GLUCOSE LIQUID

GOD – POD METHOD

For "in vitro" determination of Glucose in serum or plasma

PRINCIPLE

The oxidation of glucose to gluconic acid catalyzed by glucose oxidase producing hydrogen peroxide.
The hydrogen peroxide reacts with 4-aminoantipyrine and p-hydroxybenzoic acid in the presence of peroxidase to give a colored quinone derivative, whose coloration is proportional to the glucose concentration in the sample.

$$\text{D-Glucose} + H_2O + O_2 \xrightarrow{\text{GOD}} \text{Gluconic acid} + H_2O_2$$

$$2\,H_2O_2 + \text{4-Aminoantipyrine} + \text{p-Hydroxybenzoic acid} \xrightarrow{\text{POD}} \text{Coloured quinonic derivative} + 4\,H_2O$$

DIAGNOSTIC USE

The determination of glucose in serum or urine is used for the evaluation of disorders of the metabolism of carbohydrates.
Glucose is the major source of energy for body cells. Insulin produced in the pancreatic cells , facilitates the entry of glucose into cells of tissues.
Increased blood glucose is associated with a decrease in insulin activity or deficient in it.
In serum or plasma we found elevated glucose values mainly in patients with diabetes mellitus but also acute pancreatitis , Cushing syndrome, acromegaly and gigantism.
Hypoglycemia can occur in response to fasting, or may be due to drugs , poisons or inborn errors of metabolism.
The presence of glucose in urine without the individual having diabetes is usually a sign of disease in the renal tubules.
Glucose determination in CSF is primarily of interest in case of bacterial meningitis, which its concentration is low or not detected.

Single test result could not be used to make a clinical diagnosis. It should integrate clinical and laboratory data.

REAGENTS

Kit 1 x 100 ml (Ref. 99 82 25) Contents:
A. 1 x100 ml. Reagent.
B. 1 x 5 ml. Standard.

Ref. 99 82 84
Ref. 99 02 93

Kit 3 x 100 ml (Ref. 99 82 82) Contents:
A. 3 x100 ml. Reagent.
B. 1 x 5 ml. Standard.

Ref. 99 82 84
Ref. 99 02 93

Kit 4 x 250 ml (Ref. 99 86 60) Contents:
A. 4 x250 ml. Reagent.
B. 1 x 5 ml. Standard.

Ref. 99 01 68
Ref. 99 02 93

WORKING REAGENT PREPARATION

Reagent and standard are ready to use.

REAGENT COMPOSITION

Concentration in the reagent solution is:

Phosphate buffer pH 6.8	100 mM
p-Hydroxybenzoic acid	39.5 mM
4-Aminoantipyrine	0.8 mM
Phenol	4.5 mM
Glucose Oxidase	≥ 18 kU/l
Peroxidase	≥ 1.1 kU/l
Preservatives and stabilizers	

Standard: Aqueous solution equivalent to 100 mg/dl (5.55 mmol/L).

STORAGE AND STABILITY

The components of the kit, stored at 2-8°C, will remain stable until the expiration date stated on the label.
Signs of reagent deterioration:
Presence of particles or turbidity in the reagent. Working reagent blank >0.400.

ADDITIONAL EQUIPMENT

General laboratory equipment.
Spectrophotometer or photometer thermostatable at 37°C with a 505 nm filter. Cuvette: 1 cm light-path.

SAMPLE

Serum, plasma or C.S.F. Serum or plasma glucose (but not whole blood glucose, due to glycolytic processes) can be stored during 2 - 3 days, when refrigerated at 2-8°C.
The CSF must be clear and without debris. In these conditions the glucose is stable 48 hours at 2-8 °.

CAUTION

The reagent contains Sodium azide at 0.09%. Handle with care.
The security statements are on the label. It is advisable to look at the MSDS before using the reagent.
The disposal of the residues has to be made according to legal local regulations.

PROCEDURE

Bring the reagent and the analyzer to the working reagent

Technique	BL	SA	ST
	ml	ml	ml
Standard	–	–	0.01
Sample	–	0.01	–
Working reagent	1.0	1.0	1.0

Mix well and incubate 5 - 10 min. at 37°C or 20-25 min. at 20 – 25°C.

Reading
Wavelength: 505 nm.
Blank: the contents of BL.
Colour stability: a minimum of 1 hour, when protected from direct sunlight.

CALCULATIONS

$$\frac{\text{SA Abs.}}{\text{ST Abs.}} \times 100 = \text{mg glucose / dl}$$

Where:
SA Abs: Sample Absorption
ST Abs: Standard Absorption

S.I. Units
(mg/dl) x 0.0555 = mmol/L

REFERENCES VALUES

Serum, plasma: 75-115 mg/dl
C.S.F.: 40-80 mg/dl
Urine: 0 - 15 mg/dl
Each particular laboratory should establish its own normal range, obtained from samples of a representative population, using its own instrumentation, blood collection methods and assaying procedures.

PERFORMANCE CHARACTERISTICS

The performance characteristics depend on the method used. It is recommended to calculate these data for each particular test protocol. These results have been obtained using a manual method.

Sensitivity, as detection limit: 2.0 mg/dL
Linearity: Up to 500 mg/dL. For higher values, it is recommended to dilute the sample 1/2 in saline (NaCl 0.9%) and assay once again. Multiply the final result by 2.
Accuracy: 98.9 %.
Repetitivity, as Variation Coefficient: 0.79%
Reproducibility, as Variation Coefficient: 1.33%
Trueness: Results obtained with this reagent did not show systematic differences when compared with reference reagent.
Details of the performance studies are available on request

INTERFERENCES

Haemoglobin, higher than 200 mg/dl; Bilirubin, higher than 20 mg/dl; Uric acid, higher than 20 mg/dl; Creatinine, higher than 15 mg/dl.
Interferences caused by the anticoagulants of current use such as Heparin, EDTA or Oxalate have not been described.

QUALITY CONTROL

Control serum, Seriscann Normal (Ref. 99 41 48) and Seriscann Anormal (Ref. 99 46 85) should be included in each test series. Each particular laboratory should establish its own control program.

AUTOANALYZERS

Adaptations to different autoanalyzers are available on request.

REFERENCES

Trinder, P. (1969). Ann. Clin. Chem. 6, 24-27.

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Revision: November 2014

CE

HEMOGLOBIN

CYANMETHAEMOGLOBIN METHOD

For "in vitro" determination of Hemoglobin in whole blood

QUÍMICA CLÍNICA APLICADA S.A.

PRINCIPLE

Ferricyanide oxidizes the Fe(II) present in hemoglobin, oxyhemoglobin and carboxyhemoglobin, into Fe(III), giving rise to methaemoglobin which, in the presence of cyanide ion, produces cyanmethaemoglobin, a stable red compound that is photometrically determined.

$$HbFe(II) + Fe(III)(CN)_6^{3-} \longrightarrow HbFe(III) + Fe(II)(CN)_6^{4-}$$

$$HbFe(III) + CN^- \longrightarrow HbFe(III)CN$$

DIAGNOSTIC USE

Hemoglobin is a blood protein with quaternary structure, red-colored and has a heme group and iron inside. Its main function is to transport oxygen from the respiratory organs to the tissues, carbon dioxide from the tissues to the lungs to remove it and also participates in the regulation of blood pH.

A hemoglobin level below normal values may be due to anemia, cancer, kidney disease, bleeding, hemolysis or bone marrow damage.

High hemoglobin values may be indicative of dehydration, renal and lung chronic disease, tumors or cardiopathies.

