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

A. 510(k) Number:

k060205

B. Purpose for Submission:

Notification of intent to manufacture and market a group of reagents and their associated controls and calibrators for use on the ABX PENTRA 400

C. Measurand:

Alkaline Phosphatase, Creatinine, Calcium, CO_2, Iron, Magnesium, Phosphorus, Urea, Uric Acid

D. Type of Test:

Colorimetric and enzymatic

E. Applicant:

Horiba ABX

F. Proprietary and Established Names:

Trade/Proprietary Name:	**ABX PENTRA ALP CP**
Common or Usual Name:	ALP - Alkaline phosphatase
Trade/Proprietary Name:	**ABX PENTRA Calcium CP**
Common or Usual Name:	Calcium
Trade/Proprietary Name:	**ABX PENTRA CO2 RTU**
Common or Usual Name:	Carbon Dioxide
Trade/Proprietary Name:	**ABX PENTRA Creatinine CP**
Common or Usual Name:	Creatinine
Trade/Proprietary Name:	**ABX PENTRA Iron CP**
Common or Usual Name:	Iron
Trade/Proprietary Name:	**ABX PENTRA Magnesium RTU**
Common or Usual Name:	Magnesium

Trade/Proprietary Name: **ABX PENTRA Phosphorus CP**
Common or Usual Name: Phosphorus

Trade/Proprietary Name: **ABX PENTRA Urea CP**
Common or Usual Name: Urea

Trade/Proprietary Name: **ABX PENTRA Uric Acid CP**
Common or Usual Name: Uric Acid

Trade/Proprietary Name: **ABX PENTRA CO2 Control**
Common or Usual Name: CO2 Control

Trade/Proprietary Name: **ABX PENTRA CO2 Cal**
Common or Usual Name: CO_2 Calibrator

G. Regulatory Information:

1. Regulation section:

21 CFR 862.1050: Alkaline phosphatase Test System
21 CFR 862.1145: Calcium Test System
21 CFR 862.1160: Bicarbonate/carbon dioxide Test System
21 CFR 862.1225: Creatinine Test System
21 CFR 862.1410: Iron (non-heme) Test System
21 CFR 862.1495: Magnesium Test System
21 CFR 862.1580: Phosphorus (inorganic) Test System
21 CFR 862.1770: Urea nitrogen Test System
21 CFR 862.1775: Uric acid Test System
21 CFR 862.1660: Quality control material (assayed and unassayed)
21 CFR 862.1150: Calibrator

2. Classification:

Class II - Alkaline phosphatase, Calcium, CO_2 RTU, Creatinine, Magnesium, Phosphorus, Urea, Calibrators

Class I, reserved - Iron, Uric Acid, Controls

3. Product code:

Alkaline phosphatase- CJE
Calcium - CIC
CO_2 - KHS

Creatinine - CGX
Iron - JIY
Magnesium - JGJ
Phosphorus - CEO
Urea - CDQ
Uric Acid - KNK
CO_2 Control – JJX
CO_2 Cal - JIT

4. Panel:

   75, Chemistry

H. Intended Use:

1. Intended use(s):

   See indications for use below

2. Indication(s) for use:

   General Chemistries reagents, with associated calibrators and controls, are intended for use on ABX PENTRA 400 Clinical Chemistry Analyzer to measure a variety of analytes.

   ABX PENTRA ALP CP reagent with associated calibrators and controls are for quantitative in vitro diagnostic determination of alkaline phosphatase in human serum and plasma based on a kinetic photometric test using p-Nitrophenylphosphate. Measurements of alkaline phosphatase or its isoenzymes are used in the diagnosis and treatment of liver, bone, parathyroid, and intestinal diseases.

   ABX PENTRA Calcium CP reagent with associated calibrators and controls are for quantitative in vitro diagnostic determination of calcium in human serum and plasma based on a photometric test using orthocresolphtalein complexone. Calcium measurements are used in the diagnosis and treatment of parathyroid disease, a variety of bone diseases, chronic renal disease and tetany (intermittent muscular contractions or spasms).

   ABX PENTRA CO_2 RTU reagent with associated calibrators and controls are for quantitative in vitro diagnostic determination of carbon dioxide in human serum and plasma based on an enzymatic test using phosphoenolpyruvate (PEP), phosphorenolpyruvate carboxylase (PEPC) and an analog of NADH. Bicarbonate/carbon measurements are used in the diagnosis and treatment of numerous potentially serious disorders associated with changes in body acid-base balance.

ABX PENTRA Creatinine CP reagent with associated calibrators and controls are for quantitative in vitro diagnostic determination of creatinine in human serum and plasma based on a kinetic method using alkaline picrate (Jaffé method). Creatinine measurements are used in the diagnosis and treatment of renal diseases, in monitoring renal dialysis, and as a calculation basis for measuring other urine analytes.

ABX PENTRA Iron CP reagent with associated calibrators and controls are for quantitative in vitro diagnostic determination of iron (non-heme) in human serum and plasma based on a photometric test (Ferene method). Iron (non-heme) measurements are used in the diagnosis and treatment of diseases such as iron deficiency anemia and hemochromatosis.

ABX PENTRA Magnesium RTU reagent with associated calibrators and controls are for quantitative in vitro diagnostic determination of magnesium in human serum and plasma based on a photometric test using xylidyl blue. Magnesium measurements are used in the diagnosis and treatment of hypomagnesemia (abnormally low plasma levels of magnesium) and hypermagnesemia (abnormally high plasma levels of magnesium).

ABX PENTRA Phosphorus CP reagent with associated calibrators and controls are for quantitative in vitro diagnostic determination of phosphorus in human serum and plasma based on a UV method using phosphomolybdate. Measurement of phosphorus (inorganic) is used in the diagnosis and treatment of various disorders, including parathyroid gland and kidney diseases, and vitamin D imbalance.

ABX PENTRA Urea CP reagent with associated calibrators and controls are for quantitative in vitro diagnostic determination of urea / urea nitrogen (an end-product of nitrogen metabolism) in human serum and plasma based on an enzymatic UV test using urease and glutamate dehydrogenase. Measurements obtained by this device are used in the diagnosis and treatment of certain renal and metabolic diseases.

ABX PENTRA Uric Acid CP reagent with associated calibrators and controls are for quantitative in vitro diagnostic determination of uric acid in human serum and plasma based on the enzymatic determination of uric acid using a chromogenic system in the presence of peroxidase and uricase (Trinder method). Measurements obtained by this device are used in the diagnosis and treatment of numerous renal and metabolic disorders, including renal failure, gout, leukemia, psoriasis, starvation or other wasting conditions, and of patients receiving cytotoxic drugs.

