510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE

A. 510(k) Number:
k060854

B. Purpose for Submission:
New Device

C. Measurand:
Cholesterol
HDL Cholesterol
LDL Cholesterol
Triglycerides
HDL Cholesterol Calibrator
LDL Cholesterol Calibrator

D. Type of Test:
Quantitative immunoturbidimetric and enzymatic photometric assays

E. Applicant:
HORIBA ABX

F. Proprietary and Established Names:
ABX PENTRA 400: Lipoproteins

G. Regulatory Information:

1. Regulation section:
   21CFR Sec. 862.1150 - Calibrator.
   21CFR Sec. 862.1660 - Quality control material (assayed and unassayed).
   21CFR Sec. 862.1705 - Triglyceride test system.
   21CFR Sec. 862.1175 - Cholesterol (total) test system.
   21CFR Sec. 862.1475 - Lipoprotein test system.

2. Classification:
   Class II, Class I reserved, and Class I meets the limitations to exemptions 21 CFR §862.9 (c) (4)

3. Product code:
   JIT - Calibrator, Secondary
   JJY - Multi-Analyte Controls, All Kinds (Assayed and Unassayed)
   CDT - Lipase Hydrolysis/Glycerol Kinase Enzyme
   CHH - Enzymatic Esterase--Oxidase, Cholesterol
   LBR - LDL & VLDL Precipitation, HDL
   MRR – Low Density Lipoprotein

4. Panel:
   Chemistry (75)

H. Intended Use:

1. Intended use(s):
   See indications for use below.

2. Indication(s) for use:

   ABX PENTRA Cholesterol CP reagent with associated calibrators and controls are for quantitative in vitro diagnostic determination of cholesterol in human serum and plasma based on an enzymatic photometric test (Trinder's reaction).

   ABX PENTRA HDL Direct CP reagent with associated calibrators and controls are for quantitative in vitro diagnostic determination of High Density Lipoprotein Cholesterol (HDL-C) in human serum and plasma based on an enzymatic assay with accelerator selective detergent methodology.

   ABX PENTRA LDL Direct CP reagent with associated calibrators and controls are for quantitative in vitro diagnostic determination of Low Density Lipoprotein Cholesterol (LDL-C) in human serum and plasma based on an enzymatic colorimetric assay.

   Cholesterol measurements are used in the diagnosis and treatment of disorders involving excess cholesterol in the blood and lipid and lipoprotein metabolism disorders.

   ABX PENTRA Triglycerides CP reagent with associated calibrators and controls are for quantitative in vitro diagnostic determination of triglycerides in human serum and plasma based on an enzymatic colorimetric assay.

   Measurements obtained by this device are used in the diagnosis and treatment of patients with diabetes mellitus, nephrosis, liver obstruction, other diseases involving lipid metabolism, or various endocrine disorders.

   The ABX PENTRA HDL Cal is a calibrator for use in the calibration of quantitative Horiba ABX PENTRA HDL Direct CP method on Horiba ABX clinical chemistry analyzers.

   The ABX PENTRA LDL Cal is a calibrator for use in the calibration of quantitative Horiba ABX PENTRA LDL Direct CP method on Horiba ABX clinical chemistry analyzers.

3. Special conditions for use statement(s):
   Prescription Use

4. Special instrument requirements:
   ABX PENTRA 400 (k052007)

I. Device Description:

ABX Pentra Cholesterol CP is ready-to-use.

Reagent	Good's buffer pH 6.7	50 mmol/L
	Phenol	5 mmol/L
	4-Aminoantipyrine	0.3 mmol/L
	Cholesterol esterase (CHE)	≥ 200 U/L
	Cholesterol oxidase (CHO)	≥ 50 U/L
	Peroxidase (POD)	≥ 3 kU/L
	Sodium azide	0.95 g/L

A**BX Pentra HDL Direct CP** is ready-to-use.

Reagent 1	Good's Buffer	
	Cholesterol oxidase	< 1000 U/L
	Peroxidase	< 1300 ppg U/L
	N,N-bis(4-sulphobutyl)- m-toluidine- disodium (DSBmT)	< 1 mM
	Accelerator	< 1 mM
	Preservative	< 0.06 %
Reagent 2	Good's Buffer	
	Cholesterol esterase 4-Aminoantipyrine (4-AAP)	< 1500 U/L < 1mM
	Detergent	< 2 %
	Restrainer	< 0.15%
	Preservative	< 0.06 %
	Ascorbic acid oxidase	< 3000 U/L

ABX Pentra LDL Direct CP is ready-to-use.

