Table I

Analysis of LipoClear Treated vs. Untreated Clear Sera

			Regression Analysis		
Constituent	**Method**		**Slope**	**In'cept**	**Correl. Coef**
Glucose	oxidase	Astra Ideal	1.01	-0.35	1.00
BUN	urease	Astra Ideal	1.00	0.80	1.00
Creatinine	alk picrate	Astra Ideal	0.98	0.01	1.00
Albumin	BCG	Astra Ideal	1.02	-0.14	0.99
Total protein	biuret	OlypsDem	0.83	0.82	0.97
Calcium	CPC	Astra Ideal	0.99	-0.11	0.94
Uric Acid	uricase	Astra Ideal	1,04	-0.14	1.00
Total Bill	diazo	Astra Ideal	0.95	0.03	1.00
LDH	kinetic	Astra Ideal	0.96	-1.28	0.98
CPK	kinetic	Astra Ideal	1.00	-0.04	1.00
Alk Phos	kinetic	Astra Ideal	0.99	-0.92	1.00
SGPT	kinetic	Astra Ideal	0.94	1.47	0.99
SGOT	kinetic	OlypsDem	0.96	0.17	0.99
GGPT	kinetic	OlypsDem	0.95	0.49	0.99
Amylase	kinetic	Hitachi704	0.95	-0.39	0.99
Sodium	diluted ISE	OlypsDem	0.91	-2.61	0.95
Potassium	diluted ISE	OlypsDem	1.02	-0.23	0.98
Chloride	diluted ISE	OlypsDem	0.95	5.22	0.97
CO2	acidify	Astra Ideal	0.93	0.62	0.98

Table 2

Summary of Precision Data Using LipoClear

		Normal	Control	Abnormal	Control
Constituent	**Method**	**Mean**	**RSD**	**Mean**	**RSD**
Glucose	hexokinase	83.3	1.7	294.3	1.1
BUN	monomme	16.7	1.9	56.8	0.8
Creatinine	alk picrate	1.6	3.3	7.9	1.1
Albumin	BCG	3.4	1.7	2.3	1.9
Total protein	biuret	5.7	1.9	4.6	1.3
Calcium	CPC	9.4	3.2	12.1	1.4
Uric Acid	uricase	5.8	4.3	9.7	1.5
LDH	kinetic	149.7	3.4	399.0	1.8
SGOT	kinetic	22.9	7.2	139.2	3.8
SGPT	kinetic	24.7	13.7	106.5	4.5
Alk Phos	kinetic	145.8	3.2	418.6	5.8
Total Bill	diazo	0.6	13.4	5.6	1.7
Sodium	ISE	138.2	1.4	151.3	1.1
Potassium	ISE	4.2	3.8	7.6	2.8
Chloride	thiocyanate	100.1	1.5	113.8	1.3
CO2	acidification	15.7	2.9	27.6	1.4

Within run data n=20 all assays with a Technicon SMAC

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LipoClear ®

Product Insert Sheet

Cat No. 0104

Reagent Volume = 0. 1ml
Designated Sample volume - 0.5 ml
Contains 10 reagent pre-filled tubes.

IMPORTANT

LipoClear is designed to be used with a wide variety of analytical systems and reagents. Because of the many possible combinations, each user should verify that samples of adequate quality for their testing are produced with the LipoClear method. A method for doing that is suggested in the Quality Control section.

INTRODUCTION

Gross elevations of serum or plasma lipoproteins, especially chylomicrons and/or very low density lipoproteins, cause turbidity in the sample, with subsequent interference in some analytical methodologies which involve un-blanked spectrophotometric measurement (1).

Removal of this interfering lipemia can be accomplished by several techniques including ultracentrifugation and solvent extraction. The disadvantages of these methods include very large sample requirements, special equipment (ultracentrifuge) or the use of toxic and perhaps carcinogenic solvents (2).

Precipitation techniques using polyanions have been tried, but these alter some of the analytes or inhibit enzyme activity (3)

METHODOLOGY

LipoClear utilises a non-ionic, non-toxic polymer which causes the removal of lipoproteins (see NOTES) in grossly lipaemic specimens, yielding a clear sample suitable for the analysis of many constituents.

REAGENTS

For *in vitro* diagnostic use. LipoClear contains a non-ionic, non-toxic polymer in aqueous solution.

REAGENTS

Re-sealable bag of plug-topped micro-centrifuge tubes preloaded with reagent. Single use only.

PRECAUTIONS

No special precautions are required. Use good laboratory practice when handling.

