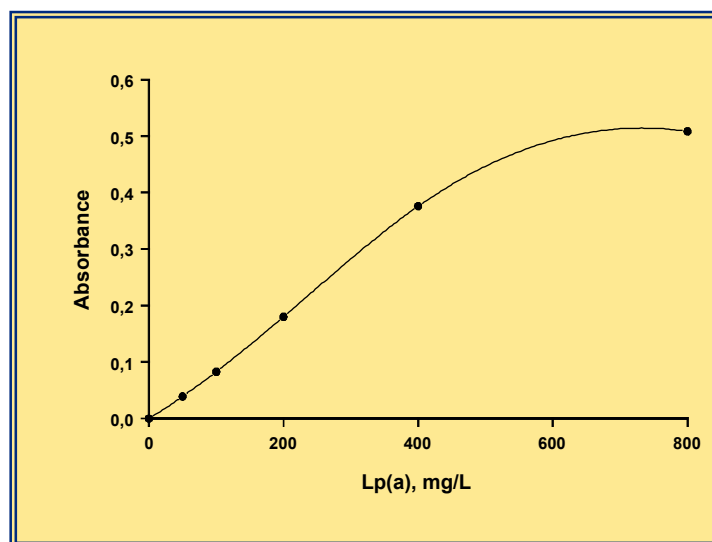


Lipoprotein (a) [Lp(a)]

Analytical Characteristics

Product characteristics have been obtained in a single experiment in a Cobas Mira plus analyser. As is well known the analytical characteristics of a clinical chemistry reagent depend on both the reagents and the instrument used. Multicenter studies indicate important differences in analytical characteristics among similar instruments. Therefore, the data expressed in the present document should be interpreted as a guide example.

Calibration Curve



Precision

	n	CV (160 mg/l)	CV (479 mg/l)	CV (715 mg/l)
Coefficient of Variation Intra-assay	10	4.7 %	4.5 %	3.4 %

	n	CV (165 mg/l)	CV (464 mg/l)	CV (720 mg/l)
Coefficient of Variation Inter -assay	10	5.1 %	3.9 %	3.5 %

Sensitivity

DL = mean + 3 standard deviation of the blank

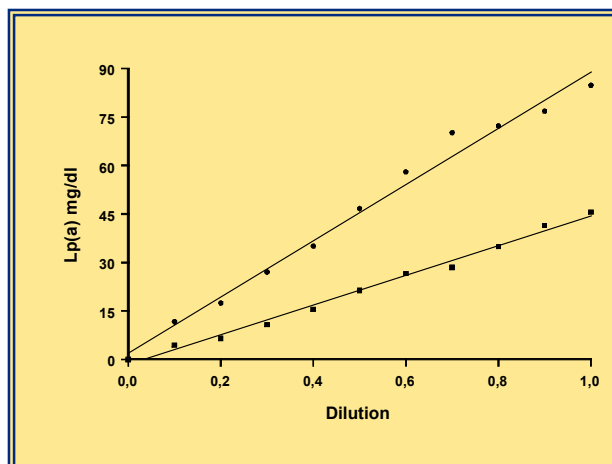
n = 20

Detection Limit (DL)

< 5 mg/L

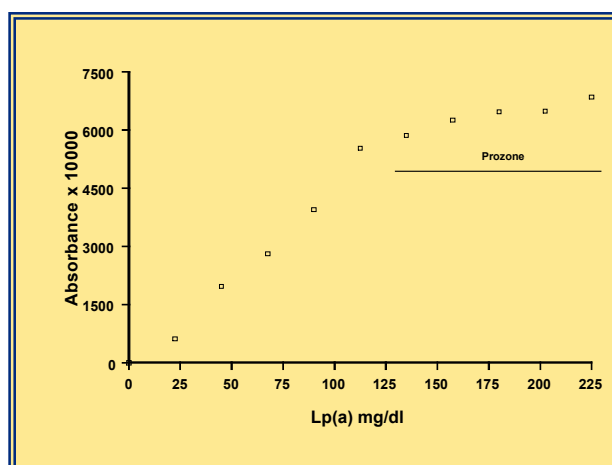
Linearity

Linearity was evaluated using serial dilutions, prepared with saline solution, of two samples, which contained values of Lp(a) in the range analysis. Within the assay's measuring range, the deviations of measurement from theoretical values did not exceed the 10 % level.



Prozone Phenomenon

The system did not show prozone phenomenon at least up to 2250 mg/L.

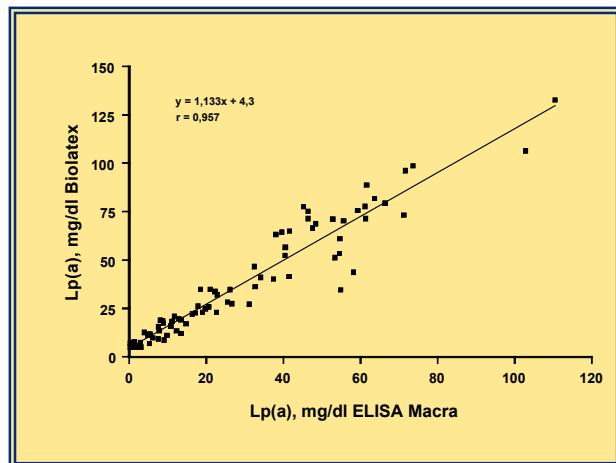


Method Comparison

Reference Method: Commercial Reagent vs Biolatex Lp(a) Reagents.