Reagent 1	MES Buffer (pH 6.3)	
	Detergent 1	< 1.0 %
	Cholesterol Esterase	< 1500 U/L
	Cholesterol Oxidase	< 1500 U/L
	Peroxidase	< 1300 ppg U/L
	4-aminoantipyrine	< 0.1 %
	Ascorbic Acid Oxidase	< 3000 U/L
	Preservative	
Reagent 2	MES Buffer (pH 6.3)	
	Detergent 2	< 1.0 %
	N,N-bis(4-sulfobutyl)-toluidine, disodium (DsBmT)	< 1.0 mM
	Preservative	

ABX Pentra Triglycerides CP is ready-to-use.

Reagent	Pipes free acid	50 mmol/L
	Sodium hydroxide	3.36 g/L
	Triton X-100	1 ml/L
	Magnesium salt	14.8 mmol/L
	p-chlorophenol	2.7 mmol/L
	ATP	3.15 mmol/L
	Sodium azide	7.99 mmol/L
	Potassium ferrocyanide	10 µmol/L
	4-aminoantipyrine	0.31 mmol/L
	Lipoprotein lipase	≥ 2000 U/L
	Glycerokinase	≥ 500 U/L
	Glycerol phosphate Oxidase	≥ 4000 U/L
	Peroxidase	≥ 500 U/L

ABX Pentra HDL Cal is a lyophilized calibrator. It is a preparation of lyophilized human serum containing lipoproteins from the various lipoprotein classes including high-density lipoproteins.

ABX Pentra LDL Cal is a lyophilized calibrator. It is a preparation of lyophilized human serum containing lipoproteins from the various lipoprotein classes including low-density lipoproteins. • The kit is composed of 2 vials of calibrator (lyophilized for 1 mL)

J. Substantial Equivalence Information:

1. Predicate device name(s):
   Roche Cholesterol Reagent
   Ultra N-Geneous HDL Cholesterol Reagent
   N-Geneous LDL Cholesterol Reagent
   Roche Reagent for Triglycerides
   Roche Apolipoprotein Standard
   Ultra N-Geneous HDL Cholesterol Reagent Calibrator
   N-Geneous LDL Cholesterol Reagent Calibrator
   Liquichek Lipids Control

2. Predicate 510(k) number(s):
   k941573, k021316, k971573, k893973, k021316, k971573, respectively

3. Comparison with predicate:

	Predicate device (k941573):	**Device :**
Device Name	**Cholesterol**	**ABX Pentra Cholesterol CP**
Manufactured by	Roche, USA	HORIBA ABX, France
Instrument	COBAS MIRA chemistry system	ABX PENTRA 400
Analytes	Cholesterol	Cholesterol

	Predicate device (k941573):	**Device :**
Device Name	**Cholesterol**	**ABX Pentra Cholesterol CP**
Method :	Enzymatic photometric test	Enzymatic photometric test
Specimen :	Serum Plasma	Serum Plasma
Certification :	Traceability to the National Reference System for Cholesterol	Traceability to the National Reference System for Cholesterol
Component reagent matrices	Single-reagent bottle, ready to use: REAGENT : 4-Aminoantipyrine, Cholesterol Esterase, Cholesterol Oxidase, Peroxidase, Phenol, buffers, stabilizers, fillers	Mono-reagent cassette, ready to use: REAGENT : Good's buffer, Phenol, 4-Aminoantipyrine, Cholesterol Esterase, Cholesterol Oxidase, Peroxidase, Sodium azide
Format	Liquid	Liquid
Labels	-	Horiba ABX specific label
Packaging	Single-reagent bottles REAGENT : 15 x 12 ml or 4 x 12 mL	Mono-reagent cassette : REAGENT : 99 mL
Controls	Commercially available quality control (not included): 2 levels of serum-based controls with known cholesterol values	Recommended quality control material (not included): ABX Pentra N Control (Normal control) ABX Pentra P Control (Pathologic control)
Calibrators	Commercially available calibrator (not included)	Recommended calibration material (not included): ABX Pentra Multical
Performance data :		
Number of tests	-	380 tests
Sample volume	3 µL/test	3 µL/test
Detection limit	2 mg/dL	4 mg/dL
Accuracy and Precision	CV Total < 2.4%	CV Total < 3.01%
Measuring range	2 mg/dL – 525 mg/dL	2.55 mg/dL – 583.26 mg/dL
Upper linearity limit	525 mg/dL (with automatic post-dilution : 1050 mg/dL)	580 mg/dL
Calibration stability	Calibration required monthly	8 days
Closed reagent stability	Until the expiration date when stored at 2-8°C 30 days at 2-8°C	24 months at 2-8°C on-board stability (refrigerated area): 48 days