The **ABX PENTRA CO_2 Cal** is a calibrator for use in the calibration of quantitative Horiba ABX PENTRA CO_2 RTU method on Horiba ABX clinical

chemistry analyzers as specified on the vial.

The **ABX PENTRA CO_2 Control** is for use in quality control by monitoring accuracy and precision for the quantitative ABX PENTRA CO_2 RTU method as specified in the enclosed annex.

3. Special conditions for use statement(s):

   For prescription use only

4. Special instrument requirements:

   ABX PENTRA 400 Clinical Chemistry Analyzer

I. Device Description:

The **ABX PENTRA ALP CP** is an in vitro diagnostic assay for the quantitative determination of alkaline phosphatase in human serum and plasma based on a kinetic photometric test using p-Nitrophenylphosphate. It is composed of a bi-reagent cassette, with 26 ml and 6.5 ml compartments.

The **ABX PENTRA Calcium CP** is an in vitro diagnostic assay for the quantitative determination of calcium in human serum and plasma based on a photometric test using orthocresolphtalein complexone. It is composed of a bi-reagent cassette, with 66 ml and 16.5 ml compartments.

The **ABX PENTRA Creatinine CP** is an in vitro diagnostic assay for the quantitative determination of creatinine in human serum and plasma based on a kinetic method using alkaline picrate (Jaffé method). It is composed of a bi-reagent cassette, with two 28 ml compartments.

The **ABX PENTRA Iron CP** is in vitro diagnostic assay for the quantitative determination of iron (non-heme) in human serum and plasma based on a photometric test (Ferene method).It is composed of a bi-reagent cassette containing 69ml of reagent 1 and 20 ml of reagent 2.

The **ABX PENTRA Magnesium RTU** is an in vitro assay for the quantitative determination of magnesium in human serum and plasma based on a photometric test using xylidyl blue. It is composed of two identical mono-reagent vials of 25 ml.

The **ABX PENTRA Phosphorus CP** is an in vitro diagnostic assay for the quantitative determination of phosphorus in human serum and plasma based on a UV method using phosphomolybdate. It is composed of a mono-reagent cassette, with 29.5 ml compartment.

The **ABX PENTRA Urea CP** is an in vitro diagnostic assay for the quantitative determination of urea / urea nitrogen (an end-product of nitrogen metabolism) in human serum and plasma based on an enzymatic UV test using urease and glutamate dehydrogenase. It is composed of a bi-reagent cassette, with 60 ml and 15 ml

compartments.

The **ABX PENTRA Uric Acid CP** is an in vitro diagnostic assay for the quantitative determination of uric acid in human serum and plasma based on the enzymatic determination of uric acid using a chromogenic system in the presence of peroxidase and uricase (Trinder method). It is composed of a bi-reagent cassette, with 60 ml and 15 ml compartments.

The **ABX PENTRA Multical** is a lyophilized human serum calibrator with chemical additives and materials of biological origin. The assigned values of the calibrator components are provided in the package labeling, ensuring optimal calibration of the appropriate **HORIBA ABX** methods on the **ABX PENTRA 400** analyzer. This calibrator is provided in ten vials of 3 ml.

The **ABX PENTRA CO_2 RTU** is an in vitro diagnostic assay for the quantitative determination of carbon dioxide in human serum and plasma based on an enzymatic test using phosphoenolpyruvate (PEP), phosphorenolpyruvate carboxylase (PEPC) and an analog of NADH. It is composed of two identical mono-reagent vials of 20 ml.

The **ABX PENTRA CO_2 Cal** is a liquid calibrator containing chemical components to be used for the calibration of the CO2 assay. The assigned value is given on the calibrator vial. This calibrator is provided in three vials of 3 ml.

The **ABX PENTRA CO_2 Control** is a liquid assayed control containing chemical components to be used for the quality control of the CO_2 assay. The assigned value is given in the package labeling. This control is provided in three vials of 3 ml.

J. Substantial Equivalence Information:

1. Predicate device name(s):

New Device	Predicate
ABX PENTRA ALP CP	Alkaline Phosphatase (Roche)
ABX PENTRA Calcium CP	Calcium (Roche)
ABX PENTRA CO_2 RTU	CO_2 Reagent (Roche)
ABX PENTRA Creatinine CP	Creatinine (Roche)
ABX PENTRA Iron CP	Raichem
ABX PENTRA Magnesium RTU	Reagent for Magnesium (Roche)
ABX PENTRA Phosphorus CP	Inorganic Phosphorus (Roche)
ABX PENTRA Urea CP	BUN (Roche)
ABX PENTRA Uric Acid CP	Uric Acid Reagent (Roche)
ABX PENTRA CO_2 Cal	CO_2 reagent standard (Roche)
ABX PENTRA CO_2 Control	Lyphocheck assayed chemistry control Level 1 & Level 2 (BioRad)

2. Predicate 510(k) number(s):

Predicate Device	510k Number
Alkaline Phosphatase (Roche)	k801242
Calcium (Roche)	k883453
CO_2 Reagent (Roche)	k031879
Creatinine (Roche)	k941837
Iron (Raichem)	K864819
Magnesium (Roche)	k901758
Inorganic Phosphorus (Roche)	k891475
BUN (Roche)	k 954000
Uric Acid (Roche)	K922762
CO_2 reagent standard (Roche)	k 031879
Lyphocheck assayed chemistry control Level 1 & Level 2 (BioRad)	k 891475

3. Comparison with predicate:

ABX PENTRA ALP CP:

	Predicate device (K801242):	Device :
Device Name	**Alkaline Phosphatase**	**ABX Pentra ALP CP**
Analytes	Alkaline phosphatase	Alkaline phosphatase
Method :	Kinetic photometric test using nitrophenylphosphate	Identical
Specimen :	Serum Plasma	Serum Plasma
Component reagent matrices	Single-reagent bottles, lyophilized: REAGENT : 2-Amino-2-methyl-1,3-propanediol (AMPD), magnesium salt, zinc sulphate, N-(2-Hydroxyethyl)ethylenediaminetriacetic acid (HEDTA), 4-Nitrophenylphosphate, buffers, stabilizers and fillers	Bi-reagent cassette, ready to use: REAGENT 1 : 2-Amino-2-methyl-1-propanol, magnesium sulphate, zinc sulphate, sodium azide REAGENT 2 : p-Nitrophenylphosphate, sodium azide

