THE OPEN UNIVERSITY OF SRI LANKA
FACULTY OF HEALTH SCIENCES
DEPARTMENT OF MEDICAL LABORATORY SCIENCES
ACADEMIC YEAR 2020/2021 – SEMESTER II

BACHELOR OF MEDICAL LABORATORY SCIENCES HONOURS
MDU4405- WORK BASED TRAINING II
FINAL EXAMINATION — DURATION: THREE HOURS

DATE: 12TH OCTOBER 2022 — TIME: 9.30 AM – 12.30 PM

INDEX NO: .....

IMPORTANT INSTRUCTIONS/INFORMATION TO CANDIDATES

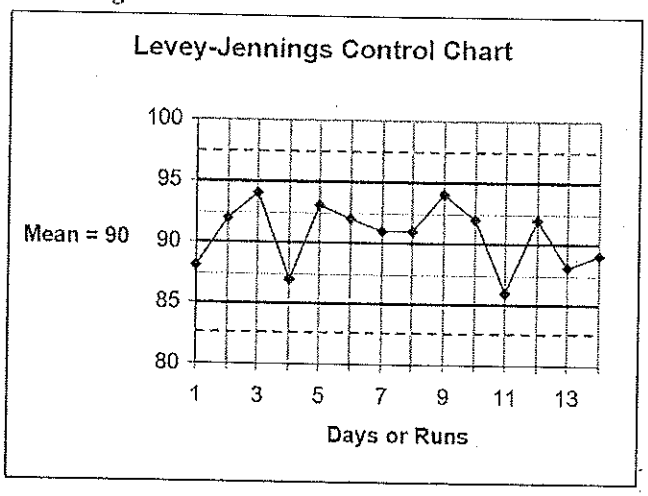
- This question paper consists of **11 pages** with **06 Practical Based Witten Questions and 01, 02 annexures related to Question No 02.**
- Write your **Index Number** in the space provided.
- Answer **ALL** questions in the given sheets.
- Do not remove any page/part of this question paper from the examination hall.
- Mobile phones and any other electronic equipment are **NOT** allowed. Leave them outside.

Practical Based Written Questions (600 marks)

Q1

1.1 In a routine Biochemistry laboratory, Quality control samples are usually run at the beginning of each shift. A lab technologist ran a QC sample for glucose analysis and obtained following results for 13 consecutive days.

2 SD Range = 85-95



1.1.1 Interpret the above chart. **(20 Marks)**

1.1.2 State the difference between assayed and unassayed control material used in a biochemistry laboratory for the analysis of Internal Quality Control. **(30 Marks)**

1.2 A newly recruited lab technologist ran a QC sample for the glucose test, and from 18th date onwards. All the values were lied within the lower range. Senior MLT advised to check the QC data of last 21 days. The QC data of last 21 days are as follows,

Mean – 75

Standard deviation - 2

Day	QC value(mg/dL)
1	76
2	74
3	75
4	77
5	76
6	75
7	76
8	75

9	75
10	75
11	75
12	77
13	76
14	75
15	75
16	77
17	75
18	71
19	70
20	70
21	70

1.2.1 Draw the Levey Jennings chart using the given data. **(20 Marks)**

1.2.2 Name the most used rules to evaluate the Levey Jennings chart in day-to-day practice. **(10 Marks)**

1.2.3 Is the QC result of Day 21 acceptable according to the rules mentioned above? Explain giving reasons. **(20 Marks)**

(Total – 100 marks)

Q2

2.1 Lipid profile, also known as lipid panel, is a combination of blood tests that help in mapping the quantities of lipids, present in the bloodstream. You are given two product inserts of Total Cholesterol and HDL Cholesterol (Annexure 01, 02).

2.1.1 Compare the similarities and differences of two test methods referring to the test principle. **(20 Marks)**

2.1.2 What is the significance of Linearity range? What would you do if you received a value higher than the highest level of detection? **(20 Marks)**

2.1.3 What is the purpose of incubating the sample and reagent mixture at 37 ^{0}C referring to the annexure 01? **(10 Marks)**

2.2 MLS undergraduate students are under your training at biochemistry section. Students are having following questions. Explain the answer giving reasons.