	Predicate device (k941573):	**Device :**
Device Name	**Cholesterol**	**ABX Pentra Cholesterol CP**
Open Reagent stability		
	Predicate device (k021316):	Device :
Device Name	Ultra N-geneous® HDL Cholesterol Reagent	ABX Pentra HDL Direct CP
Manufactured by	Genzyme, USA	HORIBA ABX, France
Instrument	Automated clinical chemistry analyzer	ABX PENTRA 400
Analytes	High Density Lipoprotein Cholesterol (HDL-C)	High Density Lipoprotein Cholesterol (HDL-C)
Method :	Accelerator Selective detergent Methodology	Accelerator Selective detergent Methodology
Specimen :	Serum Plasma	Serum Plasma
Component reagent matrices	Single reagent bottles, ready to use: REAGENT 1 : Buffer, Cholesterol oxidase, Peroxidase, N,N-bis(4-sulphobutyl)-m-toluidine-disodium (DSBmT), Accelerator, Preservative, Ascorbic oxidase REAGENT 2 : Buffer, Cholesterol esterase, 4-Aminoantipyrine (4-AAP), Detergent, Preservative	Bi-reagent cassette, ready to use REAGENT 1 : Good's buffer, Cholesterol oxidase, Peroxidase, N,N-bis(4-sulphobutyl)-m-toluidine-disodium (DSBmT), Accelerator, Preservative REAGENT 2 : Good's buffer, Cholesterol esterase, 4-Aminoantipyrine (4-AAP), Detergent, Restrainer, Preservative, Ascorbic acid oxidase
Format	Liquid	Liquid
Labels	-	Horiba ABX specific label
Packaging	Single-reagent bottles REAGENT 1 : 1 x 250 mL REAGENT 2 : 1 x 80 mL	Bi-reagent cassette : REAGENT 1 : 62 mL REAGENT 2 : 21 mL
Controls	Recommended quality control material (not included): Normal and near the concentrations for decision-making controls	Recommended quality control material (not included): ABX Pentra N Control (Normal control) ABX Pentra P Control (Pathologic control)
Calibrators	Recommended calibration material (not included): Ultra N_geneous® HDL Cholesterol Calibrator	Recommended calibration material (not included): ABX Pentra HDL Cal
Performance data :		
Number of tests	-	240 tests
Sample volume	3 µL/test	3 µL/test
Detection limit	-	1.16 mg/dL

	Predicate device (k941573):	Device :
Device Name	**Cholesterol**	**ABX Pentra Cholesterol CP**
Accuracy and Precision	CV Total < 1.5%	CV Total < 3.52%
Measuring range	33.6 mg/dL – 133 mg/dL	5.4 mg/dL – 151.9 mg/dL
Upper linearity limit	200 mg/dL	154.8 mg/dL
Calibration stability	-	14 days
Closed reagent stability	Until the expiration date when stored at 2-8°C	22 months at 2-8°C
Open Reagent stability	4 weeks at 2-8°C	on-board stability (refrigerated area): 31 days

	Predicate device (k971573):	Device :
Device Name	**N-geneous® LDL Cholesterol Reagent**	**ABX Pentra LDL Direct CP**
Manufactured by	Genzyme, USA	HORIBA ABX, France
Instrument	Automated clinical chemistry analyzer	ABX PENTRA 400
Analytes	Low Density Lipoprotein Cholesterol (LDL-C)	Low Density Lipoprotein Cholesterol (LDL-C)
Method :	Enzymatic colorimetric assay	Enzymatic colorimetric assay
Specimen :	Serum Plasma	Serum Plasma
Component reagent matrices	Single reagent bottles, ready to use: REAGENT 1 : MES buffer, Detergent 1, Cholesterol Esterase, Cholesterol Oxidase, Peroxidase, 4-Aminoantipyrine, Ascorbic Acid Oxidase, Preservative REAGENT 2 : MES buffer, Detergent 2, N,N-bis(4-sulfobutyl)-m-toluidine-disodium (DSBmT), Preservative	Bi-reagent cassette, ready to use REAGENT 1 : MES buffer, Detergent 1, Cholesterol Esterase, Cholesterol Oxidase, Peroxidase, 4-Aminoantipyrine, Ascorbic Acid Oxidase, Preservative REAGENT 2 : MES buffer, Detergent 2, N,N-bis(4-sulfobutyl)-toluidine-disodium (DSBmT), Preservative,
Format	Liquid	Liquid
Labels	-	Horiba ABX specific label
Packaging	Single-reagent bottles : REAGENT 1 : 1 x 30 mL REAGENT 2 : 1 x 10 mL	Bi-reagent cassette : REAGENT 1 : 28 mL REAGENT 2 : 10 mL