ABX Pentra Calcium CP:

	Predicate device (K883453):	Device :
Device Name	**Calcium**	**ABX Pentra Calcium CP**
Analytes	Calcium	Calcium
Method :	Photometric test using Asenazo III	Photometric test using ortho-cresolphtalein complexone (OPC)
Specimen :	Serum	Serum Plasma

	Predicate device (K883453):	Device :
Device Name	**Calcium**	**ABX Pentra Calcium CP**
Component reagent matrices	Single reagent bottles: REAGENT : Arsenazo III, buffers, stabilizers, fillers	Bi-reagent cassette, ready to use REAGENT 1 : Ethanolamine, Detergents REAGENT 2 : o-Cresolphtalein complexone, 8-Hydroxyquinoline, Hydrochloric acid
Packaging	Kit composed of single-reagent bottles REAGENT : 2 x 120 ml	Bi-reagent cassette : REAGENT 1 : 66 ml REAGENT 2 : 16.5 ml

ABX Pentra CO_2 RTU:

	Predicate device (K031879):	Device :
Device Name	**CO_2 Reagent**	**ABX Pentra CO_2 RTU**
Analytes	Carbon dioxide	Carbon dioxide
Method :	Enzymatic test using phosphoenolpyruvate (PEP), phosphoenolpyruvate carboxylase (PEPC) and NADH as cofactor	Enzymatic test using phosphoenolpyruvate (PEP), phosphoenolpyruvate carboxylase (PEPC) and an analog of NADH as cofactor
Specimen :	Serum Plasma	Serum Plasma
Component reagent matrices	Single reagent bottle, lyophilized: CO_2 REAGENT : PEP, NAD (reduced), MDH, PEPC, buffers, stabilizers and fillers	Single reagent bottle, ready to use REAGENT : Buffer, PEP, PEPC, MDH, NADH analog, activators, stabilizers, surfactant, preservative

ABX Pentra Creatinine CP:

	Predicate device (K941837):	Device :
Device Name	**Creatinine**	**ABX Pentra Creatinine CP**
Analytes	Creatinine	Creatinine
Method :	Kinetic method using alkaline picrate (modification of the Jaffé reaction)	Kinetic method using alkaline picrate (modification of the Jaffé reaction)
Specimen :	Serum Plasma Urine	Serum Plasma
Component reagent matrices	Kit composed of: REAGENT 1 : Sodium	Bi-reagent cassette, ready to use

	Predicate device (K941837):	Device :
Device Name	**Creatinine**	**ABX Pentra Creatinine CP**
	borate, stabilizers REAGENT 2 : Picric acid, Sodium borate, stabilizers	REAGENT 1 : Picric acid REAGENT 2 : Sodium hydroxide, Disodium phosphate

ABX Pentra Iron CP:

	Predicate device (K864819):	Device :
Device Name	**Iron**	**ABX Pentra Iron CP**
Analytes	Iron	Iron
Method :	Colorimetric measurement of iron is performed by releasing the protein bound iron from its carrier protein transferrin and complexing the released iron with a suitable chromogen. In this method the sample is added to an acidic buffered reagent containing hydroxylamine, thiourea and ferene®	Same
Specimen :	Serum Plasma	Serum Plasma
Component reagent matrices	acidic buffered reagent containing hydroxylamine, thiourea and ferene®	acidic buffered reagent containing hydroxylamine, thiourea and ferene®

ABX Pentra Magnesium RTU:

	Predicate device (K901758):	Device :
Device Name	**Reagent for Magnesium**	**ABX Pentra Magnesium RTU**
Analytes	Magnesium	Magnesium
Method :	Photometric test using Chlorophosphonazo III	Photometric test using xylidyl blue
Specimen :	Serum	Serum Plasma
Component reagent matrices	Kit composed of: REAGENT 1 : Chlorophosphonazo III, N-tris(hydroxymethyl)methyl-2-aminoethanesulfonic acid, Ethylenebis(oxyethylenenitrilo)tetra acetic acid (EGTA), surfactant, preservatives	Single-reagent bottle, ready to use REAGENT : Ethanolamine, GEDTA, Xylidyl blue, detergents

	Predicate device (K901758):	Device :
Device Name	**Reagent for Magnesium**	**ABX Pentra Magnesium RTU**
	REAGENT 2 : Ethylenedaminetetraacetic acid, N-tris(hydroxymethyl)methyl-2-aminoethanesulfonic acid, surfactant, preservatives	

ABX Pentra Phosphorus CP:

	Predicate device (K883962):	Device :
Device Name	**Inorganic Phosphorus**	**ABX Pentra Phosphorus CP**
Analytes	Phosphorus	Phosphorus
Method :	UV method using phosphomolybdate	Identical method : UV method using phosphomolybdate
Specimen :	Serum Urine	Serum Plasma
Component reagent matrices	Single reagent bottles, ready to use REAGENT : Ammonium molybdate, surfactants, buffers, stabilizers, fillers	Mono-reagent cassette, ready to use REAGENT : Sulfuric acid, Ammonium molybdate

ABX Pentra Urea CP:

	Predicate device (K954000):	Device :
Device Name	**BUN**	**ABX Pentra Urea CP**
Analytes	Blood Urea Nitrogen (BUN)	Urea / Blood Urea Nitrogen (BUN)
Method :	Enzymatic UV test : "Urease – Glutamate Dehydrogenase"	Identical (Enzymatic UV test : "Urease – Glutamate Dehydrogenase")
Specimen :	Serum Plasma	Serum Plasma
Component reagent matrices	Single-reagent bottle, ready to use: REAGENT : Alpha-ketoglutarate, Urease, GLDH, Adenosine diphosphate, NADH, Sodium azide, buffer, preservative, stabilizers	Bi-reagent cassette, ready to use REAGENT 1 : TRIS, 2-Oxoglutarate, ADP, Urease, GLDH (Glutamate dehydrogenase), Sodium azide REAGENT 2 : NADH, Sodium azide

ABX Pentra Uric Acid CP:

