



Calibrador A *plus*

Clinical chemistry calibrator for autoanalyzers

Kit lot: 1809276000
Calibrador A plus lot: 274690
Reagent A lot: 274730

USES

The calibrator has been designed to be used with Wiener lab.'s reagents in autoanalyzers.

Check the value chart for the constituents, since they are lot specific.

PRINCIPLE

Calibrador A plus contains the compounds usually determined in clinical chemistry laboratories.

It must be noted that the assigned values for the calibrator's different constituents have been obtained with Wiener lab.'s methods and reagents, thus, the obtained results will only be comparable to the list if the corresponding methods and reagents have been used.

PROVIDED REAGENTS

Calibrator: lyophilized serum containing metabolites in the appropriate concentrations to ensure a correct calibration of autoanalyzers.

A. Reagent A: 25 mmol/l sodium carbonate solution, pH 10.

INSTRUCTIONS FOR USE

- Open the vial, slowly pulling out the rubber stopper to avoid any loss of the lyophilized material.
- Add exactly 3 ml Reagent A (using a burette or a pipette with double calibration mark).
- Cap and mix by gentle inversion, avoiding the formation of foam. Do not shake.
- Let dissolve for 30 minutes at room temperature, mixing by inversion from time to time.
- Mix by inversion immediately before use.

WARNINGS

Reagents are for "in vitro" diagnostic use.

This calibrator has been prepared from non-reactive material to HBsAg, HCV and HIV. However, it should be handled as if it were an infectious material.

Use the reagents according to the working procedures for clinical laboratories.

The reagents and samples should be discarded according to the local regulations in force.

STABILITY AND STORAGE INSTRUCTIONS

The **Provided Reagents** are stable in refrigerator (2-10°C) until the expiration date shown on the box.

Reconstituted Calibrator: is stable for 8 hours at room temperature (<25°C), 2 days refrigerated (2-10°C) or 30 days frozen (-20°C).

In the dark, bilirubin is stable 4 hours at room temperature (<25°C), 8 hours refrigerated (2-10°C) or 2 weeks frozen (-20°C).

Avoid repeated freezing and thawing.

INSTABILITY OR DETERIORATION OF REAGENTS

Any variation of the organoleptic features of the Calibrator may be a sign of its deterioration.

PROCEDURE

Reconstituted Calibrator should be used in the same manner as an unknown sample, following the autoanalyzer parameters that come with the reagent kit in use.

REFERENCE VALUES

Calibrator values have been established using Reference Material from the National Bureau of Standards, when it was possible.

PROCEDURE LIMITATIONS

Mistakes in the reconstitution or conservation may cause erroneous results.

See PROCEDURE LIMITATIONS on the package insert of the kit in use.

WIENER LAB. PROVIDES

- 2 x 3 ml (Cat. 1918005).

REFERENCES

- Tietz, N. W. (Ed): Fundamentals of Clinical Chemistry, W. B. Saunders Co., Philadelphia, 865 (1982)
- Young, D.S., Effects of preanalytical variables on clinical laboratory test. AACC Press. Third ed. (2007).

CALIBRADOR A PLUS METABOLITES ASSIGNED VALUES (37°C)