	Predicate device (k971573):	Device :
Device Name	**N-geneous® LDL Cholesterol Reagent**	**ABX Pentra LDL Direct CP**
Controls	Commercially available quality control material (not included)	Recommended quality control material (not included): ABX Pentra N Control (Normal control) ABX Pentra P Control (Pathologic control)
Calibrators	Recommended calibration material (not included): N_geneous® LDL Cholesterol Calibrator	Recommended calibration material (not included): ABX Pentra LDL Cal
Performance data :		
Number of tests	-	100 tests
Sample volume	3 µL/test	2.4 µL/test
Detection limit	-	1.55 mg/dL
Analytical sensitivity	0.278 mg/dL	-
Accuracy and Precision	CV Total < 2.27%	CV Total < 6.39%
Measuring range	6.6 mg/dL – 992 mg/dL	1.35 mg/dL – 369.39 mg/dL
Upper linearity limit	992 mg/dL	387 mg/dL
Calibration stability	-	12 days
Closed reagent stability	Until the expiration date when stored at 2-8°C	18 months at 2-8°C
Open Reagent stability	4 weeks at 2-8°C	on-board stability (refrigerated area): 97 days

	Predicate device (k893973):	Device :
Device Name	**Triglycerides**	**ABX Pentra Triglycerides CP**
Manufactured by	Roche, USA	HORIBA ABX, France
Instrument	COBAS chemistry system	ABX PENTRA 400
Analytes	Triglycerides	Triglycerides
Method :	Enzymatic colorimetric assay	Enzymatic colorimetric assay
Specimen :	Serum Plasma	Serum Plasma
Component reagent matrices	Single reagent bottles, the combined reagents contain the	Mono-reagent cassette, ready to use

	Predicate device (k893973):	Device :
Device Name	**Triglycerides**	**ABX Pentra Triglycerides CP**
	following components: ATP, 4-Aminoantipyrine, Glycerol kinase, Glycerol phosphate oxidase, Lipases, Peroxidase, Sodium N-Ethyl-N-(3-Sulfopropyl)-m-anisidine (ESPAS), buffers, stabilizers, fillers	REAGENT : Pipes free acid, Sodium hydroxide, Triton X-100, Magnesium salt, p-chlorophenol, ATP, Sodium azide, Potassium ferrocyanide, 4-Aminoantipyrine, Lipoprotein lipase, Glycerokinase, Glycerol phosphate Oxidase, Peroxidase
Format	Liquid	Liquid
Labels	-	Horiba ABX specific label
Packaging	Kit composed of single-reagent bottles REAGENT 1 : 2 x 80 mL REAGENT 2 : 2 x 40 ml	Mono-reagent cassette : REAGENT : 99 mL
Controls	Commercially available quality control (not included): 2 levels	Recommended quality control material (not included): ABX Pentra N Control (Normal control) ABX Pentra P Control (Pathologic control)
Calibrators	Commercially available calibrator (not included)	Recommended calibration material (not included): ABX Pentra Multical
Additional Reagents	-	Cleaning solution (not included): ABX Pentra Clean-Chem CP / ABX Pentra Clean-Chem 99 CP
Performance data :		
Number of tests	-	327 tests
Sample volume	4 µL/test	3 µL/test
Detection limit	-	7 mg/dL
Accuracy and Precision	CV Total < 3.6%	CV Total < 2.83%
Measuring range	10 mg/dL - 662 mg/dL	3.1 mg/dL – 1434 mg/dL
Upper linearity limit	900 mg/dL (with automatic post-dilution : 1800 mg/dL)	1470 mg/dL, with an automatique post-dilution : 5580 mg/dL
Calibration stability	-	14 days
Closed reagent stability	Until the expiration date when stored at 2-8°C	16 months at 2-8°C
Open Reagent	Combined reagent is stable: 1 year at 2-8°C 60 days at room temperature	on-board stability (refrigerated area): 48 days