	Predicate device (K922762**):**	**Device :**
Device Name	**Uric Acid**	**ABX Pentra Uric Acid CP**
Analytes	Uric Acid	Uric Acid
Method :	A modification of the enzymatic determination of uric acid using a chromogenic system in the presence of peroxidase and uricase (Trinder method)	A modification of the enzymatic determination of uric acid using a chromogenic system in the presence of peroxidase and uricase (Trinder method)
Specimen :	Serum Plasma	Serum Plasma
Component reagent matrices	Two reagent bottles R1 and R2 containing Buffers and uricase (R1) and Peroxidase with stabilizing buffers (R2)	It is composed of a bi-reagent cassette, with 60 ml and 15 ml compartments containing Buffers and uricase (R1) and Peroxidase with stabilizing buffers (R2)

ABX Pentra CO_2 Cal:

	Predicate device (K031879):	**Device :**
Device Name	**CO_2 Standard** (included in the CO2 Reagent kit from Roche)	**ABX Pentra CO_2 Cal**
Method :	Calibration of Roche bicarbonate/CO2 measurement method	Calibration of HORIBA ABX bicarbonate/CO2 measurement method
Component matrices	Vial (liquid) Solution containing 30 mmol/l bicarbonate	Vial (liquid) Solution containing 30 mmol/l bicarbonate

ABX Pentra CO_2 Control:

	Predicate device (K891475):	**Device :**
Device Name	Lyphocheck Assayed Chemistry Control Levels 1 and 2	**ABX Pentra CO_2 Control**
Manufactured by	Bio-Rad Laboratories	HORIBA ABX, France
Instrument	-	ABX PENTRA 400
Method :	Multi-parameter control by monitoring accuracy and precision for the quantitative methods as specified in the enclosed value sheet	Single-parameter control by monitoring the performances of Bicarbonate/Total CO2 determination with ABX Pentra CO_2 RTU reagent

	Predicate device (K891475):	Device :
Device Name	Lyphocheck Assayed Chemistry Control Levels 1 and 2	**ABX Pentra CO_2 Control**
Component reagent matrices	Vial (lyophilized) Human serum based with added constituents of purified biochemicals, pure chemicals, therapeutic drugs, preservatives and stabilizers	Vial (liquid) Aqueous matrix with added CO2
Controlled molecules	The exact control values are given in the notice - Multiple parameters, including CO_2	The exact control values are given in the enclosed annex - CO_2
Performance data : **Theoretical values and confidence intervals**	- The mean values are derived from replicate analyses and are lot specific. The tests listed were performed by the reagent manufacturer and/or independent laboratories using manufacturer supported reagents and a representative sampling of this lot of control.	- The assigned values are traceable with a reference material in accordance with established protocols. - The assigned values and precise confidence interval are indicated in the annex enclosed in the kit

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

- Guidance for Industry and FDA Staff : "Format for Traditional & Abbreviated 510(k)s" : August 12, 2005

- "In vitro diagnostics devices : Guidance for the preparation of 510(k) submissions" Jan 1997

- "Guidance for Industry – In vitro diagnostics Bicarbonate/Carbon Dioxide Test System" July 1998

- "Guidance for Industry – In vitro diagnostics Urea Nitrogen Test System" July 1998

- "Guidance for Industry – In vitro diagnostics Creatinine Test System" July 1998

- "Guidance for Industry and FDA Staff Bundling Multiple Devices or Multiple Indications in a Single Submission" November 2003

- CLSI (NCCLS) :

    i) EP05-A2 – Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline-Second Edition

    ii) EP06-A - Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline

    iii) EP09-A2 – Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline -Second Edition

    iv) EP21-A - Estimation of Total Analytical Error for Clinical Laboratory Methods; Approved Guideline

L. Test Principle:

The **ABX PENTRA ALP CP** is a kinetic photometric test using p-Nitrophenylphosphate.

The **ABX PENTRA Calcium CP** is a photometric test using orthocresolphtalein complexone.

The **ABX PENTRA CO_2 RTU** is enzymatic test using phosphoenolpyruvate (PEP), phosphorenolpyruvate carboxylase (PEPC) and an analog of NADH.

The **ABX PENTRA Creatinine CP** is a kinetic method using alkaline picrate (Jaffé method).

The **ABX PENTRA Iron CP** is a photometric test based upon the Ferene method.

The **ABX PENTRA Magnesium RTU** is a photometric test using xylidyl blue.

The **ABX PENTRA Phosphorus CP** is UV method using phosphomolybdate.

The **ABX PENTRA Urea CP** is an enzymatic UV test using urease and glutamate dehydrogenase.

The **ABX PENTRA Uric Acid CP** is an enzymatic test of uric acid using a chromogenic system in the presence of peroxidase and uricase (Trinder method)

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

    a. Precision/Reproducibility:

ABX PENTRA ALP CP

Repeatability (Within run precision) - 2 controls and 3 specimens of low, medium and high concentrations were tested 20 times in a single run for each sample.

	Mean Value (U/L)	%CV
Normal Control	90.79	1.27
Abnormal Control	252.68	0.62
Specimen 1	28.05	3.98
Specimen 2	54.88	2.42
Specimen 3	430.87	0.84

Reproducibility (Total precision) - Based upon CLSI EP-5A, two specimens of low & high levels and 2 controls were tested in duplicate for 20 days, two runs per day.

	Mean Value (U/L)	%CV
Normal Control	90.79	3.62
Abnormal Control	254.38	2.39
Specimen 1	64.11	4.36
Specimen 2	190.44	2.66

ABX PENTRA Calcium CP

Repeatability (Within run precision) - 2 controls and 3 specimens of low, medium and high concentrations were tested 20 times in a single run for each sample.

	Mean Value (Mg/dL)	%CV
Normal Control	9.4	0.92
Abnormal Control	15.22	0.42
Specimen 1	6.56	0.81
Specimen 2	9.32	0.51
Specimen 3	16.36	0.51

Reproducibility (Total precision) - Based upon CLSI EP-5A, two specimens of low & high levels and 2 controls were tested in duplicate for 20 days, two runs per day.

	Mean Value (Mg/dL)	%CV
Normal Control	9.34	1.58
Abnormal Control	15.20	1.57
Specimen 1	7.04	1.49
Specimen 2	15.83	1.67

ABX PENTRA CO2 RTU

Repeatability (Within run precision) - 1 control and 3 specimens of low, medium and high concentrations were tested 20 times in a single run for each sample.

	Mean Value (Mg/dL)	%CV
Control	20.44	1.25
Specimen 1	10.93	0.78
Specimen 2	21.30	0.51
Specimen 3	32.03	0.66

Reproducibility (Total precision) - Based upon CLSI EP-5A, two specimens of low & high levels and 1 control were tested in duplicate for 20 days, two runs per day.