2.2.1 What are the purposes of performing different assays of lipid profile? **(20 Marks)**

2.2.2 If you receive a lipemic sample for lipid profile test, what would you do? **(30 Marks)**

(Total – 100 marks)

Q3

3.1 Two CSF samples of patient A and Patient B were sent to the laboratory for biochemical analysis. patient A had a history of brain damage due to an accident and patient B had a history of infection. The chief MLT observed that patient IDs were accidentally switched in the following reports during data entry.

Sample - CSF	**Report 01**
Appearance	Turbid
Protein	Increased
Glucose	Decreased
White cell count	Predominantly Neutrophils
Glucose CSF: Serum ratio	<0.4

Sample - CSF	**Report 02**
Appearance	Xanthochromic
Protein	Increased
Glucose	Normal
White cell count	slightly increased
Glucose CSF: Serum ratio	0.6

3.1.1 How did he detect that the reports were switched by looking at the given information? Explain your answer giving reasons. **(20 Marks)**

3.1.2 The ward requested results immediately. Can you issue the reports? Explain your answer. **(20 Marks)**

3.1.3 Explain the purpose of requesting serum glucose test along with CSF glucose? **(20 Marks)**

3.2 Traumatic lumbar puncture is a common inadvertent consequence whereby peripheral blood is introduced into the CSF thereby distorting the true cell counts. The CSF correction of white blood cell count reflects the true CSF WBC count through accounting for and excluding contributions from the peripheral blood.

3.2.1 Calculate corrected CSF WBC count using given data. **(20 Marks)**

$WBC_{CSF} = 50/ mm^3$

$WBC_{peripheral} = 6000/ mm^3$

$RBC_{CSF} = 5000/ mm^3$

$RCB_{Peripheral} = 4.5$ million/ mm^3

3.2.2 State two (02) conditions that increase WBC counts in CSF other than the condition mentioned in 3.1. **(20 Marks)**

(Total - 100 marks)

Q4

Marking the tissue edges aids in the identification and correct orientation of the tissue pieces during embedding. It also assists in the correct placement of the intended surface toward the face of the block, which is the first surface to meet the microtome blade.

4.1 State four (04) properties of an ink used in gross examination of histopathological specimens. **(20 Marks)**

4.2 Briefly explain how you would secure small biopsies during specimen grossing. **(20 Marks)**

4.3 What is the ratio of fixative,10% neutral buffered formalin for proper fixation of the specimen? **(10 Marks)**

4.4 If the fixative cannot be added immediately, state two (02) corrective measures you would take to preserve the specimen. **(20 Marks)**

4.5 In each of the following situations, what instructions/information you will provide as a Medical Laboratory Technician (MLT) in a histopathology laboratory. **(30 Marks)**

a) A trainee laboratory technician inquires the procedure of operating the water bath for tissue floating.

b) A nursing officer inquires the procedure of sending a sample with orientation sutures.

(Total - 100 marks)

Q5

The tissue sections, as they are prepared, are colorless and different components cannot be identified. Staining them by different colored dyes make identification and study of their morphology.

5.1 What is the significance of having a mordant in a histological stain? What is the choice of mordant in Haematoxylin? **(20 Marks)**

5.2 Briefly explain the principle of Haematoxylin and Eosin staining. **(10 Marks)**

5.3 "Special stains" are processes that generally employ a dye or chemical that has an affinity for the tissue component. Outline the principle of Von Cossa staining technique. **(10 Marks)**

5.4 You have been encountered following errors during staining. Explain the causes and solutions for each. **(40 Marks)**

a) The nuclear stain has a distinct red brown or reddish hue, often seen throughout the entire slide.

b) Sections with an overall hazy appearance.

5.5 What is the significance of Congo Red staining technique in Histopathology? State how you will interpret the results of the technique. **(20 Marks)**

(Total – 100 marks)

Q6

Section cutting is the technique of making the very thin slices of tissue specimens for the microscopic examination. There are times when proper section cannot be cut.

