



Calibrador A *plus*

Kit lot: 1612205260
Calibrador A plus lot: 205260
Reagent A lot: 205260

Clinical chemistry calibrator for autoanalyzers

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 | 4.90 | mg/dL |
| | Uricostat enzimático AA líquida | 4.90 | mg/dL |
| Albumin | Albúmina AA | 3.45 | g/dL |
| Direct bilirubin | Bilirrubina | 2.55 | mg/dL |
| | Bilirrubina Directa AA | 2.37 | mg/dL |
| | Bilirrubina Directa AA líquida | 2.27 | mg/dL |
| Total bilirubin | Bilirrubina | 5.15 | mg/dL |
| | Bilirrubina Total AA | 4.38 | mg/dL |
| | Bilirrubina Total AA líquida | 4.48 | mg/dL |
| Calcium | Ca-Color AA | 10.8 | mg/dL |
| | Ca-Color Arsenazo III AA | 10.9 | mg/dL |
| Cholesterol | Colestat enzimático AA | 170 | mg/dL |
| | Colestat enzimático AA líquida | 170 | mg/dL |
| Creatinine | Creatinina cinética AA líquida - Conventional technique | 3.60 | mg/dL |
| | Creatinina cinética AA líquida - Compensate technique | 3.90 | mg/dL |
| | Creatinina enzimática AA líquida | 3.72 | mg/dL |
| Phosphorus | Fosfatemia UV AA | 5.95 | mg/dL |
| Glucose | Glicemia enzimática AA | 193 | mg/dL |
| | Glicemia enzimática AA líquida | 193 | mg/dL |
| HDL Cholesterol | HDL Colesterol Reactivo Precipitante | 187 | mg/dL |
| | HDL Colesterol FT | 595 | mg/dL |
| Iron | Fer-color AA | 196 | µg/dL |
| | Fer-color AA líquida | 184 | µg/dL |
| Lactate | Lactate | 30.0 | mg/dL |
| LDL Cholesterol | LDL Colesterol Reactivo Precipitante | 255 | mg/dL |
| Magnesium | Mg-Color AA | 2.87 | mg/dL |
| | Magnesium CPZ | 2.75 | mg/dL |
| Total proteins | Proteínas Totales AA | 5.12 | g/dL |
| | Total Protein | 4.89 | g/dL |
| Triglycerides | TG Color GPO/PAP AA | 132 | mg/dL |
| | TG Color GPO/PAP AA líquida | 130 | mg/dL |
| UIBC | UIBC/TIBC AA líquida | 145 | µg/dL |
| Urea | Urea UV cinética AA | 101 | mg/dL |
| | Urea UV cinética AA líquida | 99.0 | mg/dL |

CALIBRADOR A PLUS ENZYMES ASSIGNED VALUES (37°C)

| Analyte | Method | Value | Unit |
|---|---|--------------|-------------|
| Alanine aminotransferase (GPT/ALT) | GPT (ALT) UV AA | 103 | U/L |
| | GPT (ALT) UV AA líquida | 103 | U/L |
| Amylase | Amilasa 405 cinética AA | 265 | U/L |
| | Amilasa 405 cinética AA líquida | 253 | U/L |
| Aspartato aminotransferase (GOT/AST) | GOT (AST) UV AA | 110 | U/L |
| | GOT (AST) UV AA líquida | 108 | U/L |
| Cholinesterase | Colinesterasa AA | 5094 | U/L |
| | Cholinesterase | 4955 | U/L |
| Creatine kinase | CK-NAC UV AA | 326 | U/L |
| | CK-NAC UV AA líquida | 333 | U/L |
| Creatine kinase - MB | CK-MB NAC UV AA líquida | 319 | U/L |
| Acid phosphatase | Fosfatasa Acida Total y Prostática cinética - FANP | 9.48 | U/L |
| | Fosfatasa Acida Total y Prostática cinética - FAT | 23.9 | U/L |
| Alkaline phosphatase | ALP 405 AA líquida | 450 | U/L |
| γ -Glutamyl transferase | γ-G test cinética AA | 117 | U/L |
| | γ-G test cinética AA líquida | 115 | U/L |
| Lactate deshydrogenase | LDH-P UV AA | 510 | U/L |
| | LDH-P UV AA líquida | 506 | U/L |
| | LDH-L | 250 | U/L |
| Lipase | Lipasa AA líquida | 100 | U/L |

Symbols

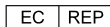
The following symbols are used in the packaging for Wiener lab. diagnostic reagent kits.



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



Manufactured by:



Authorized representative in the European Community



Harmful



"In vitro" diagnostic medical device



Corrosive / Caustic



Contains sufficient for <n> tests



Irritant



Use by



Consult instructions for use



Temperature limitation (store at)



Do not freeze



Calibrator



Biological risks



Control



Volume after reconstitution



Positive Control



Contents




Negative Control



Batch code



Catalog number

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Cert. N°: 1976/97



Wiener lab.

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