	Mean Value (Mg/dL)	%CV
Control	20.75	4.77
Specimen 1	9.53	7.70
Specimen 2	31.57	5.93

ABX PENTRA Creatinine CP

Repeatability (Within run precision) - 2 controls and 3 specimens of low, medium and high concentrations were tested 20 times in a single run for each sample.

	Mean Value (Mg/dL)	%CV
Normal Control	1.28	1.58
Abnormal Control	3.38	0.66
Specimen 1	0.59	2.09
Specimen 2	1.55	0.71
Specimen 3	7.64	0.39

Reproducibility (Total precision) - Based upon CLSI EP-5A, two specimens of low & high levels and 2 controls were tested in duplicate for 20 days, two runs per day.

	Mean Value (Mg/dL)	%CV
Normal Control	1.27	3.47
Abnormal Control	3.45	2.56
Specimen 1	1.29	3.69
Specimen 2	6.75	2.04

ABX PENTRA Iron CP
Repeatability (Within run precision) - 2 controls and 3 specimens of low, medium and high concentrations were tested 20 times in a single run for each sample.

	Mean Value (ug/dL)	%CV
Normal Control	115.36	1.89
Abnormal Control	189.92	1.5
Specimen 1	50.41	2.56
Specimen 2	95.91	2.32
Specimen 3	680.26	0.32

Reproducibility (Total precision) - Based upon CLSI EP-5A, two specimens of low & high levels and 2 controls were tested in duplicate for 20 days, two runs per day.

	Mean Value (ug/dL)	%CV
Normal Control	116.83	2.98
Abnormal Control	191.05	2.61
Specimen 1	74.4	3.61
Specimen 2	510.99	1.78

ABX PENTRA Magnesium RTU
Repeatability (Within run precision) - 2 controls and 3 specimens of low, medium and high concentrations were tested 20 times in a single run for each sample.

	Mean Value (Mg/dL)	%CV
Normal Control	2.44	2.02
Abnormal Control	4.19	1.28
Specimen 1	1.58	2.28
Specimen 2	2.27	1.92
Specimen 3	2.86	1.98

Reproducibility (Total precision) - Based upon CLSI EP-5A, two specimens of low & high levels and 2 controls were tested in duplicate for 20 days, two runs per day.

	Mean Value (Mg/dL)	%CV
Normal Control	2.50	3.19
Abnormal Control	4.27	2.80
Specimen 1	2.20	2.63
Specimen 2	3.19	2.79

ABX PENTRA Phosphorus CP

Repeatability (Within run precision) - 2 controls and 3 specimens of low, medium and high concentrations were tested 20 times in a single run for each sample.

	Mean Value (Mg/dL)	%CV
Normal Control	4.08	1.26
Abnormal Control	6.34	0.77
Specimen 1	2.39	2.48
Specimen 2	3.48	1.61
Specimen 3	9.19	1.38

Reproducibility (Total precision) - Based upon CLSI EP-5A, two specimens of low & high levels and 2 controls were tested in duplicate for 20 days, two runs per day.

	Mean Value (Mg/dL)	%CV
Normal Control	4.01	2.50
Abnormal Control	6.35	1.82
Specimen 1	2.50	3.56
Specimen 2	11.44	1.38

ABX PENTRA Urea CP

Repeatability (Within run precision) - 2 controls and 3 specimens of low, medium and high concentrations were tested 20 times in a single run for each sample.

Urea Nitrogen:

	Mean Value (Mg/dL)	%CV
Normal Control	40.1	2.27
Abnormal Control	155.6	1.66
Specimen 1	12.9	2.76
Specimen 2	44.6	1.58
Specimen 3	182.7	1.80

Blood Urea Nitrogen:

	Mean Value (Mg/dL)	%CV
Normal Control	18.73	2.27
Abnormal Control	72.78	1.66
Specimen 1	6.02	2.76
Specimen 2	20.86	1.58
Specimen 3	85.46	1.80

Reproducibility (Total precision) - Based upon CLSI EP-5A, two specimens of low & high levels and 2 controls were tested in duplicate for 20 days, two runs per day.

Urea Nitrogen:

	Mean Value (Mg/dL)	%CV
Normal Control	39.4	2.14
Abnormal Control	153.2	1.93
Specimen 1	149.9	2.14
Specimen 2	70.12	1.97

Blood Urea Nitrogen:

	Mean Value (Mg/dL)	%CV
Normal Control	18.45	2.14
Abnormal Control	71.69	1.93
Specimen 1	19.24	2.14
Specimen 2	70.12	1.97

ABX PENTRA Uric Acid CP

Repeatability (Within run precision) - 2 controls and 3 specimens of low, medium and high concentrations were tested 20 times in a single run for each sample.

	Mean Value (Mg/dL)	%CV
Normal Control	4.62	0.45
Abnormal Control	11.63	0.34
Specimen 1	2.53	1.24
Specimen 2	4.58	0.91
Normal Control	7.19	1.02

Reproducibility (Total precision) - Based upon CLSI EP-5A, two specimens of low & high levels and 2 controls were tested in duplicate for 20 days, two runs per day.

	Mean Value (Mg/dL)	%CV
Normal Control	4.64	2.81
Abnormal Control	11.73	1.39
Specimen 1	4.67	2.64
Specimen 2	6.74	2.51

b. Linearity/assay reportable range:

Linearity studies across the measuring range of the assay were performed via protocols based upon CLSI EP6-A. The studies demonstrated linearity of the

assays and the linear regression statistics listed below. In addition, post dilution studies were performed to validated the automated dilution function and range.

ABX PENTRA ALP CP

The measuring range of the assay is 6 – 1500 U/L; Post dilution up to 6000 U/L.

Linear regression statistics: $y = 0.9461x + 15.89$; $R^2 = 0.9993$

ABX PENTRA Calcium CP

The measuring range of the assay is 0.16 – 20 mg/dL; Post dilution up to 40 mg/dL.

Linear regression statistics: $y = 1.0451x – 0.1221$; $R^2 = 0.9994$

ABX PENTRA CO2 RTU

The measuring range of the assay is 1.8 – 60.8 mmol/L; Post dilution up to 121 mmol/L.

Linear regression statistics: $y = 1.0201x – 0.2967$; $R^2 = 0.9999$

ABX PENTRA Creatinine CP

The measuring range of the assay is 0.11 – 15.8 mg/dL; Post dilution up to 79 mg/dL.