Single test result could not be used to make a clinical diagnosis. It should integrate clinical and laboratory data.

REAGENTS

1 x 100 ml. (Ref. 99 60 23). Contents:

1 x 100 ml **Concentrated (1:10) Drabkin's** reagent. Ref. 99 03 11

Kit 3 x 100 ml. (Ref. 99 60 30). Contents:

3 x 100 ml **Concentrated (1:10) Drabkin's** reagent. Ref. 99 03 11

WORKING REAGENT PREPARATION

To prepare working reagent is necessary to dilute 1:10 the concentrated Drabkin's reagent with deionized water.

Add 900 ml of deionized water to 100 ml of concentrated reagent.

WORKING REAGENT COMPOSITION

Concentrations in the reagent solution are:

Potassium ferricyanide	0.5 mM
Potassium cyanide	0.8 mM
Preservatives and stabilizers	

STORAGE AND STABILITY

The components of the kit, stored at room temperature (≤ 25ºC), will remain stable until the expiration date stated on the label.

Signs of reagent deterioration:

Presence of particles or turbidity in the reagent. Working reagent blank >0.1

ADDITIONAL EQUIPMENT

General laboratory equipment.

Spectrophotometer or photometer thermostatable at 37ºC.

Light path cuvette: 1 cm.

SAMPLE

Whole blood with Heparin or EDTA.

Hemoglobin is stable1 week when stored at 2-8ºC.

CAUTION

The reagent contains Cyanide, that is poisonous. Security pipettes shall be used. Handle with care.

The security statements are on the label. It is advisable to look at the MSDS before using the reagent.

The disposal of the residues has to be made according to legal local regulations

QUALITY CONTROL

Each particular laboratory should establish its own quality control program and measures for avoiding results deviations.

AUTOANALYZERS

Adaptations to different autoanalyzers are available on request.

PROCEDURE

Technique	BL ml	SA ml
Sample	-	0.010
Reagent	2.5	2.5

Mix and allow to stand 10 min. at room temperature (20-25ºC). Read the absorbance.

Reading

Wavelength: 546 nm; 540 nm.

Blank: the contents of BL.

Colour stability: a minimum of 8 hours.

CALCULATIONS

With factor

Abs sample x 37 = g Haemoglobin / dL

The value of the Calculation Factor is obtained by:

$$20 g/dl \ / \ 0{,}545_{540nm}$$

The value of Abs. 0.545 is the result that you could obtain after processing a Hemoglobin sample, under the conditions indicated in the procedure, with a concentration of 20 g/dl hemoglobin.

S.I. Units

(g/dL) x 0.155 = mmol/L

REFERENCES VALUES

Men: 13-18 g/dL

Women: 11-16g/dL

The stated values are for guidance. It is advisable that each laboratory determines its own reference values.

CONVERSION OF HEMOGLOBIN VALUES

100 % Hemoglobin = 16 g/dL

g/dL Hb	% Hemoglobin	g/dL Hb	% Hemoglobin
18.0	112.5	12.8	80.0
17.6	110.0	12.4	77.5
17.2	107.5	12.0	75.0
16.8	105.0	11.6	72.5
16.4	102.5	11.2	70.0
16.0	100.0	10.8	67.5
15.6	97.5	10.4	65.0
15.2	95.0	10.0	62.5
14.8	92.5	9.6	60.0
14.4	90.0	9.2	57.5
14.0	87.5	8.8	55.0
13.6	85.0	8.4	52.5
13.2	82.5	8.0	50.0

PERFORMANCE CHARACTERISTICS

Performance of the reagent depends on the reagent itself and also depends on method and analyzer used.

The results indicated are obtained using a manual method.

Sensitivity, as detection limit: 2.0 g/dL

Linearity: Up to 25 g of hemoglobin/dL

Accuracy: 95.2 %.

Repetitivity as Variation Coefficient: 2.74%

Reproducibility, as Variation Coefficient: 2.98%

Trueness: Results obtained with this reagent did not show systematic differences when compared with reference reagent

Details of the performance studies are available on request

INTERFERENCES

No interferences are known.

The use of disposable equipment is recommended to prevent unwanted contamination.

REFERENCES

Van Kampen, E.J., Zijlstra, W.G.(1961). Clin. Chim. Acta, 6, 538-544.

International Committee for Standarization in Haematology (1978). J.Clin. Path., 31, 139-143.

CE

TOTAL PROTEIN

BIURET METHOD

For "in vitro" determination of Total Proteins in serum or plasma

PRINCIPLE

In alkaline solution, the proteins form with copper(II) ions a colored complex, highly stable, which is spectrophotometrically measurable and proportional to the concentration of protein in the sample.

DIAGNOSTIC USE

The determination of the total protein in serum are used in the study of the nutritional status or edematous processes.

Total protein levels are high (> 9.0g/dl) in: Hyperimmunoglobulinaemia, mono or polyclonal gammopathy, dehydration, chronic liver disease and and neoplasms, especially myeloma

The values lower than 6.0 g/dl are associated with protein loss in cases of gastroenteropathies, burns, nephrotic syndrome or due to decreased protein synthesis in chronic liver disease, malabsorption syndrome, agammaglobulinemia or malnutrition.

In cases of pregnancy, administration of intravenous fluids, chronic alcoholism, heart failure or hyperthyroidism, the blood protein values are also lower than normal.

Single test result could not be used to make a clinical diagnosis. It should integrate clinical and laboratory data.

REAGENTS

Kit 3 x 100 ml. (Ref. 99 71 80). Contents:
A. 3 x 100 ml Biuret reagent. Ref. 99 96 02
B. 1 x 5 ml Standard. Ref. 99 02 46

WORKING REAGENT PREPARATION

Reagent and standard are ready to use.

REAGENT COMPOSITION

The reagent composition is as follows:

NaOH	0.47 M
Potassium iodide	23.3 mM
Copper (II) sulphate	6.5 mM
Sodium-Potassium Tartrate	22.1 mM
Preservatives and stabilizers	

Standard: Aqueous solution of Proteins equivalent to 5 g/dl (50 g/L).

STORAGE AND STABILITY

When kept at room temperature (≤ 25ºC), the reagent will remain stable until the expiration date stated on the label.
The Standard, however, should be stored at 2°-8° C.
It is therefore recommended, to take the standard out of the kit box and store it accordingly.

Signs of reagent deterioration:
Presence of particles or turbidity in the reagent.
Working reagent blank >0.300

ADDITIONAL EQUIPMENT

General laboratory equipment.
Spectrophotometer or photometer with a 540 nm filter. Cuvette: 1 cm light path

CAUTION

The reagent contains Sodium azide at 0.09%. Handle with care.
The security statements are on the label. It is advisable to look at the MSDS before using the reagent.
The disposal of the residues has to be made according to legal local regulations.

SAMPLE

Serum or plasma, free from haemolysis. The sample will remain stable for up to 5 days, when kept at 2-8ºC.
When using other corporal fluids as sample (amniotic liquid, urine, exudates, etc) it is advisable to take into account the margin values to test and the sensitivity of the reagent. See Performance characteristics.

PROCEDURE

Technique	BL	ST	SA
	ml	ml	ml
Sample	—	—	0.02
Standard	—	0.02	—
Reagent	1.00	1.00	1.00

Mix well and let stand for 10 min. at room temperature (20-25ºC).

Reading
Wavelength: 540 nm.
Blank: BL contents.
Colour stability. a minimum of 3 hours.