6.1 State the cause/s for the following errors and the remedial actions for each. **(20 Marks)**

a) Tear or scratch across part of section

b) Cracks across the section parallel to knife

6.2 Imagine you are the senior MLT of Histopathology laboratory and state two (02) the important steps that you may implement to achieve proper control of the pre-analytical process. **(20 Marks)**

6.3 Outline three (03) types of EQA programs used to evaluate the quality of your histopathology laboratory. **(30 Marks)**

6.4 What is the purpose of using a positive and negative controls when performing histological staining? **(10 Marks)**

6.5 State two (02) post analytical aspects that you should consider when working in a histopathology laboratory. **(20 Marks)**

(Total – 100 marks)

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Annexure 01

BIOLABO
www.biolabo.fr
MANUFACTURER:
BIOLABO SAS,
Les Hautes Rives
02160, Maizy, France

CHOLESTEROL CHOD PAP

Ready-to-use Liquid

Reagent for quantitative determination of Total Cholesterol in human serum and plasma

REF LP80106 R1 2 x 100 mL R2 1 x 5 mL

IVD

CE

Made In France

I: corresponds to significant modifications

TECHNICAL SUPPORT AND ORDERS
Tel: (33) 03 23 25 15 50
support@biolabo.fr
Latest revision: www.biolabo.fr

INTENDED USE

I This reagent is designated for professional use in laboratory. It may be used with manual procedure on spectrophotometer or with Biochemistry Clinical Analyzer.
This quantitative test is to determine the concentration of Total Cholesterol in human serum or plasma.

GENERALITIES (1) (2)

I Hypercholesterolemia can be observed in case of dietary imbalance, in in hepatic and thyroid disorders, certain cases of diabetes, nephrotic syndrome, pancreatitis, myeloma or familial hypercholesterolemia.
Total cholesterol increased levels may be isolated or associated to other increased lipids (hyperlipidemia).
A decreased level of cholesterol may be due to deficiencies or malnutrition, cancer or hyperthyroidism.

PRINCIPLE (4)

Enzymatic method described by Allain and al., which reaction scheme is as follows:

Cholesterol esters $\xrightarrow{CE}$ Cholesterol + free fatty acids

Cholesterol + O_2 $\xrightarrow{CO}$ Cholesten 4 one 3 + H_2O_2

2 H_2O_2 + Phenol + PAP $\xrightarrow{POD}$ Quinoneimine (pink) + 4 H_2O

REAGENTS

R1 CHOLESTEROL CHOD PAP Reagent

Phosphate buffer	100	mmol/L
Chloro-4-phenol	5	mmol/L
Sodium Cholate	2.3	mmol/L
Triton x 100	1.5	mmol/L
Cholesterol oxydase (CO)	≥ 100	IU/L
Cholesterol esterase (CE)	≥ 170	IU/L
Peroxydase (POD)	≥ 1200	IU/L
4 - Amino – antipyrine (PAP)	0.25	mmol/L
PEG 6000	167	µmol/L
Preservative		

According to 1272/2008 regulation, vial R1 is not classified as dangerous

R2 CHOLESTEROL CHOD PAP Standard
Cholesterol 200 mg/dL (5.17 mmol/L)

Attention Danger

Skin Irrit. 2 : H315 – Causes skin irritation
Eye Dam. 1: H318 – Causes serious eye damage
Flam. Liq. 3: H226 – Flammable liquid and vapor

P210: Keep away from heat/sparks/open flames/hot surfaces – No smoking,
P280: Wear protective gloves/protective clothing/eye protection/face protection,
P302+P352: IF ON SKIN: Wash with soap and water,

P305+P351+P338: IF IN EYES: Rinse continuously with water for several minutes. Remove contact lenses if present and easy to do – continue rinsing,
P501: Dispose of contents/container in accordance with dangerous waste regulations.
I Classification due to N-Propanol and Tergitol 10 - < 25%, For more details, refer to Safety Data Sheet (MSDS)

SAFETY CAUTIONS

- Refer to current Material Safety Data Sheet available on request or on www.biolabo.fr
- Verify the integrity of the contents before use.
- Waste disposal: Respect legislation in force in the country.
- All specimens or reagents of biological origin should be handled as potentially infectious. Respect legislation in force in the country.