Linear regression statistics: $y = 0.9448x + 20.05$; $R^2 = 0.9997$

ABX PENTRA Iron CP

The measuring range of the assay is 7.42 – 1004 µg/dL; Post dilution up to 5020 µg/dL.

Linear regression statistics: $y = 1.0065x – 0.3502$; $R^2 > 0.9999$

ABX PENTRA Magnesium RTU

The measuring range of the assay is 0.17 – 4.64 mg/dL; Post dilution up to 13.92 mg/dL.

Linear regression statistics: $y = 0.9277x + 0.0515$; $R^2 = 0.998$

ABX PENTRA Phosphorus CP

The measuring range of the assay is 0.28 – 24.18 mg/dL; Post dilution up to 96.72 mg/dL.

Linear regression statistics: $y = 1.0146x – 0.043$; $R^2 = 0.9998$

ABX PENTRA Urea CP

The measuring range of the assay is 0.9 - 300 mg/dL(0.9 – 140.3mg/dL for BUN); Post dilution up to 1500 mg/dL (up to 701.5 for BUN).

Linear regression statistics: $y = 0.9878x + 0.1583$; $R^2 = 0.9998$

ABX PENTRA Uric Acid CP

The measuring range of the assay is 0.19 - 25 mg/dL; Post dilution up to 75 mg/dL.

Linear regression statistics: $y = 1.0173x – 1.2204$; $R^2 > .9999$

c. Traceability, Stability, Expected values (controls, calibrators, or methods):

Protocols and acceptance criteria for on-board and shelf life stability studies were described and found to be acceptable.

ABX Pentra CO_2 Control traceability

The ABX Pentra CO_2 Control is gravimetrically prepared to a concentration of 20mmol/l sodium bicarbonate. The value of the ABX Pentra CO_2 Control is assigned using a biochemistry analyzer, e.g. Hitachi 911.

ABX Pentra CO_2 Calibrator traceability

ABX Pentra CO_2 Cal is made from a secondary reference material, traceable to NIST 723c to a concentration of 30 mmol/l sodium bicarbonate. The Master Lot is stored under the same conditions as a normal production lot, and has the same expiration date: 15 months after production at 2-8°C. The target value is determined by the median of all results yielded from the 6 devices (150 measurements/parameter).

d. Detection limit:

Method: Based upon the Valtec guideline (Vassault et *al*., Ann. Biol. Clin., 1986, (44), 686-745)

Minimum Detection Limit (MDL) was calculated from 30 measurements of saline water (0.9 g/l)
Formula : MDL = mean of measurements + 4.65 SD (mean of measurement = 0 when negative

Using the above criteria, the following minimum detection limits were determined:

ABX PENTRA ALP CP - 6 U/L

ABX PENTRA Calcium CP - 0.16 Mg/dL

ABX PENTRA CO2 RTU - 1.8 mmol/L

ABX PENTRA Creatinine CP - 0.11 Mg/dL

ABX PENTRA Iron CP - 7.42 µg/dL

ABX PENTRA Magnesium RTU - 0.17 Mg/dL

ABX PENTRA Phosphorus CP - 0.28 Mg/dL

ABX PENTRA Urea CP - 0.9 Mg/dL

ABX PENTRA Uric Acid CP - 0.19 Mg/dL

e. Analytical specificity:

Substances were added to pooled Human serum samples at two different measurand concentrations (normal and high). The base serum with each interfering substance was then serially diluted with the same base serum containing saline instead of interfering substance to adjust for analyte concentration.

Method: Based upon the Valtec guideline (Vassault et *al*., Ann. Biol. Clin., 1986, (44), 686-745)

ABX PENTRA ALP CP - Hemoglobin up to 195 µmol/l (3.36 g/l or 336 mg/dl), total bilirubin up to 470 µmol/l (27.5 mg/dl), direct bilirubin up to 250 µmol/l (14.6 mg/dl) and triglycerides (as Intralipid ®, representative of lipemia) up to 7 mmol/l (612.5 mg/dl) do not interfere with ALP determination by this test.

ABX PENTRA Calcium CP - Hemoglobin up to 195 µmol/l (3.36 g/l or 336 mg/dl), Total Bilirubin up to 101 µmol/l (5.91 mg/dl), direct bilirubin up to 1357 µmol/l (79.4 mg/dl) and triglycerides (as Intralipid ®, representative of lipemia) up to 7 mmol/l (612.5 mg/dl) do not interfere with calcium determination by this test.

ABX PENTRA CO2 RTU - Hemoglobin up to 195 µmol/l (336mg/dl), total bilirubin up to 250 µmol/l (14.6 mg/dl), direct bilirubin up to 370 µmol/l (21.6 mg/dl) and triglycerides (as Intralipid ®, representative of lipemia) up to 7 mmol/l (612.5 mg/dl) do not interfere with bicarbonates determination by this test.

ABX PENTRA Creatinine CP - Hemoglobin up to 319 µmol/l (550 mg/dl), total bilirubin up to 176 µmol/l (10.30 mg/dl), direct bilirubin up to 92 µmol/l (5.38 mg/dl), triglycerides (as Intralipid ®, representative of lipemia) up to 7

mmol/l (612.5 mg/dl) and glucose up to 22.5 mmol/l (405 mg/dl) do not interfere with creatinine determination by this test.

ABX PENTRA Iron CP - Hemoglobin up to 104 µmol/l (180 mg/dl), total bilirubin up to 321 µmol/l (18.78 mg/dl), direct bilirubin up to 289 µmol/l (16.91 mg/dl) and triglycerides (as Intralipid ®, representative of lipemia) up to 7 mmol/l (612.5 mg/dl) do not interfere with Iron determination by this test.

ABX PENTRA Magnesium RTU - Hemoglobin up to 195 µmol/l (336 mg/dl), total bilirubin up to 290 µmol/l (16.97 mg/dl), direct bilirubin up to 520 µmol/l (30.42 mg/dl) and triglycerides (as Intralipid ®, representative of lipemia) up to 7 mmol/l (612.5 mg/dl) do not interfere with Magnesium determination by this test.

ABX PENTRA Phosphorus CP - Hemoglobin up to 72.5 µmol/l (1.25 g/l or 125 mg/dl), total bilirubin up to 102.6 µmol/l (6 mg/dl), direct bilirubin up to 427 µmol/l (25 mg/dl) and triglycerides (as Intralipid ®, representative of lipemia) up to 3 mmol/l (262.5 mg/dl) do not interfere with Phosphorus determination by this test.