	Predicate device (k893973):	Device :
Device Name	**Triglycerides**	**ABX Pentra Triglycerides CP**
stability	(15-25°C)	

	Predicate device (k021316):	Device :
Device Name	**Ultra N-geneous® HDL Cholesterol Calibrator**	**ABX Pentra HDL Cal**
Manufactured by	Genzyme, USA	HORIBA ABX, France
Instrument	Chemistry systems	ABX PENTRA 400
Method :	Calibration of Genzyme Ultra N-geneous HDL Cholesterol assay	Calibration of HORIBA ABX HDL Cholesterol measurement method
Component matrices	Vials (lyophilized) Human serum based	Vials (lyophilized) Human serum based, with preservative
Calibrated molecules	HDL Cholesterol	HDL Cholesterol
Format	Lyophilized	Lyophilized
Labels	-	Horiba ABX specific label
Packaging	Kit composed of : 1 x 1 mL vial	Kit composed of : 2 x 1 mL vial
Performance data : **Calibration value** **Closed stability** **Open stability**	 - Assigned by procedures traceable to the National Reference System for Cholesterol (NRS/CHOL) - - The concentration of component is given on the vial label Up to the expiration date at 2-8°C 14 days at 2-8°C 4 weeks at –70°C	 - Assigned by procedures traceable to the National Reference System for Cholesterol (NRS/CHOL) - The concentration of component is lot specific - The concentration is given in the enclosed annex 24 months at 2-8°C 14 days at 2-8°C 4 weeks at –70°C

	Predicate device (k971573):	Device :
Device Name	**N-geneous™ LDL Cholesterol Calibrator**	**ABX Pentra LDL Cal**
Manufactured by	Genzyme, USA	HORIBA ABX, France
Instrument	Chemistry systems	ABX PENTRA 400
Method :	Calibration of Genzyme N-	Calibration of HORIBA ABX

	Predicate device (k971573):	Device :
Device Name	**N-geneous™ LDL Cholesterol Calibrator**	**ABX Pentra LDL Cal**
	geneous LDL Cholesterol assay	LDL Cholesterol measurement method
Component matrices	Vials (lyophilized) Human serum based	Vials (lyophilized) Human serum based, with preservative
Calibrated molecules	LDL Cholesterol	LDL Cholesterol
Format	Lyophilized	Lyophilized
Labels	-	Horiba ABX specific label
Packaging	Kit composed of : 1 x 1 mL vial	Kit composed of : 2 x 1 mL vial
Performance data : **Calibration value** **Closed stability** **Open stability**	 - Assigned by procedures traceable to the National Reference System for Cholesterol (NRS/CHOL) - - The concentration of component is given on the vial label Up to the expiration date at 2-8°C 2 weeks at 2-8°C	 - Assigned by procedures traceable to the National Reference System for Cholesterol (NRS/CHOL) - The concentration of component is lot specific - The concentration is given in the enclosed annex 24 months at 2-8°C 2 weeks at 2-8°C

K. Standard/Guidance Document Referenced (if applicable):

CLSI - Evaluation of Precision Performance of Clinical Chemistry Devices; Approved Guideline-Second Edition - EP05-A2
CLSI - Evaluation of the Linearity of Quantitative Analytical Methods; Approved Guideline - EP06-A
CLSI - Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline - Second Edition - EP09-A2

L. Test Principle:

ABX PENTRA Cholesterol CP

''CHOD-PAP'': enzymatic photometric test.
Determination of cholesterol after enzymatic hydrolysis and oxidation (3,4). The colorimetric indicator is quinoneimine which is generated from 4-aminoantipyrine and phenol by hydrogen peroxide under the catalytic action of peroxidase (Trinder's reaction)

ABX PENTRA HDL Direct CP
The assay is a homogeneous method for directly measuring HDL-C levels in serum or plasma without the need for any off-line pretreatment or centrifugation steps.

The method is in a two reagent format and depends on the properties of a unique detergent, as illustrated. This method is based on accelerating the reaction of cholesterol oxidase (CO) with non-HDL unesterified cholesterol and dissolving HDL selectively using a specific detergent.
In the first reagent, non-HDL unesterified cholesterol is subject to an enzyme reaction and the peroxide generated is consumed by a peroxidase reaction with DSBmT yielding a colorless product.