CALCULATIONS

$$\frac{\text{SA Abs}}{\text{ST Abs}} \times 5 = \text{g of proteins / dl}$$

Where:
SA Abs: Sample Absorption
ST Abs: Standard Absorption

SI Units
(g/dl) x 10 = g/L

REFERENCES VALUES

Adults: 6.4-8.3 g/dl
Children
Newborns: 4.6-7.0 g/dl
< 1 year: 5.1 - 7.3 g/dl
1 - 2 years: 5.6 - 7.5 g/dl
> 3 years: 6,0 - 8.0 g/dl

The stated values are for guidance. Each particular laboratory should establish its own reference range.

PERFORMANCE CHARACTERISTICS

Performance of the reagent depends on the reagent itself and also depends on method and analyzer used.
The results indicated are obtained using a manual method.

Sensitivity, as detection limit: 0.10 g/dl
Linearity: Up to 12g/dL. For higher values, it is recommended to dilute the sample with saline (NaCl 0.9%) and assay once again. Multiply the final result by dilution factor.
Accuracy: 98.7 %.
Repetitivity as Variation Coefficient: 0.85%
Reproducibility, as Variation Coefficient: 1.13%
Trueness: Results obtained with this reagent did not show systematic differences when compared with reference reagent.
Details of the performance studies are available on request

INTERFERENCES

No interferences are known
The use of disposable equipment is recommended to prevent unwanted contamination.

QUALITY CONTROL

It is recommended to include control sera, Seriscann Normal (Normal Control Serum) (Ref. 99 41 48) and Seriscann Abnormal (Abnormal Control Serum) (Ref. 99 46 85),in each test series for assuring the obtained values .

Each particular laboratory should establish its own quality control program and measures for avoiding results deviations

AUTOANALYZERS

Adaptations to different autoanalyzers are available on request.

REFERENCES

Wiechselbaum, T.E. (1946). Am. J. Clin. Pathol., 16, 40 - 49.
Gornall, A.G., Bardawill, C.J., David, M.M. (1948). Biol. Chem., 177, 751-766.
Peters, T. (1968). Clin. Chem., 14, 1147-1159.

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vision: February 2014

BILIRUBIN (TOTAL AND DIRECT)
BILIRUBIN (TOTAL) BILIRUBIN (DIRECT)

CE

267 X Lyon

REF 1110005	REF 1111010	REF 1112005
BD 2 x 50 mL	BT 2 x 100 mL	B (T+D) 2 x 100 mL
CONTENTS	CONTENTS	CONTENTS
RD.Reagent 2 x 40 mL RN.Reagent 1 x 20 mL CAL 1 x 1 mL	RT.Reagent 2 x 80 mL RN.Reagent 2 x 20 mL CAL 1 x 1 mL	RT.Reagent 1 x 80 mL RD.Reagent 1 x 80 mL RN.Reagent 2 x 20 mL CAL 1 x 1 mL
For *in vitro* diagnostic use only		

BILIRUBIN

TOTAL AND DIRECT
Colorimetric method
END POINT

PRINCIPLE

Bilirubin is converted to coloured azobilirubin by diazotized sulfanilic acid and is measured photometrically. Of the two bilirubin fractions in serum –bilirubin-glucuronide and free bilirubin which is bound to albumin– only the former reacts directly, while free albumin reacts after being displaced from protein by an accelerator. The difference of two measurements total bilirubin (with accelerator) and direct bilirubin (without accelerator) enables the calculation of indirect bilirubin. The terms «direct» and «indirect» bilirubin refers exclusively to the reaction characteristics in the presence or absence of an accelerator or solubilizer and are only approximate equivalents of the two bilirubin fractions.[1,2]

REAGENT COMPOSITION

RT *Sulfanilic acid 29 mmol/L, hydrochloric acid 0.24 mol/L, Duposol® 3% (w/v).*

RD Sulfanilic acid 29 mmol/L, hydrochloric acid 0.24 mol/L.

RN Sodium nitrite 11.6 mmol/L.

CAL **Bilirubin Calibrator.**
Bilirubin freeze-dried into a protein matrix. Concentration value is traceable to Certified Reference Material CRM 909b (NIST). The concentration of total T and direct D Bilirubin is stated on the label and is lot-specific. The target values are derived using LINEAR reagents on the Cobas Mira.®

STORAGE AND STABILITY

Store at 2-8ºC.
All the kit compounds are stable until the expiry date stated on the label. Do not use reagents over the expiration date.
Store the vials tightly closed, protected from light and prevented contaminations during the use.
Discard if appear signs of deterioration:
- Presence of particles and turbidity.
- Blank absorbance (A) at 540 nm > 0.050 in 1cm cuvette.
- Reagent RN if it develops a yellow coloration.

REAGENT PREPARATION

Working reagents. Mix 1 mL RN + 4 mL RT (Total) or 1 mL RN + 4 mL RD (Direct). Stable for 8 days at 2-8ºC.
Calibrator. Reconstitute the vial by adding exactly 1.0 mL of distilled water. Mix carefully and let stand for 5-10 minutes before use. The stability of bilirubin in the dark is: 8 hours 16-25ºC, 2 days 2-8ºC and 28 days –20ºC frozen once.

SAMPLES

Fresh hemolysis-free serum.
Store in the dark until use.
Samples can be frozen at –15ºC or below in which case bilirubin is stable for 2 months.

INTERFERENCES

- Lipemia (intralipid < 5 g/L) does not interfere.
- Direct Bilirubin. (Hemoglobin 2 g/L) may affect the results.
- Total Bilirubin. (Hemoglobin 16 g/L) does not interfere.
- Other drugs and substances may interfere[3].
- Lipemic samples interfere with the assay. The interference can be corrected by preparing a sample blank before applying the general formula of calculation.

MATERIALS REQUIRED

- Photometer or colorimeter capable of measuring absorbance at 540 ± 20 nm.
- Constant temperature incubator set at 37ºC. Use the same temperature for assay of calibrator, controls and samples.
- Pipettes to measure reagent and samples.

PROCEDURE

TOTAL BILIRUBIN

1. Pipette into labelled tubes:

TUBES	Reagent Blank	Sample Blank	Sample	CAL
Distilled water	100 µL	–	–	–
Sample	–	100 µL	100 µL	–
CAL	–	–	–	100 µL
RT	–	1.0 mL	–	–
Working reagent	1.0 mL	–	1.0 mL	1.0 mL

2. Mix thoroughly and let the tubes stand for 2 minutes at room temperature.
3. Read the absorbance (A) of the sample blanks at 540 nm against distilled water.
4. Read the absorbance (A) of the samples at 540 nm against the reagent blank.

The color is stable for at least 60 minutes at room temperature.

DIRECT BILIRUBIN

1. Pipette into labelled tubes:

TUBES	Reagent Blank	Sample Blank	Sample	CAL
Distilled water	100 µL	–	–	–
Sample	–	100 µL	100 µL	–
CAL	–	–	–	100 µL
RD	–	1.0 mL	–	–
Working reagent	1.0 mL	–	1.0 mL	1.0 mL

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...Mª Claret, 8 bis. 08390 Montgat – Barcelona (Spain)

2. Mix thoroughly and let the tubes stand for exactly 5 minutes at 37°C.
3. Read the absorbance (A) of the sample blanks at 540 nm against distilled water.
4. Read the absorbance (A) of the samples at 540 nm against the reagent blank.

CALCULATIONS

$$\frac{A_{Sample} - A_{Sample\ blank}}{A_{Cal}} \times C_{Cal} = \text{mg/dL total or direct bilirubin}$$

Samples with concentrations higher than 20 mg/dL should be diluted 1:2 with saline and assayed again. Multiply results by 2.