ABX PENTRA Urea CP - Hemoglobin up to 267 µmol/l (460 mg/dl), total bilirubin up to 380 µmol/l (22.23 mg/dl), direct bilirubin up to 400 µmol/l (23.40 mg/dl) and triglycerides (as Intralipid ®, representative of lipemia) up to 7 mmol/l (612.5 mg/dl) do not interfere with Urea/BUN determination by this test.

ABX PENTRA Uric Acid CP - Hemoglobin up to 290 µmol/l (500 mg/dl), total bilirubin up to 616 µmol/l (36 mg/dl), direct bilirubin up to 513 µmol (30 mg/dl) and triglycerides (as Intralipid ®, representative of lipemia) up to 7 mmol/l (612.5 mg/dl) do not interfere with uric acid determination by this test.

f. Assay cut-off:

Not applicable

2. Comparison studies:

a. Method comparison with predicate device:

ABX PENTRA ALP CP

A total of 105 samples were compared with the Roche Alkaline Phosphatase reagent (predicate) on the Roche MIRA Plus.

$y = 1.0692x - 5.1259$, $r^2 = 0.9981$

Additional studies were performed to provide complementary data covering the Alkaline Phosphatase assay range 6 – 1500 U/L. Samples were spiked or diluted depending upon test conditions (high or low range study). Low range study: sample range 7.2 – 35.5U/L, n=14, y=0.8789x-1.6928, r^2=0.9833. High Range study: sample range 1247.8 – 1598U/L, n=12, y=1.0634x+43.3, r^2=0.932.

ABX PENTRA Calcium CP

A total of 95 samples were compared with the Roche Calcium reagent (predicate) on the Roche MIRA Plus.

y = 1.128x - 0.2145, r^2=0.9501

Additional studies were performed to provide complementary data covering the Calcium assay range 0.6 – 20.10 mg/dl. Samples were spiked or diluted depending upon test conditions (high or low range study). Low range study: sample range 0.24 – 11.19 mg/dl, n=15, y=1.0409x + 0.1034, r^2=0.9982. High Range study: sample range 16.8 – 22.46mg/dl, n=15, y=1.2507x – 1.9012, r^2=0.9626

ABX PENTRA CO_2 RTU

A total of 97 samples were compared with the Roche CO_2 reagent on the Roche MIRA Plus.

y = 0.927x - 1.615, r^2 = 0.9763

Additional studies were performed to provide complementary data covering the CO_2 RTU assay range 1.8 – 60.8 mmol/l. Samples were spiked or diluted depending upon test conditions (high or low range study). Low range study: sample range 1.2 – 14.8 mmol/l, n=15, y=0.9986x + 0.2329, r^2=0.9936. High Range study: sample range 23.2 – 41.9 mmol/l, n=14, y=1.0784x – 2.7369, r^2=0.9217

ABX PENTRA Creatinine CP

A total of 95 samples were compared with the Roche Creatinine reagent on the Roche MIRA Plus.

y = 1.0109x - 18.735, r^2 = 0.9955

Additional studies were performed to provide complementary data covering the Creatinine assay range 0.11 – 15.8 mg/dl. Samples were spiked or diluted depending upon test conditions (high or low range study). Low range study: sample range 0.08 – 1.02 mg/dl, n=16, y=1.0417x + 0.0779, r^2=0.9438. High Range study: sample range 8.82 - 16.35 mg/dl, n=13, y=1.0241x – 0.7807, r^2=0.9759

ABX PENTRA Iron CP

A total of 98 samples were compared with the Raichem Iron reagent on the Roche MIRA Plus.

$y = 1.1307x + 0.88$, $r^2 = 0.9975$

Additional studies were performed to provide complementary data covering the Creatinine assay range 0.11 – 15.8 mg/dl. Samples were spiked or diluted depending upon test conditions (high or low range study). Low range study: sample range 0.08 – 1.02 mg/dl, n=16, $y=1.0417x + 0.0779$, $r^2=0.9438$. High Range study: sample range 8.82 - 16.35 mg/dl, n=13, $y=1.0241x – 0.7807$, $r^2=0.9759$

ABX PENTRA Magnesium RTU

A total of 75 samples were compared with the Roche Magnesium reagent on the Roche MIRA Plus.

$y = 1.2532x – 0.1018$, $r^2 = 0.9712$

Additional studies were performed to provide complementary data covering the Magnesium assay range 0.17 – 4.64 mg/dl. Samples were spiked or diluted depending upon test conditions (high or low range study). Low range study: sample range 0.19 – 1.38 mg/dl, n=18, $y=1.1644x - 0.2428$, $r^2=0.8674$. High Range study: sample range 0.19 – 6.42 mg/dl, n=93, $y=1.2707x – 0.3034$, $r^2=0.9849$.

ABX PENTRA Phosphorus CP

A total of 105 samples were compared with the Roche Phosphorus reagent on the Roche MIRA Plus.

$y = 1.035x + 0.0858$, $r^2 = 0.9967$

Additional studies were performed to provide complementary data covering the Phosphorus assay range 0.28 – 24.18 mg/dl. Samples were spiked or diluted depending upon test conditions (high or low range study). Low range study: sample range 0.25 – 2.23 mg/dl, n=14, $y=1.1075x - 0.0029$, $r^2=0.9896$. High Range study: sample range 15.16 – 25.05 mg/dl, n=13, $y=1.2156x – 2.9012$, $r^2=0.978$

ABX PENTRA Urea CP

A total of 108 samples were compared with the Roche BUN reagent on the Roche MIRA Plus.

Urea (mmol/L)

$y = 1.039x + 0.116$, $r^2 = 0.9904$

BUN (mg/dL)

$y=1.039x+0.697$, $r^2 = 0.9905$

Additional studies were performed to provide complementary data covering the BUN assay range 0.9 – 140.3 mg/dl. Samples were tested based upon recommendations in NCCLS (CLSI) EP-9A2 guidance. Samples were spiked or diluted depending upon test conditions (high or low range study). Low range study: sample range 0.79 – 5.25 mg/dl, n=15, $y=0.8334x + 0.1903$, $r^2=0.9484$. High Range study: sample range 95.79 – 138.89 mg/dl, n=13, $y=0.8862x + 14.677$, $r^2=0.993$.

ABX PENTRA Uric CP

A total of 98 samples were compared with the Roche Uric Acid reagent on the Roche MIRA Plus.