The second reagent consists of a detergent capable of solubilizing HDL specifically, cholesterol esterase (CE) and chromagenic coupler to develop color for the quantitative determination of HDL-C.

ABX PENTRA LDL Direct CP
The assay is an homogeneous method for directly measuring LDL-C levels in serum or plasma, without the need for any off-line pretreatment or centrifugation steps.

The method is in a two reagent format and depends on the properties of a unique detergent. This detergent (Reagent 1) solubilizes only the non LDL lipoprotein particles. The cholesterol released is consumed by cholesterol esterase and cholesterol oxidase in a non color forming reaction. A second detergent (Reagent 2) solubilizes the remaining LDL particles and a chromogenic coupler allows for color formation. The enzyme reaction with LDL-C in the presence of the coupler produces color that is proportional to the amount of LDL cholesterol present in the sample.

ABX PENTRA Triglycerides CP
Enzymatic determination of triglycerides according to the following reactions:

$$\text{Triglycerides} + H_2O \xrightarrow{\text{Lipoprotein lipase}} \text{Glycerol} + \text{fatty acids}$$

$$\text{Glycerol} + \text{ATP} \xrightarrow{\text{Glycerokinase}} \text{Glycerol-3-phosphate} + \text{ADP}$$

$$\text{Glycerol-3-Phosphate} + O_2 \xrightarrow{\text{Glycerol-3-phosphate Oxidase}} H_2O_2 + \text{DHAP}$$

$$2H_2O_2 + \text{4-AAP} + \text{p-Chlorophenol} \xrightarrow{\text{Peroxidase}} \text{Quinoneimine} + 4H_2O$$

(DHAP = Dihydroxyacetone phosphate, 4-AAP = 4-aminoantipyrine)

M. Performance Characteristics (if/when applicable):

1. Analytical performance:
   a. *Precision/Reproducibility:*
      ABX PENTRA Cholesterol CP

Two control materials and three specimens were tested 20times in a single run. The results are presented in the table below.

	Mean value mg/dL	CV %
Normal control	113	0.82
Pathological control	186	0.74
Specimen 1	117	1.21
Specimen 2	191	0.53
Specimen 3	389	0.62

In accordance with CLSI guideline EP-5A, two control materials and two specimens were tested in duplicate for 20 days, two times a day (N=80). The results are presented in the table below.

	Mean value mg/dL	CV %
Normal control	109	2.96
Pathological control	183	2.34
Specimen 1	170	2.80
Specimen 2	250	3.01

ABX PENTRA HDL Direct CP

Two control materials and three specimens were tested 20times in a single run. The results are presented in the table below.

	Mean value mg/dL	CV %
Normal control	35.82	1.29
Pathological control	81.72	0.79
Specimen 1	27.94	1.32
Specimen 2	48.59	1.91
Specimen 3	97.39	0.62

In accordance with CLSI guideline EP-5A, two control materials and two specimens were tested in duplicate for 20 days, two times a day (N=80). The results are presented in the table below.

	Mean value mg/dL	CV %
Normal control	35.83	2.88
Pathological control	80.35	3.06
Specimen 1	47.07	3.52
Specimen 2	80.16	2.69

ABX PENTRA LDL Direct CP

Two control materials and three specimens were tested 20times in a single run. The results are presented in the table below.

	Mean value mg/dL	CV %
Normal control	61.26	1.01
Pathological control	75.08	2.82
Specimen 1	111.26	0.91
Specimen 2	141.45	1.00
Specimen 3	191.16	0.63

In accordance with CLSI guideline EP-5A, two control materials and two specimens were tested in duplicate for 20 days, two times a day (N=80). The results are presented in the table below.

	Mean value mg/dl	CV %
Normal control	60.64	5.59
Pathological control	74.27	6.39
Specimen 1	156.58	3.94
Specimen 2	191.62	4.04

ABX PENTRA Triglycerides CP
Two control materials and three specimens were tested 20times in a single run. The results are presented in the table below.

	Mean value mg/dL	CV %
Normal control	126	2.52
Pathological control	214	0.82
Specimen 1	60	2.83
Specimen 2	108	1.84
Specimen 3	232	1.00

In accordance with CLSI guideline EP-5A, two control materials and two specimens were tested in duplicate for 20 days, two times a day (N=80). The results are presented in the table below.