If results are to be expressed as SI units apply:
mg/dL x 17.1 = µmol/L

REFERENCE VALUES[4]

ADULTS

Total	Up to 1.0 mg/dL
Direct	Up to 0.2 mg/dL

NEWBORNS (TOTAL BILIRUBIN)

Age	Premature	Full- term
Up to 24 h	1.0 - 6.0 mg/dL	2.0 - 6.0 mg/dL
Up to 48 h	6.0 - 8.0 mg/dL	6.0 - 7.0 mg/dL
3-5 days	10.0 - 15.0 mg/dL	4.0 - 12.0 mg/dL

It is recommended that each laboratory establishes its own reference range.

QUALITY CONTROL

The use of a standard to calculate results allows to obtain an accuracy independent of the system or instrument used.
To ensure adequate quality control (QC) each run should include a set of controls (normal and abnormal) with assayed values handled as unknowns.

REF **1980005** HUMAN MULTISERA NORMAL
Borderline level of bilirubin. Assayed.

REF **1985005** HUMAN MULTISERA ABNORMAL
Elevated level of bilirubin. Assayed.

If the values are found outside of the defined range, check the instrument, reagents and procedure.
Each laboratory should establish its own Quality Control scheme and corrective actions if controls do not meet the acceptable tolerances.

CLINICAL SIGNIFICANCE

Hyperbilirubinemia (an abnormal elevation of bilirubin, whether conjugated or unconjugated) in plasma is an indication of a disturbance in bilirubin metabolism. This condition is caused either by an overproduction of bilirubin or by an impairment in the metabolic pathway. The increase in bilirubin production is usually caused by a rapid destruction of erythrocytes, *resulting from blood* diseases such as haemolilytic anemia. *In newborns the increase in* bilirubin may be caused by Rh, ABO, or *other blood group* incompatibility, by sepsis, hepatic immaturity, or by a variety of hereditary defects in bilirubin conjugation.
An impairment in the bilirubin metabolism is caused either by an enzyme deficiency or by a physical obstruction in bilirubin flow such as biliary (bile duct) obstruction. The hyperbilirubinemia leads to *kernicterus* (deposition of unconjugated bilirubin in brain and nerve cells) or *jaundice* (discoloration of mucus membranes, sclera and skin caused by the deposition of bilirubin pigment).

NOTES

- For bilirubin determination in newborns pipette 50 µL of sample or standard, and follow the exposed procedure.
- These reagents may be used in several automatic analyzers. Instructions for many of them are available on request.
- This method may be used with different instruments. Any application to an instrument should be validated to demonstrate that results meet the performance characteristics of the method. *It is recommended to validate periodically the instrument. Contact to the distributor for any question on the application method.*

ANALYTICAL PERFORMANCE

- ***Detection Limit (Direct Bilirubin) :*** 0.09 mg/dL
- ***Detection Limit (Total Bilirubin) :*** 0.03 mg/dL
- ***Linearity :*** Up to 20 mg/dL
- ***Precision:***

	Direct Bilirubin				Total Bilirubin			
mg/dL	Within-run		Between-run		Within-run		Between-run	
Mean	0.79	1.82	0.79	1.82	1.61	4.85	1.61	4.85
SD	0.03	0.06	0.03	0.07	0.03	0.05	0.05	0.11
CV%	4.23	3.02	4.28	4.11	2.00	1.13	3.28	2.32
N	10	10	10	10	10	10	10	10

- ***Sensitivity (Direct Bilirubin) :*** 0.171 A / mg/dL
- ***Sensitivity (Total Bilirubin) :*** 0.073 A / mg/dL
- ***Correlation (Total Bilirubin) :*** This assay (y) was compared with a similar commercial method (x). The results were:

  N = 52 r = 0.96 y = 0.99x + 0.113

  The analytical performance has been generated using on automatic instrument. Results may vary depending on the instrument.

REFERENCES

1. Walters, M.I. and Gerarde, H.W. Microchemical Journal. 15, 231 (1970).
2. Pearlman, F.C. and Lee, R.T.Y. Clin. Chem. 20/4, 447 (1974).
3. Young DS. Effects of drugs on clinical laboratory tests, 5th ed. AACC Press, 2000.
4. Tietz, N.W., Fundamentals of Clinical Chemistry, p.940. W.B. Saunders Co., Philadelphia , 1987.

CHOLESTEROL LIQUID

CHOD - POD METHOD

For "in vitro" determination of Cholesterol in serum or plasma.

QUÍMICA CLÍNICA APLICADA S.A.

PRINCIPLE

Cholesterol present in serum or plasma, originates a coloured complex, according to the following reactions, which can be quantified by spectrophotometry.

$$\text{Cholesterol esters} + H_2O \xrightarrow{\text{Chol. Esterase}} \text{Cholesterol} + \text{Fatty acids}$$

$$\text{Cholesterol} + H_2O + O_2 \xrightarrow{\text{Col. Oxidasa}} \text{Cholestenone} + H_2O_2$$

$$H_2O_2 + \text{4-Aminoantipyrine} + \text{3,5 – Dichlorophenol} \xrightarrow{\text{POD}} \text{Coloured quinonic derivative} + 4\,H_2O$$

DIAGNOSTIC USE

The cholesterol in serum or plasma can be of exogenous origin, ingested with the diet, or endogenous synthesized primarily in the liver. It is transported by lipoproteins and it is excreted in the bile.

The study of the serum cholesterol level allows the detection and classification of the hyperlipidemia and risk assessment for heart disease.

Cholesterol levels are low in hypolipoproteinemia, hyperthyroidism and in some anemia.

Single test result cannot be used to make a clinical diagnosis. It should integrate clinical and laboratory data.

REAGENTS

Kit 1 x 100 ml. (Ref. 99 52 82). Contents:

A. 1 x 100 ml. Reagent. — Ref. 99 52 20

B. 1 x 5 ml. Standard. — Ref. 99 02 48

Kit 3 x 100 ml. (Ref. 99 52 80). Contents:

A. 3 x 100 ml. Reagent. — Ref. 99 52 20

B. 1 x 5 ml. Standard. — Ref. 99 02 48

Kit 2 x 250 ml. (Ref. 99 50 12). Contents:

A. 2 x 250 ml. Reagent. — Ref. 99 01 59

B. 1 x 5 ml. Standard. — Ref. 99 02 48

WORKING REAGENT PREPARATION

Reagent and standard are ready to use.

WORKING REAGENT COMPOSITION

Concentration in the reagent solution is:

Mes buffer pH 6.5	75 mM
Phenol	6 mM
2,4-Dichlorophenol	0.2 mM
4-Aminoantipyrine	0.5 mM
Cholesterol Esterase	≥ 500 kU/L
Cholesterol Oxidase	≥ 300 kU/L
Peroxidase	≥ 1200 kU/L
Non reactive Stabilizers	

Standard: Solution of Cholesterol in isopropanol/water equivalent to 200 mg/dl (5.18 mmol/L).

STORAGE AND STABILITY

The components of the kit, when stored at 2-8ºC, will remain stable until the expiration date stated on the label.

Signs of reagent deterioration:

Presence of particles or turbidity in the reagent.

Working reagent blank >0.500

ADDITIONAL EQUIPMENT

General laboratory equipment.

Spectrophotometer or photometer thermostable at 37ºC.

SAMPLE

Serum, or plasma. Samples are stable 1 week at 2-8ºC, and up to three months at -20º C.

CAUTION

The reagent contains phenol. Handle with care. The safety statements are on the label. It is advised to read SDS before reagent handling. Waste products must be handled as per local regulations.