Analyte	Method	Value	Unit
Uric acid	Uricostat enzimático AA	4.79	mg/dL
	Uricostat enzimático AA líquida	4.72	mg/dL
Albumin	Albúmina AA	3.55	g/dL
Direct bilirubin	Bilirrubina	2.52	mg/dL
	Bilirrubina Directa AA	2.35	mg/dL
	Bilirrubina Directa AA líquida	2.02	mg/dL
Total bilirubin	Bilirrubina	4.74	mg/dL
	Bilirrubina Total AA	3.86	mg/dL
	Bilirrubina Total AA líquida	3.91	mg/dL
Calcium	Ca-Color AA	10.7	mg/dL
	Ca-Color Arsenazo III AA	10.7	mg/dL
Cholesterol	Colestat enzimático AA	154	mg/dL
	Colestat enzimático AA líquida	156	mg/dL
Creatinine	Creatinina cinética AA líquida - Conventional technique	3.72	mg/dL
	Creatinina cinética AA líquida - Compensate technique	4.05	mg/dL
	Creatinina enzimática AA líquida	3.73	mg/dL
Phosphorus	Fosfatemia UV AA	5.96	mg/dL
Glucose	Glicemia enzimática AA	191	mg/dL
	Glicemia enzimática AA líquida	191	mg/dL
	Glucose HK	193	mg/dL
HDL Cholesterol	HDL Colesterol Reactivo Precipitante	172	mg/dL
	HDL Colesterol FT	546	mg/dL
Iron	Fer-color AA	200	µg/dL
	Fer-color AA líquida	188	µg/dL
Lactate	Lactate	30.1	mg/dL
LDL Cholesterol	LDL Colesterol Reactivo Precipitante	234	mg/dL
Magnesium	Mg-Color AA	3.00	mg/dL
	Magnesium CPZ	2.95	mg/dL
Total proteins	Proteínas Totales AA	5.14	g/dL
	Total Protein	5.07	g/dL
Triglycerides	TG Color GPO/PAP AA	128	mg/dL
	TG Color GPO/PAP AA líquida	128	mg/dL
UIBC	UIBC/TIBC AA líquida	148	µg/dL
Urea	Urea UV cinética AA	104	mg/dL
	Urea UV cinética AA líquida	104	mg/dL

CALIBRADOR A PLUS ENZYMES ASSIGNED VALUES (37°C)

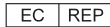
Analyte	Method	Value	Unit
Alanine aminotransferase (GPT/ALT)	GPT (ALT) UV AA	112	U/L
	GPT (ALT) UV AA líquida	112	U/L
Amylase	Amilasa 405 cinética AA	265	U/L
	Amilasa 405 cinética AA líquida	258	U/L
Aspartato aminotransferase (GOT/AST)	GOT (AST) UV AA	115	U/L
	GOT (AST) UV AA líquida	117	U/L
Cholinesterase	Colinesterasa AA	5104	U/L
	Cholinesterase	4947	U/L
Creatine kinase	CK-NAC UV AA	339	U/L
	CK-NAC UV AA líquida	344	U/L
Creatine kinase - MB	CK-MB NAC UV AA líquida	431	U/L
Acid phosphatase	Fosfatasa Acida Total y Prostática cinética - FANP	9.28	U/L
	Fosfatasa Acida Total y Prostática cinética - FAT	25.6	U/L
Alkaline phosphatase	ALP 405 AA líquida	509	U/L
γ -Glutamyl transferase	γ -G test cinética AA	122	U/L
	γ -G test cinética AA líquida	122	U/L
Lactate deshydrogenase	LDH-P UV AA	522	U/L
	LDH-P UV AA líquida	522	U/L
	LDH-L	268	U/L
Lipase	Lipasa AA líquida	129	U/L

Symbols

The following symbols are used in the packaging for Wiener lab. diagnostic reagent kits.



This product fulfills the requirements of the European Directive 98/79 EC for "in vitro" diagnostic medical devices



Authorized representative in the European Community



"In vitro" diagnostic medical device



Contains sufficient for <n> tests



Use by



Temperature limitation (store at)



Do not freeze



Biological risks



Volume after reconstitution



Contents



Batch code



Manufactured by:



Harmful



Corrosive / Caustic



Irritant



Consult instructions for use



Calibrator



Control




Positive Control



Negative Control



Catalog number

 Wiener Laboratorios S.A.I.C.
Riobamba 2944
2000 - Rosario - Argentina
<http://www.wiener-lab.com.ar>
Tech.Dir.: Viviana E. Cétola
Biochemist
A.N.M.A.T. Registered product
Cert. N°: 1976/97



Wiener lab.

2000 Rosario - Argentina