	Mean value mg/dL	CV %
Normal control	128	1.91
Pathological control	216	1.70
Specimen 1	132	1.57
Specimen 2	243	1.37

b. Linearity/assay reportable range:
The reagent linearity is determined according to the recommendations found in the CLSI (NCCLS), EP6-A protocol. As a result of the testing, the following represent the linear range for each assay.

ABX PENTRA Cholesterol CP
Low linearity: 4 mg/dL
High linearity: 580 mg/dL

ABX PENTRA HDL Direct CP
Low linearity: 1.16 mg/dL
High linearity: 154.8 mg/dL.

ABX PENTRA LDL Direct CP
Low linearity: 1.55 mg/dL
High linearity: 387 mg/dL

ABX PENTRA Triglycerides CP
Low linearity: 7 mg/dL
High linearity: 1470 mg/dL, with automatic post-dilution: 5880 mg/dL

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*
Calibrators for Cholesterol and Triglyceride, and controls for Cholesterol, HDL, LDL and Triglyceride see k052007.

ABX PENTRA and HDL, LDL Calibrators and L/H Controls
Real time stability at 2-8°C was investigated for Calibrator, High Controls and Low Controls.

Real time stability study on reconstituted material was performed at regular intervals over a period providing data to support claims at 2-8°C (All) and – 20°C (Lipoproteins), and – 70°C (HDL).

Traceability

ABX PENTRA Cholesterol CP
Certification
Traceability to the National Reference System for Cholesterol was established by performing a direct comparison with the cholesterol reference method using human specimens that cover the National Cholesterol Education Program (NCEP) medical decision points. The ability to meet the NCEP's performance criteria for accuracy was demonstrated through testing and certification by the Cholesterol Reference Method Laboratory Network (CRMLN).

The results of the direct comparison and precision studies are as follows:
Among-run %CV : 1.5%
Average %Bias : -2.5%
Total Error : 5.6%

d. *Detection limit:*

ABX PENTRA Cholesterol CP:
Minimum Detection Limit (MDL) is calculated from 30 measurements of saline. Formula: MDL = mean of measurements + 4.65 SD (mean of measurement = 0 when negative)
From the MDL value, the minimum detection limit assigned for this method is 4 mg/dL.

ABX PENTRA HDL Direct CP
From the MDL value, the test range low assigned for this method is 1.16 mg/dL.

ABX PENTRA LDL Direct CP
From the MDL value, the test range low assigned for this method is 1.55 mg/dL.

ABX PENTRA Triglycerides CP
From the MDL value, the test range low assigned for this method is 7 mg/dL.

e. Analytical specificity:

ABX PENTRA Cholesterol CP
Hemoglobin: No significant influence is observed up to 336 mg/dL
Triglycerides: No significant influence is observed up to 612.5 mg/dL
(as Intralipid®, representative of lipemia)
Total Bilirubin: No significant influence is observed up to 20.5 mg/dL
Direct Bilirubin: No significant influence is observed up to 6.8 mg/dL
Other limitations are given by way of literature reference known to affect this methodology.

ABX PENTRA HDL Direct CP
Hemoglobin: No significant influence is observed up to 479 mg/dl.
Triglycerides: No significant influence is observed up to 612.5 mg/dL.
(as Intralipid®, representative of lipemia)
Total Bilirubin: No significant influence is observed up to 11.7 mg/dl.
Direct Bilirubin: No significant influence is observed up to 28.1 mg/dl.

ABX PENTRA LDL Direct CP
Hemoglobin: No significant influence is observed up to 336 mg/dl.
Triglycerides: No significant influence is observed up to 612.5 mg/dL.
(as Intralipid®, representative of lipemia)
Total Bilirubin: No significant influence is observed up to 29.2 mg/dl.
Direct Bilirubin: No significant influence is observed up to 10.8 mg/dl.

ABX PENTRA Triglycerides CP
Hemoglobin: No significant influence is observed up to 500 mg/dl
Total Bilirubin: No significant influence is observed up to 22.5 mg/dl
Direct Bilirubin: No significant influence is observed up to 22.5 mg/dl

f. Assay cut-off:
Not Applicable

2. Comparison studies:

a. Method comparison with predicate device:

ABX PENTRA Cholesterol CP
135 patient samples (serum) are correlated with a commercial reagent taken as reference according to the recommendations found in the

CLSI (NCCLS), EP9-A2 protocol. Values ranged from 2.55 to 583.26 mg/dL.