I Any serious incident that has occurred in connection with the device is notified to the manufacturer and the competent authority of the Member State in which the user and/or patient is based.

REAGENTS PREPARATION

Ready for use.

STABILITY AND STORAGE

Stored away from light, well cap in the original vial at 2-8°C, reagents are stable when stored and used as described in the insert:

Unopened:
- Until the expiry date stated on the label of the Kit.

Once opened:
- Transfer requested quantity, well recap vials and store at 2-8°C
- Reagent is stable at least 3 months when free from contamination.
- Discard reagent (R1) if cloudy or if reagent blank at 500 nm > 0.400.

SPECIMEN COLLECTION AND HANDLING (2)

Serum or plasma (Heparin or EDTA).
Do not use oxalate, fluoride or citrate. Collect on fasting patient. Separate serum from cells within 2 hours.

Cholesterol is stable:
- 5-7 days at 2-8°C
- 3 months at –20°C
- Many years at –70°C.
- Avoid repeated freezing and thawing

LIMITS (2) (3) (5)

Enzymatic methods increase analytic specificity. Cholesterol oxidase also reacts with 3β-hydroxycholesterols (insignificant quantity in human serum – i.e. DHEA, pregnenolone).

For a more comprehensive review of factors affecting this assay refer to the publication of Young D.S or N. W. Tietz.

MATERIALS REQUIRED BUT NOT PROVIDED

1. Basic medical analysis laboratory equipment.
2. Spectrophotometer or Biochemistry Clinical Analyzer

QUALITY CONTROL

- REF 95010 EXATROL-N Level I.
- REF 95011 EXATROL-P Level II.
- External quality control program.

It is recommended to control in the following cases:

- At least once a run.
- At least once within 24 hours.
- When changing vial of reagent.
- After maintenance operations on the instrument.

If control is out of range, apply following actions:

1. Prepare a fresh control serum and repeat the test.
2. If control is still out of range, use a new vial of calibrator or a fresh calibrator and repeat the test.
3. If control is still out of range, repeat with a new vial of reagent.

If control is still out of range, please contact BIOLABO technical support or your local Agent.

EXPECTED VALUES (2)

Values for adults, estimated in term of risk for atherosclerotic diseases:

Total cholesterol	mg/dL	[mmol/L]
Recommended values	< 200	[< 5.18]
Low risk	200-239	[5.18-6.19]
High risk	≥ 240	[≥ 6.22]

Each laboratory should establish its own normal ranges for the population that it serves.

PERFORMANCES

on KENZA 240TX Analyser, 37°C, 505 nm

Linearity Range: between 9 and 500 mg/dL

Detection limit: approx. 2 mg/dL

Precision:

Within-run N = 20	*Low level*	*Normal level*	*High level*
Mean (mg/dL)	119	208	299
S.D. mg/dL	2.5	5.0	7.7
C.V. %	2.1	2.4	2.6

Between run N = 20	*Low level*	*Normal level*	*High level*
Mean (mg/dL)	123	201	299
S.D. mg/dL	2.1	4.2	5.6
C.V. %	1.7	2.3	1.9

Analytical Sensitivity: approx. 0.3246 abs for 100 mg/dL

Interferences:

Turbidity	No interference up to 0.288 OD
Total bilirubin	Negative interference from 295 µmol/L
Direct bilirubin	Negative interference from 190 µmol/L
Ascorbic acid	Negative interference from 998 mg/dL
Glucose	No interference up to 1089 mg/dL
Haemoglobin	No interference up to 405 µmol/L

Other substances may interfere (see § Limits)

On the board stability: 2 months

Calibration Stability: 2 months

Make a new calibration when changing reagent batch, if quality control results are found out of the established range and after maintenance operations.