QUALITY CONTROL

Control serum, Seriscann Normal (Ref. 99 41 48) and Seriscann Anormal (Ref. 99 46 85) should be included in each test series. Each particular laboratory should establish its own control program.

AUTOANALYZERS

Adaptations to different autoanalyzers are available on request.

PROCEDURE

Procedure	BL ml	SA ml	ST ml
Sample	--	0.01	--
Standard	--	--	0.01
Working Reagent	1.00	1.00	1.00

Mix well and let stand for 5 min. at 37ºC, or 10 min at room temperature (20 - 25ºC).

Reading

Wavelength: 546 nm, 505 nm.

Blank: the contents of BL.

Colour stability: 1 hour (when protected from direct sunlight)

CALCULATIONS

$$\frac{\text{SA Abs.}}{\text{ST Abs.}} \times 200 = \text{mg Cholesterol/dl}$$

Where:

SA Abs: Sample Absorption

ST Abs: Standard Absorption

SI Units

(mg/100 dl) x 0.0259 = mmol/L

REFERENCE VALUES

Clinical interpretation

According to the recommendations of the European Atherosclerosis Society.

	Lipid disorder
Cholesterol < 200 mg/dl Triglycerides < 200 mg/dl	NO
Cholesterol 200 - 300 mg/dl Cholesterol-HDL < 35mg/dl	SI
Cholesterol > 300 mg/dl Triglycerides > 200 mg/dl	SI

PERFORMANCE CHARACTERISTICS

The performance characteristics depend on the method used. It is recommended to calculate these data for each particular test protocol. These results have been obtained using a manual method.

Sensitivity, as detection limit: 2 mg/dl

Linearity: 700 mg/dl. For higher concentrations dilute the sample 1/2 with saline (NaCl 0.9%). Multiply the final result by 2.

Accuracy: 98.6%

Repetitivity, as CV%: 0.87%

Reproducibility, as CV%: 1.44%

Trueness: Results obtained with this reagent did not show systematic differences when compared with reference reagent.

Details of the performance studies are available on request

INTERFERENCES

There are no interferences by Hemoglobin ut to 200 mg/dl, as well by Bilirubin up to 15 mg/dl.

Do not pipette directly from the bottle of reagent, to avoid undesirable contamination.

REFERENCES

Fiedewald, W., Levy, R., Fredrickson, D.S. (1972). Clin.Chem, 18, 499-502.

Allain,.C.C.,Poon. L.S.,Chan,C.S.G.,Richmond,W., Fu.P.C. (1974) Clin. Chem., 20, 470-475.

Zoppi, F., Fellini.D. (1976), Clin. Chem., 22, 690-691.

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Revision: July 2013

CE

COD 11790 1 x 50 mL	4 x 50 mL
STORE AT 2-8°C	
Reagents for measurement of CK concentration Only for *in vitro* use in the clinical laboratory	

CE

CREATINE KINASE (CK)
IFCC

PRINCIPLE OF THE METHOD

Creatine kinase (CK) catalyzes the phosphorylation of ADP, in the presence of creatine phosphate, to form ATP and creatine. The catalytic concentration is determined from the rate of NADPH formation, measured at 340 nm, by means of the hexokinase (HK) and glucose-6-phosphate dehydrogenase (G6P-DH) coupled reactions[1].

$$\text{Creatine phosphate} + \text{ADP} \xrightarrow{\text{CK}} \text{Creatine} + \text{ATP}$$

$$\text{ATP} + \text{Glucose} \xrightarrow{\text{HK}} \text{ADP} + \text{Glucose - 6 - phosphate}$$

$$\text{Glucose - 6 - phosphate} + \text{NADP}^+ \xrightarrow{\text{G6P-DH}} \text{6 - Phosphogluconate} + \text{NADPH} + \text{H}^+$$

CONTENTS

	COD 11790	COD 11791
A. Reagent	1 x 40 mL	4 x 40 mL
B. Reagent	1 x 10 mL	4 x 10 mL

COMPOSITION

A. Reagent: Imidazol 125 mmol/L, EDTA 2 mmol/L, magnesium acetate 12.5 mmol/L, D-glucose 25 mmol/L, N-acetyl cysteine 25 mmol/L, hexokinase 6000 U/L, NADP 2.4 mmol/L, pH 6.7.

B. Reagent: Creatine phosphate 250 mmol/L, ADP 15 mmol/L, AMP 25 mmol/L, P1,P5-di(adenosine-5'-)pentaphosphate, 102 µmol/L, glucose-6-phosphate dehydrogenase 8000 U/L.

STORAGE

Store at 2-8°C.

Reagents are stable until the expiry date shown on the label when stored tightly closed and if contaminations are prevented during their use.

Indications of deterioration:

– Reagents: Presence of particulate material, turbidity, absorbance of the blank over 0.300 at 340 nm (1 cm cuvette).

REAGENT PREPARATION

Working Reagent: Pour the contents of the Reagent B into the Reagent A bottle. Mix gently. Other volumes can be prepared in the proportion: 4 mL Reagent A + 1 mL Reagent B.

Stable for 15 days at 2-8°C. The working reagent must be protected from light.

ADDITIONAL EQUIPMENT

– Analyzer, spectrophotometer or photometer with cell holder thermostatable at 25, 30 or 37°C and able to read at 340 nm.

– Cuvettes with 1 cm light path.

SAMPLES

Serum collected by standard procedures.

Creatine kinase in serum is stable for 7 days at 2-8°C.

PROCEDURE

1. Bring the Working Reagent and the instrument to reaction temperature.
2. Pipette into a cuvette: (Note 1)

Sample	50 µL
Working Reagent	1.0 mL

3. Mix and insert the cuvette into the photometer. Start the stopwatch.
4. After 3 minutes, record initial absorbance and at 1 minute intervals thereafter for 3 minutes.
5. Calculate the difference between consecutive absorbances, and the average absorbance difference per minute (ΔA/min).

CALCULATIONS

The CK concentration in the sample is calculated using the following general formula:

$$\Delta A/\text{min} \times \frac{Vt \times 10^6}{\varepsilon \times l \times Vs} = \text{U/L}$$

The molar absorbance (ε) of NADPH at 340 nm is 6300, the lightpath (l) is 1 cm, the total reaction volume (Vt) is 1.05, the sample volume (Vs) is 0.05, and 1 U/L are 16.67 nkat/L. The following formulas are deduced for the calculation of the catalytic concentration:

ΔA/min	x 3333 = U/L x 55561 = nkat/L

REFERENCE VALUES

Reaction Temperature	Men[2]		Women[2]	
	U/L	nKat/L	U/L	nKat/L
25°C	10-65	167-1084	7-55	117-917
30°C	15-105	250-1750	10-80	167-1334
37°C	38-174	633-2900	26-140	433-2334

Children have higher CK concentrations than adults[2]. These ranges are given for orientation only; each laboratory should establish its own reference ranges.

QUALITY CONTROL

It is recommended to use the Biochemistry Control Serum level I (cod. 18005, 18009 and 18042) and II (cod. 18007, 18010 and 18043) to verify the performance of the measurement procedure.

Each laboratory should establish its own internal Quality Control scheme and procedures for corrective action if controls do not recover within the acceptable tolerances.

METROLOGICAL CHARACTERISTICS

– Detection limit: 9.2 U/L = 153 nkat/L

– Linearity limit: 1300 U/L = 21671 nkat/L. For higher values dilute sample 1/2 with distilled water and repeat measurement.