The equation for the regression line obtained is:

Y = 0.95 x + 1.90 with a correlation coefficient r^2 = 0.9943.

ABX PENTRA HDL Direct CP

121 patient samples are correlated with a commercial reagent taken as reference according to the recommendations found in the CLSI (NCCLS), EP9-A2 protocol. Values ranged from 3.5 to 155.3 mg/dL

The equation for the regression line obtained is:

Y = 0.91 x + 1.98 with a correlation coefficient r^2 = 0.9768

ABX PENTRA LDL Direct CP

122 patient samples are correlated with a commercial reagent taken as reference according to the recommendations found in the CLSI (NCCLS), EP9-A2 protocol. Values ranged from 0.3 to 385.6 mg/dL

The equation for the regression line obtained is:

Y = 0.96 x – 0.21, with a correlation coefficient r^2 =0.9963

ABX PENTRA Triglycerides CP

135 patient samples are correlated with a commercial reagent taken as reference according to the recommendations found in the CLSI (NCCLS), EP9-A2 protocol. Values ranged from 8.2 to 274.2 mg/dL

The equation for the regression line obtained is:

Y = 0.99 x + 0.20, with a correlation coefficient r^2 =0.9994

b. Matrix comparison:

ABX PENTRA Cholesterol CP

To demonstrate equivalence of Cholesterol results in serum and Plasma Heparin-Lithium samples, comparison study was performed. 40 samples (103-373 mg/dL) were evaluated on Pentra 400 analyzer using ABX Pentra Cholesterol CP reagent.

The equation for the regression line obtained is:

Y = 0.9903 x + 1.8467 with a correlation coefficient r = 0.996

ABX PENTRA HDL Direct CP

To demonstrate equivalence of HDL Cholesterol results in serum and Plasma Heparin-Lithium samples, comparison study was performed. 43 samples (35-118 mg/dL) were evaluated on Pentra 400 analyzer using ABX Pentra HDL Direct CP reagent.

The equation for the regression line obtained is:

Y = 0.9467 x + 1.5252 with a correlation coefficient r = 0.996

ABX PENTRA LDL Direct CP

To demonstrate equivalence of LDL Cholesterol results in serum and Plasma Heparin-Lithium samples, comparison study was performed. 41 samples (53-362 mg/dL) were evaluated on Pentra 400 analyzer using ABX Pentra LDL Direct CP reagent.

The equation for the regression line obtained is:

Y = 0.9681 x + 0.2352 with a correlation coefficient r = 0.999

ABX PENTRA Triglycerides CP

To demonstrate equivalence of Triglycerides results in serum and Plasma Heparin-Lithium samples, comparison study was performed. 41 samples (47-728 mg/dL) were evaluated on Pentra 400 analyzer using ABX Pentra Triglycerides CP reagent.
The equation for the regression line obtained is:
Y = 0.9694 x – 1.7717 with a correlation coefficient r = 0.999

3. Clinical studies:
   a. *Clinical Sensitivity:*
   Not Applicable

   b. *Clinical specificity:*
   Not Applicable

   c. Other clinical supportive data (when a. and b. are not applicable):
   Not Applicable

4. Clinical cut-off:
   Not Applicable

5. Expected values/Reference range:
   ABX PENTRA Cholesterol CP
   Desirable: < 200 mg/dL
   Borderline high risk: 200 - 239 mg/dL
   High risk: > 240 mg/dL
   Cholesterol Education Program (NCEP) medical decision points

   ABX PENTRA HDL Direct CP
   Men: 30 - 70 mg/dL
   Women: 30 - 85 mg/dL (literature)
   According to the NCEP, HDL values greater than or equal to 40mg/dL are considered desirable, and values greater than or equal to 60mg/dL are considered to offer some protection against coronary heart disease. Values below 40 mg/dL are considered to be a significant independent risk factor for coronary heart disease.

   ABX PENTRA LDL Direct CP
   The following NCEP cut-points for patient classification are used for the prevention and management of coronary heart disease.

LDL Cholesterol	Classification
< 130 mg/dL	Desirable
130-159 mg/dL	Borderline High Risk
160 mg/dL	High Risk

ABX PENTRA Triglycerides CP
The following NCEP cut- points been classified according to the risk of developing cardiovascular diseases:
Normal: < 150 mg/dL
Low risk: 150 - 200 mg/dL
High: 200 - 500 mg/dL
Extremely high: > 500 mg/dL

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.