Performances and stability data on Kenza 450TX/ISE and Kenza ONE are available on request

I On Kenza 450TX, clinical comparison study with commercially available reagent using serum specimens between 29 and 320 mg/dL (n=138):

y = 0.9108 x + 9.8254, R = 0.9815

CALIBRATION (6)

- REF 95015 Multicalibrator traceable *to SRM 1951c*
- Standard (vial R2)

The calibration frequency depends on proper instrument functions and on the preservation of the reagent.

PROCEDURE

Detailed Kenza 240TX procedure is available on request

Wavelength: 505 nm

Temperature: 37°C

	Automated analyzer	Manual procedure
Reagent	300 µL	1000 µL
Standard, Controls, Specimen	3 µL	10 µL
Mix. Let stands for 5 minutes at 37°C or 10 minutes at room temperature. Record absorbance at 500 nm (480-520) against reagent blank. Colour is stable for 1 hour.		

1- Performances with manual procedure should be validated by user.

2- Kenza applications and other applications proposal are available on request

CALCULATION

Calculate the result as follows:

$$\text{Result} = \frac{\text{Abs (Assay)}}{\text{Abs (Standard)}} \times \text{Standard concentration}$$

Automatic Biochemistry analyzer:

The analyzer provides directly result.
For more details about calibration and calculation of results, refer to User's manual and specific application.

REFERENCES

(1) *TIETZ N.W. Text book of clinical chemistry, 3rd Ed. C.A. Burtis, E.R. Ashwood, W.B. Saunders (1999) p. 826-835.*
(2) *Clinical Guide to Laboratory Test, 3rd Ed., N.W. TIETZ (1995) p. 130-131.*
(3) *YOUNG D.S., Effect of Drugs on Clinical laboratory Tests, 4th Ed. (1995) p. 3-143 to 3-164*
(4) *Allain C. C. et al., Clin. Chem. (1974), 20/4, p.470-475*
(5) *Allan C., Deacon et Peter J. G. Dawson, Clin. Chem. (1979) 25/6, p.976-984*
(6) *SRM: Standard Reference material ®*

Manufacturer	Expiry date	In vitro diagnostic	Storage temperature	Demateriafized water	Biological risk
Product Reference	See insert	Batch number	Store away from light	Sufficient for	Dilute with

HDL-CHOLESTEROL Direct Method

Reagent for quantitative determination of HDL-Cholesterol in human serum or plasma

BIOLABO
www.biolabo.fr
MANUFACTURER:
BIOLABO SAS,
Les Hautes Rives
02160, Maizy, France

REF 90206 (200-250 Tests)	R1: 1 x 60 mL	R2: 1 x 20 mL
REF 90406 (400-500 Tests)	R1: 2 x 60 mL	R2: 2 x 20 mL
Enclosed in each Kit REF 95506:	R1: 1 x 2 mL	R2: 1 x 5 mL

TECHNICAL SUPPORT AND ORDERS
Tel: (33) 03 23 25 15 50
support@biolabo.fr
Latest revision: www.biolabo.fr

CE

IVD

Made In France

I: corresponds to significant modifications

I INTENDED USE

This reagent is designated for professional use in laboratory (automated method).
It allows the quantitative determination of HDL-Cholesterol in human serum and plasma.

I GENERALITIES (1) (3)

The principal role of high density lipoproteins (HDL) in lipid metabolism is the uptake and transport of cholesterol from peripherical tissues to the liver through a process known as reverse cholesterol transport. Low HDL cholesterol levels are strongly associated with an increased risk of coronary heart disease and coronary artery disease. Hence, the determination of serum HDL-Cholesterol is a useful tool in identifying high-risk patients. Increased Total Cholesterol/HDL-Cholesterol ratio is significant of an increased risk of atherosclerosis.

PRINCIPLE

Accelerator selective detergent methodology.
Direct method, without specimen pre-treatment.
During the first phase, LDL, VLDL particles and Chylomicrons generate free Cholesterol, which through an enzymatic reaction, produce Hydrogen peroxide. The generated peroxide is consumed by a peroxidase reaction with DSBmT yielding a colorless product.

During the second phase, specific detergent solubilizes HDL-Cholesterol. In conjunction with CO and CE action, POD + 4-AAP develop a colored reaction which is proportional to HDL-Cholesterol concentration. The absorbance is measured at 600 nm.