– Repeatibility (within run):

Mean Concentration	CV	n
175 U/L = 2917 nkat/L	1.8 %	20
567 U/L = 9452 nkat/L	0.7 %	20

– Reproducibility (run to run):

Mean Concentration	CV	n
175 U/L = 2917 nkat/L	1.3 %	25
567 U/L = 9452 nkat/L	1.1 %	25

– Sensitivity: 0.3 ΔmA·L/U·min = 5 ΔmA·L/nkat·min

– Trueness: Results obtained with this reagent did not show systematic differences when compared with reference reagents. Details of the comparison experiments are available on request.

– Interferences: Bilirubin (< 20 mg/dL) and hemoglobin (< 10 g/L) do not interfere. Lipemia (triglycerides > 5 g/L) interfere. Other drugs and substances may interfere[3].

These metrological characteristics have been obtained using an analyzer. Results may vary if a different instrument or a manual procedure are used.

DIAGNOSTIC CHARACTERISTICS

Creatine kinase (CK) plays an important role in muscle by providing ATP, when muscle contracts, from ADP and using creatine phosphate as the phosphorylation reservoir.

Serum CK originates mainly in muscle and its concentration is subject to a number of physiological variations (sex, age, muscle mass, physical activity and race).

Serum CK concentration is greatly elevated in patients with some diseases of skeletal muscle (muscular distrofy, myositis, polymyositis, malignant hyperthermia, trauma, acute rhabdomyolysis), of the central nervous system (acute cerebrovascular disease, cerebral ischemia, Reye's syndrome) and of the thyroid (hypothyroidism)[2,4].

After a myocardial infarction, CK elevation begins in 3-6 hours and peaks at 24-36 hours. The enzyme is rapidly cleared from the plasma, so that it is common for the activity to return to normality in 3-4 days[2,4].

Clinical diagnosis should not be made on the findings of a single test result, but should integrate both clinical and laboratory data.

NOTES

1. These reagents may be used in several automatic analysers. Instructions for many of them are available on request.

BIBLIOGRAPHY

1. IFCC methods for the measurement of catalytic concentration of enzymes. Part 7: IFCC method for creatine kinase. JIFCC 1989; 1: 130-139.
2. Tietz Textbook of Clinical Chemistry, 3rd edition. Burtis CA, Ashwood ER. WB Saunders Co., 1999.
3. Young DS. Effects of drugs on clinical laboratory tests, 3th ed. AACC Press, 1997.
4. Friedman and Young. Effects of disease on clinical laboratory tests, 3th ed. AACC Press, 1997.

HIERRO-CAB

MÉTODO CON CROMAZUROL B

Para la determinación “in vitro” de hierro en suero o plasma

QUÍMICA CLÍNICA APLICADA S.A.

PRINCIPIO

El hierro sérico, en presencia de Cromazurol B (CAB) y bromuro de cetil-trimetilamonio (CTMA), forma un complejo coloreado que se puede cuantificar espectrofotométricamente a 620 nm. La intensidad del color producido es proporcional a la concentración de hierro en la muestra.

UTILIDAD DIAGNÓSTICA

El hierro se encuentra distribuido en el organismo, mayoritariamente formando parte de la hemoglobina y de la mioglobina.

Valores bajos de hierro se encuentran en anemia por deficiencia de hierro y por enfermedades infecciosas. Se encuentran valores elevados de hierro en enfermedades hepáticas, hemocromatosis y en concentraciones elevadas de transferrina.

Una única prueba de laboratorio no permite establecer un diagnóstico. Los resultados se han de evaluar en el contexto de todos los datos clínicos y de laboratorio obtenidos

REACTIVOS

Kit 2 x 100 mL. (Ref. 99 11 83). Contiene:

A. 2 x 100 mL Reactivo CAB	Ref. 99 12 00
B. 1 x 5 mL Estándar	Ref. 99 02 90

PREPARACIÓN DEL REACTIVO DE TRABAJO

El reactivo y standard están listos para su uso.

COMPOSICIÓN DEL REACTIVO

Las concentraciones en la disolución reactiva son:

Tampón acetato pH 4,7	50 mM
CAB	0,16 mM
CTMA	2,5 mM
Cloruro de guanidinio	2,1 M
Conservantes y estabilizantes	

Estándar: Disolución acuosa de hierro equivalente a 200 µg/dL (35,8 µmol/L).

ADVERTENCIA

El estándar incluído en el kit ha sido ajustado para el lote del reactivo.

Si se desea, en lugar del estándar, puede utilizarse un calibrador tipo sérico (QCA Ref. 99 62 80).

CONSERVACIÓN Y ESTABILIDAD

Los componentes del kit mantenidos a temperatura ambiente (≤ 25ºC), son estables hasta la fecha de caducidad indicada en la etiqueta. Una vez abierto el reactivo es estable durante 6 semanas a temperatura ambiente (≤ 25ºC).

Indicaciones de alteración de los reactivos:

Presencia de partículas o turbidez. Blanco del reactivo de trabajo > 0,600.

MATERIAL NECESARIO NO SUMINISTRADO

Material común de laboratorio

Espectrofotómetro, analizador automático o fotómetro.

MUESTRA

Suero exento de hemólisis o plasma.

El hierro sérico es estable durante 7 días a 2 - 8ºC.

PRECAUCIONES

Las indicaciones de seguridad se encuentran en la etiqueta de los productos. Manipular con precaución.

Se aconseja consultar la ficha de datos de seguridad antes de la manipulación del reactivo.

La eliminación de residuos debe hacerse según la normativa local vigente.

CONTROL DE CALIDAD

Es recomendable la inclusión de sueros control, Seriscann Normal (Ref. 99 41 48) y Seriscann Anormal (Ref. 99 46 85), en cada proceso de medida para verificar los resultados.

Se aconseja que cada laboratorio establezca su propio programa de control de calidad y los procedimientos de corrección de las desviaciones en las medidas.

AUTOANALIZADORES

Adaptaciones a distintos analizadores automáticos, disponibles bajo demanda.

PROCEDIMIENTO

Técnica	BL mL	ST mL	PR mL
Muestra	--	--	0,05
Standard	--	0,05	--
Reactivo	1,00	1,00	1,00

Mezclar bien e incubar 10-15 min a temperatura ambiente (20-25ºC).

Lectura

Longitud de onda: 620 nm

Blanco: el contenido del tubo BL

Estabilidad del color: un mínimo de 90 min

CÁLCULOS

$$\frac{\text{Abs. PR}}{\text{Abs. ST}} \times 200 = \text{µg de hierro / dL}$$

Donde:

Abs. PR: Absorbancia de la muestra

Abs. ST: Absorbancia del estándar

Unidades SI

(µg/dL) x 0,1791 = µmol/L

VALORES DE REFERENCIA

Hombres: 60 - 160 µg/dL

Mujeres: 37 - 145 µg/dL

Estos valores son orientativos. Se recomienda que cada laboratorio establezca sus propios valores de referencia.

PRESTACIONES. CARACTERÍSTICAS DE FUNCIONAMIENTO

Las características de funcionamiento de un producto dependen tanto del reactivo como del sistema de lectura empleado.

Los resultados siguientes se han obtenido de forma manual.

Sensibilidad, como límite de detección: 15 µg/dL

Linealidad: Hasta 500 µg/dL. Para concentraciones superiores, diluir la muestra con agua desionizada (1+1). Multiplicar el resultado final por 2.

Exactitud, como % de recuperación: 104,2%

Precisión en la serie, como CV%: 2,24%

Precisión entre series, como CV%: 1,10%

Veracidad. Los resultados obtenidos con el reactivo no presentan diferencias significativas al compararlo con el reactivo considerado de referencia.

