Comparison of LipoClear® versus CataClear and their Effects on Clinical Chemistry Analytes

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Introduction:

Lipaemia may interfere with any assay utilising light transmission. Lipid-clearing agents such as "LipoClear®" may be used to clear lipaemia from samples. Whilst LipoClear ® clears lipids efficiently it may be unsuitable for the measurement of certain parameters. LipoClear® cannot be used to clarify samples intended for lipid or coagulation analysis. It can falsely increase phosphate, may cause a significant loss of protein, possibly due to lipoprotein loss, and is unsuitable for electrolyte testing. LipoClear® may have negative effects on a greater number of analytes than those declared by the manufacturer. ***Could a novel lipid clearing agent such as "CataClear" perform more efficiently than "LipoClear®?"***

Methods:

Sera with varying Lipaemic Indices (LI) were selected for analysis; n = 62, range 4-176. Each primary serum sample was aliquoted into three 300 µL aliquots and labelled as "untreated", "LipoClear®-treated" and "CataClear-treated". Lipoclear® is provided by StatSpin, IRIS International, USA. CataClear was provided by Nuuchem, Armagh, N. Ireland free of charge for evaluation. Sera with lipid-clearing agent were treated as per manufacturer instructions. This treatment allowed lipid-free sera to be analysed for a profile of 26 analytes alongside neat, untreated samples on the Roche Cobas 8000 analysers.

Results:

Mean results of untreated, LipoClear®-treated and CataClear-treated samples are shown in Table 1.

Table 1: *The mean result for each parameter measured in non-lipaemic and lipaemic samples after lipid removal with LipoClear® and CataClear.*

Tests	Average result non-lipaemic samples: LipoClear® treated	Average result lipaemic samples: LipoClear® treated	Average result non-lipaemic samples: CataClear treated	Average result lipaemic samples CataClear treated
n	35	27	35	27
Na (mmol/L)	156	154	155	155
K (mmol/L)	5.3	5.3	4.6	4.7
Cl (mmol/L)	110	108	104	103
CK (U/L)	114	122	130	134
Transferrin (g/L)	2.76	2.65	2.93	2.98
CRP (mg/L)	3.1	2.0	5.3	6.6
Urea (mmol/L)	6.1	6.0	5.6	5.6
HDL-C (mmol/L)	1.54	1.16	0.61	1.13
Creat (µmol/L)	90	95	82	88
GGT (U/L)	28	32	17	98
Amylase (U/L)	71	77	83	105
Iron (µmol/L)	17.9	14.3	19.6	17.4
LDH (U/L)	316	311	355	362
Total Protein (g/L)	71	67	72	68
ALP (U/L)	73	74	70	127
ALT (U/L)	30	26	30	19
AST (U/L)	32	25	32	19
Calcium (mmol/L)	2.50	2.44	2.07	2.03
Urate (µmol/L)	349	340	331	340
Mg(mmol/L)	0.92	0.86	0.70	0.70
Bilirubin (µmol/L)	11	19	12	24
PO4 (mmol/L)	1.28	1.37	1.17	1.24
Glucose (mmol/L)	5.4	7.2	5.0	7.0
Albumin (g/L)	43	40	43	42
Trigs (mmol/L)	0.9	2.7	0.4	1.6
Chol (mmol/L)	3.7	4.3	1.0	3.6
L-index	5	35	21	123
H-index (µmol/L)	4.90	9	5	8
I-index (µmol/L)	19	31	19	12

To assess the effectiveness of the lipid clearing reagents, the recovery (R) for each analyte, post-treatment, was calculated; R = Ca/Cx x 100; where Cx is the mean value of analytes pre-treatment and Ca is the mean value of analytes post-treatment. Analyte recovery was compared to desirable specifications for imprecision (DSI) obtained from the Westgard website[1] (Table 2).

Table 2: *Analyte recovery after treatment of samples with L-indices >50 with LipoClear® and CataClear. Values in red represent recoveries within the DSI.*

		Samples treated with LipoClear®	Samples Treated with CataClear
Test	DSI	% Change in Recovery Samples with L-indices >50	% Change in Recovery Samples with L-indices >50
Na (mmol/L)	0.3	-7.37	-7.84
K(mmol/L)	2.3	-7.80	3.75
Cl (mmol/L)	0.6	-7.66	-3.20
CK (U/L)	11.4	8.96	-0.27
Transferrin (g/L)	1.5	4.61	-6.83
CRP (mg/L)	21.1	51.52	-53.36
Urea (mmol/L)	6.05	-8.59	-2.36
HDL-C (mmol/L)	3.65	4.98	7.37
Creatinine (µmol/L)	2.98	-8.65	-0.88
GGT (U/L)	6.7	214.12	2.79
Amylase (U/L)	4.4	18.84	-12.79
Iron µ)	13.3	5.93	-13.09
LDH (U/L)	4.3	16.12	-0.29
Total Protein (g/L)	1.38	4.11	3.53
ALP (U/L)	3.23	63.44	-4.83
ALT (U/L)	9.7	22.26	68.17
AST (U/L)	6.15	8.07	43.41
Calcium (mmol/L)	1.05	-2.30	17.33
Urate (µmol/L)	4.3	-4.43	-4.41
Mg (mmol/L)	1.8	-2.94	19.56
Bilirubin (µmol/L)	10.9	-7.92	-27.24
PO4 (mmol/L)	4.08	-9.49	-0.63
Glucose (mmol/L)	2.8	-8.03	-5.26
Albumin (g/L)	1.6	-1.68	-6.65
Trigs (mmol/L)	9.95	81.52	194.08
Chol (mmol/L)	2.98	49.01	78.27
L-index		68.59	-51.70
H-Index (µmol/L)		26.64	48.17
I-Index (µmol/L)		2.65	159.44

Conclusions and Study Limitations:

- LipoClear® displayed unacceptable recovery rates on more analytes than those declared by the manufacturer.
- In LipoClear®-treated samples, only 3 of the 26 measured analytes remained within the DSI.
- CataClear-treated samples demonstrated minimally better performance; 6 of the 26 analytes measured remained within the DSI.
- CataClear was easier use than LipoClear®.
- There was a lack of lipaemic samples with L-indices >50.
- More samples with higher L-indices are required to definitely determine whether lipid-clearing agents, such as LipoClear® and/or CataClear, are fit for purpose in routine Clinical Chemistry laboratory.

References:

1. Ricós, C., Alvarez, V., Cava, F., García-Lario, J. V., Hernández, A., Jiménez, C. V., Minchinela, J., Perich, C. and Simón, M. (1999) 'Current databases on biological variation: pros, cons and progress', Scand J Clin Lab Invest, 59(7), pp. 491-500.