LDL = Low density lipoproteins
VLDL = Very low density lipoproteins
CO = Cholesterol Oxidase
4-AAP = 4-Aminoantipyrine
HDL = High density lipoproteins
POD = Peroxidase
CE = Cholesterol Esterase
AAO = Ascorbate Oxidase
DSBmT = N,N-bis (4-sulphobutyl)-m-toluidine-disodium

REAGENTS COMPOSITION

R1 HDL-CHOLESTEROL Accelerator

Good's Buffer		
CO	< 1000	UI/L
POD	< 1300	ppg UI/L
DSBmT	< 1	mmol/L
AAO	< 3000	UI/L
Accelerator	< 1	mmol/L
Preservative	< 0.06	%

R2 HDL-CHOLESTEROL Selective Detergent

Good's Buffer		
CE	< 1500	UI/L
4-AAP	< 1	mmol/L
Detergent	< 2	%
Stabilizer	< 0.15	%
Preservative	< 0.06	%

EUH210: Safety data sheet available on request
EUH208: Contains CO, POD, and CE. May produce an allergic reaction.

According to 1272/2008/EC regulation, these reagents are not classified as dangerous

REF 95506 HDL LDL CK-MB CALIBRATOR
Vial R1: Lyophilised serum (human origin)
Vial R2: Diluent
See batch specific values in REF 95506 enclosed IFU

SAFETY CAUTIONS

- Refer to current Material Safety Data Sheet available on request or on www.biolabo.fr
- Verify the integrity of the contents before use.
- Waste disposal: Respect legislation in force in the country.
- All specimens or reagents of biological origin should be handled as potentially infectious. Respect legislation in force in the country.

! Any serious incident that has occurred in connection with the device is notified to the manufacturer and the competent authority of the Member State in which the user and/or patient is based.

REAGENTS PREPARATION

Ready for use.

STABILITY AND STORAGE

Stored away from light, well caped in the original vial at 2-8°C, and used as described, reagents are stable:
Unopened:
- Until expiry date stated on the label.

Once opened,
- 2 separated reagents are stable for at least 3 months at 2-8°C, 24 h at room temperature.

Discard any reagent if cloudy or if reagent blank at 620 nm > 0.050.

This kit should be refrigerated during transport.

SPECIMEN COLLECTION AND HANDLING (4)

Specimens should be collected after 12 h–14 h fasting.

Plasma: collected on EDTA or lithium/sodium heparinate.
Centrifuge and remove plasma from blood cells as soon as possible (within 3 hours).

Serum: Centrifuge and remove serum from blood cells as soon as possible (within 3 hours).

HDL-Cholesterol in specimen is stable for:
- 1 to 3 days at 2-8°C
- 1 month at - 20°C.

LIMITS (5)

This reagent may interfere with the magnesium determination

MATERIAL REQUIRED BUT NOT PROVIDED

1. Medical analysis laboratory equipment.
2. Spectrophotometer or Biochemistry Clinical Analyzer

QUALITY CONTROL

- REF 95516 HDL LDL CK-MB Control level 1
- REF 95526 HDL LDL CK-MB Control level 2
- External quality control program.

It is recommended to control in the following cases:

- At least once a run.
- At least once within 24 hours.
- When changing vial of reagent.
- After maintenance operations on the instrument.

If control is out of range, apply following actions:

1. Prepare a fresh control serum and repeat the test
2. If control is still out of range, use a new vial of fresh calibrator
3. If control is still out of range, use a new vial of reagent and reassay

If control is still out of range, please contact BIOLABO technical support or your local Agent.

EXPECTED VALUES (6)

Serum or plasma	mg/dL	[mmol/L]
Low level (Risk factor)	< 40	< 1.0
High level (Protective factor)	> 60	> 1.5

Each laboratory should establish its own normal ranges for the population that it serves.