Los datos detallados del estudio de las prestaciones del reactivo están disponibles bajo demanda.

INTERFERENCIAS

No utilizar muestras hemolizadas.

Las concentraciones de bilirrubina hasta 15 mg/dL y cobre hasta 500 µg/dL no interfieren en el test.

Debe evitarse la contaminación por hierro del material a utilizar, por lo que se recomienda el uso de material de plástico desechable.

Se desaconseja la introducción de pipetas en el frasco de reactivo, para evitar contaminaciones.

BIBLIOGRAFÍA

Ihara, K., Hasegawa, S., Naito, K. (2003) Anal. Sci., 19, 265-268.

Tabacco, A., Moda, E., Tarli, P., Veri, P., (1981) Clin. Chim. Acta, 114, 287-290.

Brivio, G., Brega, A., Torelli, G., (1986) La Ricerca Clin. Lab. 16, 523-532.

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Revisión: 01.2017

PRO4_REG9_FECAB_6A

CE

IRON - CAB

CHROMAZUROL B METHOD

For “in vitro” determination of iron in serum or plasma

QUÍMICA CLÍNICA APLICADA S.A.

PRINCIPLE

Iron reacts with Chromazurol B and cetyltrimethyl-ammonium bromide (CTMA) to form a coloured ternary complex with an absorbance maximum at 620 nm. The intensity of the colour produced, is directly proportional to the concentration of iron in the sample.

DIAGNOSTIC USE

Iron is distributed in the body forming part of hemoglobin and myoglobin.
Low iron concentations are found in infectious diseases and anemia. High levels of iron are presented in liver disease, hemochromatosis, and at high levels of Transferrin.

Single test result could not be used to make a clinical diagnosis. It should integrate clinical and laboratory data.

REAGENTS

Kit 2 x 100 mL. (Ref. 99 11 83). Contents:

A. 2 x 100 mL CAB reagent	Ref. 99 12 00
B. 1 x 5 mL Standard	Ref. 99 02 90

WORKING REAGENT PREPARATION

Reagent and standard are ready to use.

REAGENT COMPOSITION

The reagent´s composition is as follows:

Sodium acetate buffer pH 4.7	50 mM
CAB	0.16 mM
CTMA	2.5 mM
Guanidinium chloride	2.1 M
Preservatives and stabilizers	

Standard: Aqueous solution of iron equivalent to 200 µg/dL (35.8 µmol/L).

> **WARNING**
> The standard included in the kit has been adjusted for the reagent. If desired you can use a serum-based calibrator. (QCA Ref. 99 62 80).

STORAGE AND STABILITY

When stored at room temperature (≤ 25ºC), the components of this kit will remain stable until the expiration date stated on the label. Once opened the CAB reagent is stable for 6 weeks at room temperature (≤ 25ºC).

Signs of reagent deterioration:

Presence of particles or turbidity in the reagent. Working reagent blank > 0.600.

ADDITIONAL EQUIPMENT

General laboratory equipment.
Spectrophotometer or photometer or autoanalyzer .

SAMPLE

Non hemolyzed serum or plasma.
Serum iron is stable for up to 7 days at 2-8ºC.

CAUTION

The safety statements are on the label. Handle with care.
We advice to read MSDS before reagent handling.
Waste products must be handled as per local regulations.

QUALITY CONTROL

Control serum, Seriscann Normal (Ref. 99 41 48) and Seriscann Abnormal (Ref. 99 46 85) should be included in each test series.
Each particular laboratory should establish its own control program.

AUTOANALYZERS

Adaptations to different autoanalyzers are available on request.

PROCEDURE

Technique	BL mL	ST mL	SA mL
Sample	--	--	0.05
Standard	--	0.05	--
Reagent	1.00	1.00	1.00

Mix well and incubate 10-15 min at room temperature (20-25ºC).

Reading

Wavelength: 620 nm
Blank: Contents of BL
Colour stability: 90 min

CALCULATIONS

$$\frac{\text{SA Abs}}{\text{ST Abs}} \times 200 = \text{µg de hierro / dL}$$

Where:
SA Abs: Sample Absorbance
ST Abs: Standard Absorbance

SI Unit

(µg/dL) x 0,1791 = µmol/L

REFERENCES VALUES

Men: 60 - 160 µg/dL
Women: 37 - 145 µg/dL

The stated values are for guidance. It is advisable that each laboratory determines its own reference values.

PERFORMANCE CHARACTERISTICS

The performance characteristics depend on the method used. It is recommended to calculate these data for each particular test protocol. These results have been obtained using a manual method.

Sensitivity, as detection limit: 15 µg/dL
Linearity: 500 µg/dL. Samples that give higher concentration should be diluted in deionised water (1+1) and the final result has to be multiplied per 2.
Accuracy: 104.2%
Repetitivity, as CV%: 2.24%
Reproducibility, as CV%: 1.10%
Trueness: Results obtained with this reagent did not show systematic differences when compared with reference reagent.

Details of the performance studies are available on request.

INTERFERENCES

Hemolyzed serum samples should be discarded.
Concentrations of bilirubin up to 15 mg/dL and copper up to 500 µg/dL do not interfere with the assay.

It is recommended to use disposable plasticware to run the tests to avoid any possible undesirable contamination.
Do not introduce pipettes into the reagent bottle, to avoid any possible undiserable contamination.

REFERENCES

Ihara, K., Hasegawa, S., Naito, K. (2003) Anal. Sci., 19, 265-268.
Tabacco, A., Moda, E., Tarli, P., Veri, P., (1981) Clin. Chim. Acta, 114, 287-290.
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CE

FER - CAB

MÉTHODE UTILISANT LE CHROMAZUROL B

Pour la détermination in vitro du fer dans le sérum ou le plasma

PRINCIPE

Le fer sérique, en présence de Chromazurol B (CAB) et de bromure de cétyltriméthylammonium (CTMA), forme un complexe coloré quantifiable par spectrophotométrie à 620 nm. L'intensité de la coloration produite est proportionnelle à la concentration de fer présent dans l'échantillon.

UTILITÉ DE DIAGNOSTIC

Le fer contenu dans le corps se trouve dans l'hémoglobine et la myoglobine.
On observe de faibles taux de fer en cas d'anémie ferriprive et anémie due à des maladies infectieuses. Des taux de fer élevés sont observés en cas de maladies du foie, d'hémochromatose et de concentrations élevées de transferrine.

Un test de laboratoire unique ne peut pas établir un diagnostic. Les résultats doivent être évalués dans le contexte de toutes les données cliniques et de laboratoire obtenus.

RÉACTIFS

Kit 2 x 100 mL. (Réf. 99 11 83). Contenu:

A. 2 x 100 mL Réactif CAB.	Réf. 99 12 00
B. 1 x 5 mL Étalon.	Réf. 99 02 90

PRÉPARATION DU RÉACTIF DE TRAVAIL

Réactif et étalon sont prêts à l'emploi.

COMPOSITION DU RÉACTIF

Les concentrations dans la solution réactive sont les suivantes:

Tampon acétate pH 4,7	50 mM
CAB	0,16 mM
CTMA	2,5 mM
Chlorure de guanidinium	2,1 M
Conservateurs et stabilisants	

Étalon: Solution aqueuse de fer équivalente à 200 µg/dL (35,8 µmol/L).

AVERTISSEMENT

L'étalon fourni avec le kit est adapté pour son utilisation avec le lot du réactif.
Si vous le souhaitez, au lieu de l'étalon, vous pouvez utiliser un calibrateur sérique (par ex. QCA Réf. 99 62 80).