Samples: 80

Analyzer: Macra (ELISA) vs Cobas Mira plus



$$y = 1.133x + 4.3$$

$$r = 0.957$$

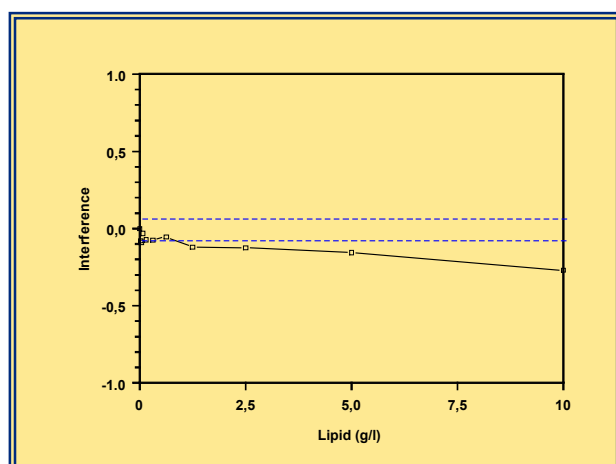
$$n = 80$$

Specificity. Interferences

Intralipid

The horizontal blue lines show the tolerance for the value with interferent. This values are: concentration without interferent $\pm 3 \times$ standard deviation intra-assay.

Sample without interferent (m) and sample with interferent (m_i):

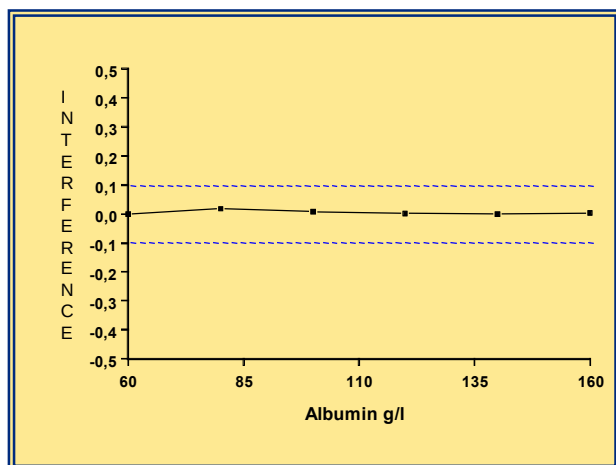


$$Interference = \frac{m_i - m}{m}$$

Proteins

The horizontal blue lines show the tolerance for the value with interferent. This values are: concentration without interferent $\pm 3 \times$ standard deviation intra-assay.

Sample without interferent (m) and sample with interferent (m_i):

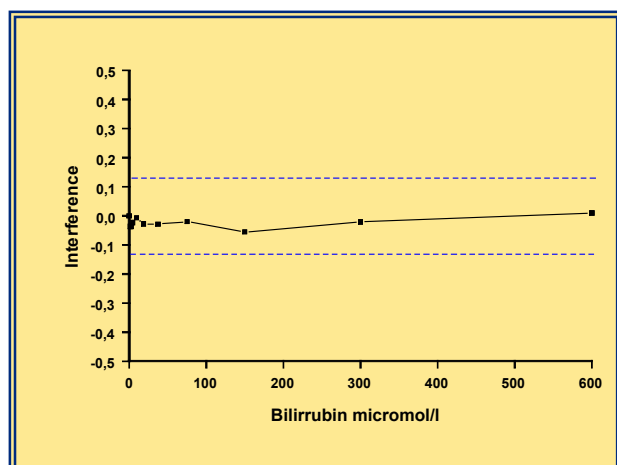


$$Interference = \frac{m_i - m}{m}$$

Bilirubin

The horizontal blue lines show the tolerance for the value with interferent. This values are: concentration without interferent $\pm 3 \times$ standard deviation intra-assay.

Sample without interferent (m) and sample with interferent (m_i):

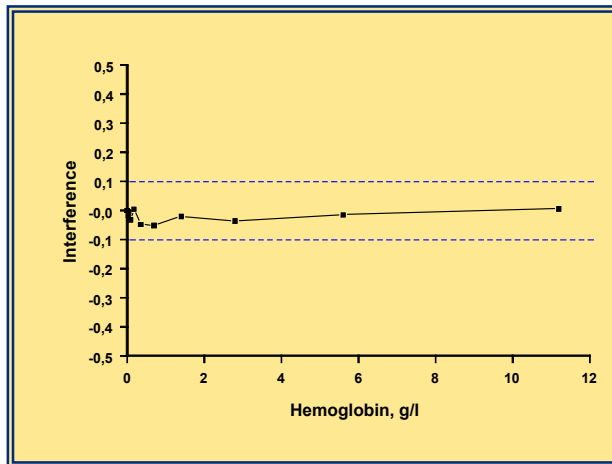


$$Interference = \frac{m_i - m}{m}$$

Haemoglobin

The horizontal blue lines show the tolerance for the value with interferent. This values are: concentration without interferent $\pm 3 \times$ standard deviation intra-assay.

Sample without interferent (m) and sample with interferent (m_i):



$$Interference = \frac{m_i - m}{m}$$