PERFORMANCES

On Kenza 240TX, 37°C, 620 nm

Linearity Range: between 9 mg/dL (LQ) and 189 mg/dL

Detection limit: approx. 0.3 mg/dL

Precision:

Within-run N = 20	*Low level*	*Normal level*	*High Level*
Mean (mg/dL)	36	52	103
S.D. mg/dL	0.8	1.1	1.7
C.V. %	2.1	2.1	1.6

Between Run N = 20	*Low level*	*Normal level*	*High level*
Mean (mg/dL)	32	48	100
S.D. mg/dL	1	1.5	2
C.V. %	3.2	3.1	2.0

Comparison studies with commercially available reagent:
Realized on human specimens (n=94) between 14 and 96 mg/dL
y = 1.0438 x + 1,77 r = 0.9908

Analytical sensitivity: approx. 0.012 abs for 10 mg/dL

Interferences:

Turbidity	No interference up to 0.171 abs
Total bilirubin	No interference up to 369 µmol/L
Direct bilirubin	No interference up to 457 µmol/L
Ascorbic acid	No interference up to 2500 mg/dL
Glucose	No interference up to 950 mg/dL
Hemoglobin	No interference up to 317 µmol/L

Other substances may interfere (see § Limits)

On the board stability: 2 months

Calibration stability: 24 hours

Make a new calibration when changing reagent batch, if quality control results are found out of the established range and after maintenance operations.

Performances and stability data on Kenza 450TX/ISE and Kenza One are available on request.

CALIBRATION

- REF 95506 HDL LDL CK-MB Calibrator traceable to SRM® 1951 (Standard Reference Material®) assayed on CDC (Center for Disease Control)

The calibration frequency depends on proper instrument functions and on the preservation of the reagent.

PROCEDURE

Manual method :

Let stand reagents and specimens at room temperature

Set up the instrument to read micro-volumes.	Blank	Calibrator	Assay
Reagent R1	300 µL	300 µL	300 µL
Calibrator		3 µL	
Specimen			3 µL
Mix vigorously, let stand for 5 minutes at 37°C. Record absorbance A1 at 600 nm against reagent blank			
Add	Blank	Calibrator	Assay
Reagent R2	100 µL	100 µL	100 µL
Mix vigorously, let stand for 5 minutes at 37°C. Record absorbance A2 at 600 nm against reagent blank			

1- Performances with manual procedure should be validated by user.
2- Kenza applications and other applications proposal are available on request.

CALCULATION

With calibrator REF 95506:

Calculate ΔAbs. = (A2 – 0,75 A1) for assay and calibrator.

Replace in the formula as follows:

$$\text{HDL-C} = \frac{\Delta\text{Abs. Assay}}{\Delta\text{Abs. Calibrator}} \times \text{Calibrator concentration}$$

mg/dL x 0.02586 = mmol/L

REFERENCES

(1) *Badimon L. L., Badimon L., Fuester V., Regression of atherosclerotic lesions by HDL plasma fraction in the Cholesterol-fed rabbit, Journal of clinical investigation, (1990), 85, p.1234-1241.*

(2) *Clinical Guide to Laboratory Test, 4th Ed., N.W. TIETZ (2006) p. 564-569*

(3) *Gotto, A.M., Lipoprotein metabolism and the ethiology of hyperlipidemia, Hospital Practice, 23 ; Suppl. 1, 4 (1988)*

(4) *Warnick, G. Russel, Wood, Peter D., National Cholesterol Education Program Recommendations for Measurement of High-Density Lipoprotein Cholesterol: Executive Summary, Clinical Chemistry, Vol. 41, No 10, 1427-1433 (1995)*

(5) *National Committee for Clinical Laboratory Standards, National Evaluation Protocols for Interference Testing, Evaluation Protocol No 7, Vol. 6, No 13, (Aug. 1986).*

(6) *Recommandations de l'AFSSAPS sur la prise en charge thérapeutique du patient dyslipémique, p.9 (Mars 2005).*

Licence n° PCT/JP97/04442, PCT/JP00/03860

Manufacturer	Expiry date	In vitro diagnostic	Storage temperature	Dematerialized water	Biological risk
Product Reference	See Insert	Batch number	Store away from light	Sufficient for	Dilute with