CONSERVATION ET STABILITÉ

Conservés à température ambiante (≤ 25ºC), les composants du kit sont stables jusqu'à la date de péremption indiquée sur l'étiquette. Après ouverture, le réactif est stable pendant 6 semaines à température ambiante (≤ 25ºC).

Indications d'altération du réactif:

Présence de particules ou de turbidité. Blanc du réactif de travail > 0,600.

MATÉRIEL NÉCESSAIRE MAIS NON FOURNI

Matériel courant de laboratoire.
Spectrophotomètre, analyseur automatique ou photomètre.

ÉCHANTILLON

Sérum non hémolysé ou plasma.
Le fer sérique est stable pendant 7 jours à une température comprise entre 2 et 8ºC.

PRÉCAUTIONS D'EMPLOI

Les indications de sécurité sont sur l'étiquette des produits. Manipuler avec précaution.
On conseille de consulter la fiche des données de sécurité avant de manipuler le réactif.
L'élimination des déchets doit être effectuée conformément aux normes en vigueur.

CONTRÔLE DE QUALITÉ

Nous recommandons l'inclusion de sérums de contrôle Seriscann normale (Réf. 99 41 48) et Seriscann anormale (Réf 99 46 85) dans chaque processus de mesure pour vérifier les résultats.
Nous suggérons que chaque laboratoire d'établir son propre programme et les procédures de correction des écarts dans les mesures de contrôle qualité.

ANALYSEURS AUTOMATIQUES

Des adaptations à différents analyseurs automatiques sont disponibles sur demande.

TECHNIQUE

Technique	BL mL	ÉTALON mL	ESSAI mL
Échantillon	--	--	0,05
Étalon	--	0,05	--
Réactif	1,00	1,00	1,00

Bien mélanger puis incuber 10 à 15 minutes à température ambiante (20 à 25ºC).

Lecture

Longueur d'onde: 620 nm
Blanc: le contenu du tube BL
Stabilité de la coloration: 90 minutes minimum

CALCULS

$$\frac{\text{Abs. ESSAI}}{\text{Abs. ÉTALON}} \times 200 = \text{µg de fer/dL}$$

Où:
Abs ESSAI: Absorbance de l'éssai
Abs. ÉTALON: Absorbance de l'étalon

Unités SI

(µg/dL) x 0,1791 = µmol/L

VALEURS DE RÉFÉRENCE

Hommes: 60 - 160 µg/dL
Femmes: 37 - 145 µg/dL

Les valeurs données sont indicatives. Il est recommandé que chaque laboratoire établisse ses propres valeurs de référence.

PERFORMANCE. CARACTÉRISTIQUES DE FONCTIONNEMENT

Le fonctionnement du produit dépend tant du réactif que du système de lecture manuel ou automatique utilisé. Les résultats suivants ont été obtenus avec une technique manuelle.

Sensibilité comme limite de détection:15 µg/dL
Linéarité: L'essai est linéaire jusqu'à 500 µg/dL. Pour des valeurs supérieures, diluer l'échantillon avec de l'eau déionisée (1+1). Multiplier le résultat par 2.
Exactitude: le pourcentage de récupération est de 104,2%.
Coefficient de variation dans la série: 2,24 %
Coefficient de variation entre les séries: 1,10%
Justesse. Les résultats obtenus avec le réactif ne sont pas significativement différents par rapport au réactif de référence considéré.

L'étude détaillée de la performance du réactif est disponible sur demande.

INTERFÉRENCES

Ne pas utiliser d'échantillons hémolysés.
Les concentrations de bilirubine jusqu'à 15 mg/dL et de cuivre jusqu'à 500 µg/dL n'interfèrent pas avec l'essai.
Il est recommandé d'éviter la contamination du matériel à utiliser par le fer. L'utilisation de matériel en plastique jetable est par conséquent conseillée.
L'introduction de pipettes dans le flacon de réactif est déconseillée afin d'éviter des contaminations.

BIBLIOGRAPHIE

Ihara, K., Hasegawa, S., Naito, K. (2003) Anal. Sci., 19, 265-268.
Tabacco, A., Moda, E., Tarli, P., Veri, P., (1981) Clin. Chim. Acta, 114, 287-290.
Brivio, G., Brega, A., Torelli, G., (1986) La Ricerca Clin. Lab. 16, 523-532.

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Révision: 01.2017
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HIERRO - CAB
IRON - CAB

A

3, PG III UN: 1993

H226

P210,P233,P280,P303+P361+P353,P370+P378,P403+P235,P501

ES - HIERRO (CAB), REACTIVO

Atención

Peligro: Líquidos y vapores inflamables.
Precaución: Mantener alejado del calor, de superficies calientes, de chispas, de llamas abiertas y de cualquier otra fuente de ignición. No fumar. Mantener el recipiente herméticamente cerrado. Llevar guantes/prendas/gafas/máscara de protección. EN CASO DE CONTACTO CON LA PIEL (o el pelo): Quitar inmediatamente todas las prendas contaminadas. Aclararse la piel con agua/ducharse. En caso de incendio: Utilizar los medios descritos en punto 5 de la Ficha de Datos de Seguridad. Almacenar en un lugar bien ventilado. Mantener en lugar fresco. Eliminar el contenido/el recipiente según el punto 13 de la Ficha de Datos de Seguridad.

GB - IRON (CAB), REAGENT

Warning

Hazard: Flammable liquid and vapour.
Precautionary: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Keep container tightly closed. Wear protective gloves/protective clothing/eye protection/face protection. IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower. In case of fire: Use the means described in point 5 of the Safety Data Sheet. Store in a well-ventilated place. Keep cool. Dispose the contents/container according to point 13 of the Safety Data Sheet.

PT - FERRO (CAB), REAGENTE

Atenção

Perigo: Líquido e vapor inflamáveis.
Precaução: Manter afastado do calor, superfícies quentes, faísca, chama aberta e outras fontes de ignição. Não fumar. Manter o recipiente bem fechado. Usar luvas de protecção/vestuário de protecção/protecção ocular/protecção facial. SE ENTRAR EM CONTACTO COM A PELE (ou o cabelo): retirar imediatamente toda a roupa contaminada. Enxaguar a pele com água/tomar um duche. Em caso de incêndio: Recorra aos meios descritos no ponto 5 da Ficha de Dados de Segurança. Armazenar em local bem ventilado. Conservar em ambiente fresco. Eliminar o conteúdo / recipiente de acordo com o ponto 13 da Ficha de Segurança.

FR - FER (CAB), RÉACTIF

Attention

Danger: Liquide et vapeurs inflammables.
Précaution: Tenir à l'écart de la chaleur, des surfaces chaudes, des étincelles, des flammes nues et de toute autre source d'inflammation. Ne pas fumer. Maintenir le récipient fermé de manière étanche. Porter des gants de protection/des vêtements de protection/un équipement de protection des yeux/du visage. EN CAS DE CONTACT AVEC LA PEAU (ou les cheveux): Enlever immédiatement tous les vêtements contaminés. Rincer la peau à l'eau/Se doucher. En cas d'incendie: Utiliser les moyens décrits au point 5 de la fiche de données de sécurité. Stocker dans un endroit bien ventilé. Tenir au frais. Éliminer le contenu / récipient conformément au point 13 de la fiche de données de sécurité.

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ES - HIERRO ESTÁNDAR, 200 uG/DL

GB - IRON STANDARD, 200 uG/DL

PT - FERRO STANDARD, 200 uG/DL

FR - FERRO STANDARD, 200 uG/DL

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QUIMICA CLINICA APLICADA S.A.
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