REAGENT PREPARATION

None required. A small amount of dry reagent at or near the lip of the tube will not interfere.

STORAGE & STABILITY

Store at refrigerator temperature (2° – 8^{O} C). Do not use past the 'use before' date. Keep the unused microtubes sealed in the original re-closable bag.

INDICATIONS OF DETERIORATION

The reagent should be clear and colourless. Discard if reagent becomes cloudy or develops any colour. Discard if reagent shows any sign of evaporation leaving a residue.

SPECIMEN REQUIREMENT

Fresh serum is the preferred specimen. Frozen or refrigerated samples should be allowed to come to room temperature before processing. Cleared specimen must be analysed within one hour of clearing to prevent additional loss of serum proteins.

INTERFERING SUBSTANCES

No substance has yet been identified.

PROCEDURE

1. Check product number before proceeding.
2. Allow reagent tube to come to room temperature (let stand for 10 minutes).
3. Proceed with sample addition using the above information for "designated sample volume".

NOTE: If wrong sample volume is used, incorrect results may be obtained.

SAMPLE ADDITION (PIPETTING)

1. Pipette designated sample volume of turbid specimen into the LipoClear tube, then cap tube.
2. Shake well or vortex to mix.
3. Allow tube to stand at room temperature for 5 minutes, then centrifuge.

CENTRIFUGATION

1. Statspin centrifuges—place LipoClear tubes in an RT12 Tube Rotor. Install the RT12 Rotor. Centrifuge on the "LipoClear / 95 seconds" cycle on the Statspin MP and RP ("long" cycle on earlier models (1 & 3).
2. Routine (low speed) "clinical" centrifuges- spin LipoClear tube at 2,000 x G for 20 minutes.
3. High-speed micro-centrifuges - spin LipoClear tube at 10,000 x G for 2 minutes.

SAMPLE REMOVAL & ANALYSIS

1. Remove cleared sample for analysis as described in NOTES below.
2. Proceed with sample analysis.

ALL RESULTS MUST BE MULTIPLIED BY 1.2 TO COMPENSATE FOR THE DILUTION OF THE ORIGINAL SAMPLE

NOTES

The lipids will form either a precipitate, a tight button at the bottom of the tube or form a "pedicle" of floating fats. If the operator decants the tube in one smooth motion this pedicle will remain clinging to the tube and the clear subnatant sample will decant easily.

Occasionally, especially when the triglycerides exceed 2500 mg/di, this pedicle may be too thick to allow the sample to leave the tube. In these cases a fine tipped pipette may be used to penetrate the pedicle to remove the clear sample. If any lipid is transferred with the sample it may be necessary to re-centrifuge the specimen and repeat the decantation.

Infrequently, this treatment will not adequately clarify a specimen. In these cases, remove designated sample volume of specimen from the original LipoClear tube to a second LipoClear tube and repeat the procedure.

REMEMBER, in these cases to multiply the results by 1.44 to account for the dual dilution.

QUALITY CONTROL

Each user should establish performance characteristics of LipoClear with their own analytical system. A method for doing that is to select 10 or more non-lipaemic samples. A portion of those samples should be treated with LipoClear, another portion analysed without treatment. The results from the treated specimens, after multiplying by 1.2 should agree with results from the untreated portion within twice the precision of the analytical system.

PERFORMANCE CHARACTERISTICS

It is up to the operator to establish performance characteristics of this reagent with their own analytical system.

LIMITATIONS

- Each analytical system should be verified using normal samples to ensure no interference by this reagent.
- LipoClear CANNOT be used to clarify specimens requiring lipid testing.
- LipoClear CANNOT be used to clarify plasma to be used for coagulation testing.
- LipoClear CANNOT be used for the samples requiring estimation of monoclonal gammopathy immunoglobulins.
- There is a loss of approximately 0.4 to 0.8g/c11 protein after LipoClear treatment. This is probably due to the loss of lipoproteins.
- Phosphorus was seen to be spuriously elevated by about 10% on several analytical systems.
- Some analysers measure electrolytes on undiluted samples. In those instances, the electrolyte results should not be multiplied by 1.2. The user should determine an appropriate correction factor for each electrolyte by comparing normal specimens treated with LipoClear vs. untreated (see Quality Control).

REFERENCES

1) Young, 0.5 et al, Clin. Chem. 21 pp 10-4320 (1975)
2) Package insert from LIPOSOL TM BioSol Ltd. Ann Arbor, MI 48104
3) Ortega, M and S Rodenas. Clin. Chem. Acta 92: 135-139 (1979)