml	2 x 500ml	2 x 5ml

INTENDED USE
This reagent is intended for quantitative determination of albumin concentration in human serum or plasma.

CLINICAL SIGNIFICANCE
Albumin synthesized in liver is a major plasma protein that functions the regulation and distribution of cellular fluids, hormones, metabolism of endogeneous substances such as calcium, bilirubin and fatty acids. Hyperalbuminemia is significant in dehydration. Hypoalbuminemia is common in various illnesses, liver disease, skin burns, tissue damage and inflammation.

PRINCIPLE OF THE METHOD
Albumin complexes with BCG dye at an acidic pH, the absorption of the BCG-albumin complex is directly proportional to the concentration of albumin present when measured between 580 – 630 nm with absorbance maxima at 620 nm.

$$\text{Albumin} + \text{BCG} \xrightarrow{\text{acidic medium}} \text{BCG-albumin complex}$$

KIT COMPONENTS
Composition :
R1 - Albumin Reagent : Bromocresol Green 0.104 g/l, Succinate Buffer 94.84 mmol/l , Sodium Azide 15.38 mmol/l, Surfactant
R2 - Albumin Standard : 3.8 g/dl, Bovine Serum Albumin (BSA) : 38 g/l

MATERIALS REQUIRED BUT NOT PROVIDED
Laboratory instrumentation, Spectrophotometer UV/VIS with thermostatic cuvette holder or clinical chemistry analyzer: semi automated, calibrated micropipettes, glass or high quality polystyrene cuvettes, test tube/rack, heating bath, controls, saline.

REAGENT PREPARATION, STORAGE & STABILITY
Reagent is ready to use. Keep away from direct light sources.
Stability: up to expiration date on labels at 2-8 °C.
Upon opening of kit, store Reagent R1 at 15 -30 °C and standard at 2-8 °C.
Stability since first opening of vials: $\geq$ 60 days.

REAGENT DETERIORATION
1. Discard the reagent if absorbance exceeds 0.10 against distilled water.
2. Keep the Standard vial plugged after use, in order to avoid deterioration.

WARNINGS AND PRECAUTIONS
1. Reagent may contain some non-reactive and preservative components. It is recommended to handle carefully, avoiding contact with skin and ingestion.
2. Specimens should be considered infectious and handled appropriately.
3. Perform the test according to the general "Good Laboratory Practice" (GLP) guidelines.

SPECIMEN
Serum (preferred) plasma (heparinate or EDTA). Venostasis should be avoided in specimen collection because hemoconcentration increases the concentrations of albumin and other plasma proteins.

Programme Parameter for MERILYZER CliniQuant

Reading Mode	End Point
Standard Conc.	3.8 (g/dl)
Filter – 1 (nm)	620
Temperature	37 °C
Volume (µl)	500

CE
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Delay Time (Sec)	5
Reaction Direction	Increase
Reference Low	3.2
Reference High	5.0
Linearity Limit	6

TEST PROCEDURE

Dispense	Blank	Standard	Sample
Reagent 1	1ml	1ml	1ml
Distilled water	10 µl	-	-
Standard	-	10 µl	-
Sample	-	-	10 µl
Mix, incubate for 1 min at 37°C. Read absorbance of standard (As) and samples (Ax) against reagent blank			

RESULT CALCULATION

Serum/plasma:

albumin g/dl = Ax/As x concentration of Standard

SI conversion factor: 1 g/dl x 10 = 1 g/l

EXPECTED VALUES

3.2 - 5 g/dl OR 32 – 50 g/l

It is recommended that each laboratory verifies this range or derives reference interval for the population it serves.

QUALITY CONTROL AND CALIBRATION

It is recommended to perform internal quality control with assayed normal (BioNorm) and assayed abnormal (BioPath), to confirm the validity of the test and assure the accuracy of patient result. Using the recommended Calibrator (BioCal) or the Standard included, calibrate the assay:

a. When using a new reagent or lot

b. When QC values are out of range

PERFORMANCE CHARACTERISTICS

1. Linearity

The linearity is up to 6 g/dl or 60 g/l.

2. Sensitivity/ Limit of detection (LOD)

The limit of detection is 0.02 g/dl.

The limit of quantification is 0.05 g/dl.

3. Interferences

No interference has been observed for the following

Hemoglobin up to 100 mg/dl; Bilirubin up to 20 mg/dl

Triglycerides up to 800 mg/dl

4. Precision

Intra-assay precision

	Mean	SD	CV
n = 20	g/dl	g/dl	%
sample 1	4.67	0.009	0.2
sample 2	3.41	0.01	0.3

Inter -assay precision

	Mean	SD	CV
n = 20	g/dl	g/dl	%
sample 1	4.43	0.09	1.92
sample 2	3.33	0.05	1.63

5. Methods Comparison

Comparison was done between reference Albumin Reagent and CliniQuant - FSR Albumin Reagent (test).

N = 36 y = 1.110x - 0.048

r^2 = 0.940

LIMITATIONS

Samples with values above 6 .0 g/dl should be diluted with 0.9% saline, re-run and results multiplied by dilution factor.

WASTE DISPOSAL

This product is made to be used in professional laboratories. Please consult local regulations for correct waste disposal.

REFERENCES

1. Burtis, C.A., Ashwood, E.R., editors. Tietz Textbook of Clinical Chemistry. 2nd ed. Philadelphia, W.B. Saunders Company, 1994, p. 700 - 704.

2. Data on file: Meril Diagnostics.

IFU/ALBFSR01/01

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Symbols used on Meril Diagnostics labels:

REF	Catalogue No.		Attention See Instruction for Use
LOT	Batch No.	IVD	*In vitro* Diagnostics
	Expiry Date		Consult Instruction for Use
	Manufacturer		Storage Temperature
	Keep Dry		Keep Away from Sunlight
	Manufacturing Date		Do not use if package is damaged
EC REP	Authorized European Representative in the European Community		