$y=0.0936x+14.14.13$, $r^2 = 0.9579$

Additional studies were performed to provide complementary data covering the Uric Acid assay range 0.19 – 25 mg/dl. Samples were spiked or diluted depending upon test conditions (high or low range study). Low range study: sample range 0.15 – 2.42 mg/dl, n=15, $y=0.899x -0.001$, $r^2=0.9927$. High Range study: sample range 7.74 – 23.96 mg/dl, n=19, $y=0.942x - 0.122$, $r^2=0.9936$.

b. Matrix comparison:

Method : To demonstrate equivalence of analyte results in serum and Plasma Heparin-Lithium samples, comparison study was performed on samples that were evaluated on Pentra 400 analyzer using ABX Pentra reagents. Comparisons were made serum vs plasma for corresponding samples.

ABX PENTRA ALP CP

Slope: $y = 0.9486x + 0.2488$, $r^2 = 0.992$, N = 45 on serum versus Lithium-Heparin Plasma

ABX PENTRA Calcium CP

Slope: $y = 0.6903x + 0.7822$, $r^2 = 0.649$, N = 43 on serum versus Lithium-Heparin Plasma

Because of 3 outliers at the higher end of the range, the sponsor also performed Passing-Bablock analysis:

Variable X : Serum
Variable Y : Plasma

In mmol/l:
y = 0.9714x +0.0943

Intercept 95% CI: -0.2190 to 0.4271
Slope 95% CI: 0.8387 to 1.1000

ABX PENTRA CO_2 RTU

Slope: y = 0.9200x - 0.1700, r^2 = 0.7569, N=33 on serum versus Lithium-Heparin Plasma

ABX PENTRA Creatinine CP

Slope: y = 1.0227x-4.1072, N=34 on serum versus Lithium-Heparin Plasma

ABX PENTRA Iron CP

Slope: y = 0.9885x+0.348, r^2 = 0.7569, N=40 on serum versus Lithium-Heparin Plasma

ABX PENTRA Magnesium RTU

Slope: y = 0.971x – 0.0185, r^2 = 0.9883, N=41 on serum versus Lithium-Heparin Plasma

ABX PENTRA Phosphorus CP

Slope: y = 0.9858x + 0.0255, r^2 = 0.9981, N=42 on serum versus Lithium-Heparin Plasma

ABX PENTRA Urea CP

Urea (mmol/L)

Slope: y = 0.9986x + 0.0211, r^2 = 0.994, N=43 on serum versus Lithium-Heparin Plasma

BUN (mg/dL)

Slope: y = 0.9986x + 0.0593, r^2 = 0.994, N=43 on serum versus Lithium-Heparin Plasma

ABX PENTRA Uric Acid CP

Slope y=1.0224x-2.3035 r^2 = 0.9952, N=36 on serum versus Lithium-Heparin Plasma

The results support equivalency of serum specimens and Heparin-Lithium Plasma for the above assays.

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 ALP CP

Adults (37°C) : (1)		
Women 20 - 50 years	[U/l]	42 - 98
Men 20 - 50 years	[U/l]	53 - 128
Women > 60 years	[U/l]	53 - 141
Men > 60 years	[U/l]	56 - 119

Children (37°C) : (2)		Female	Male
1 - 30 days	[U/l]	48 - 406	75 - 319
1 month - 1 year	[U/l]	124 - 341	82 - 383
1 - 3 year(s)	[U/l]	108 - 317	104 - 345
4 - 6 years	[U/l]	96 - 297	93 - 309
7 - 9 years	[U/l]	69 - 325	86 - 315
10 - 12 years	[U/l]	51 - 332	42 - 362
13 - 15 years	[U/l]	50 - 162	74 - 390
16 - 18 years	[U/l]	47 - 119	52 - 171

References:

1. Burtis CA, Ashwood ER. Eds. Tietz textbook of clinical chemistry. 3rd ed. Philadelphia: W. B. Saunders Company, 1999. p. 1829.

2. Soldin JS, Hicks JM. Pediatric reference ranges. Washington: AACC Press, 1996. p. 5.

ABX PENTRA Calcium CP

Serum / Plasma: 8.6 - 10.3 mg/dl (2.15 - 2.57 mmol/l)

Reference:
Endres D.B., Rude R.K. Mineral and bone metabolism. In: Burtis C.A., Ashwood E.R., editors. Tietz Textbook of Clinical Chemistry. 3rd ed. Philadelphia: W.B. Saunders Company; 1999. p. 1395-1457.

ABX PENTRA CO2 RTU

Adults: 22 - 29 mmol/l.

Reference:
Müller-Plathe O. Acid base balance and blood gases. In: Thomas L., editor. Clinical laboratory diagnostics. 1st ed. Frankfurt: T.H. BooksVerlagsgesellschaft; 1998. p.318-329.

ABX PENTRA Creatinine CP

Men		Women		
8	13	6	12	mg/L
0.8	1.3	0.6	1.2	mg/dL
71	115	53	106	µmol/L

Reference:
Tietz, N.W. Clinical guide to laboratory tests, 3ème Ed, (W.B. Saunders eds. Philadelphia USA), (1995), 186.

ABX PENTRA Iron CP

	µg/dl	µmol/l
Children		
2 weeks	63-201	11-36
6 months	28-135	5-24
12 months	35-155	6-28
2 – 12 years	22-135	4-24

	ug/dl	umol/l
Women		
25 years	37-165	6.6-29.5
40 years	23-134	4.1-24.0
60 years	39-149	7.0-26.7
Pregnant Women		
12th gestational week	42-177	7.6-31.6
At term	25-137	4.5-24.5
6 weeks postpartum	16-150	2.9-26.9
Men		
25 years	40-155	7.2-27.7
40 years	35-168	6.3-30.1
60 Years	40-120	7.2-21.5

Reference: Thomas L. Clinical Laboratory Diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 273-5.

ABX PENTRA Magnesium RTU

Neonates: 1.2 - 2.6 mg/dl (0.48 - 1.05 mmol/l)
Children: 1.5 - 2.3 mg/dl (0.60 - 0.95 mmol/l)
Women: 1.9 - 2.5 mg/dl (0.77 - 1.03 mmol/l)
Men: 1.8 - 2.6 mg/dl (0.73 - 1.06 mmol/l)

References :
- Thomas L. Clinical Laboratory Diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 231-241.
- Sitzmann FC. Normalwerte. München: Hans Marseille Verlag GmbH: 1986. p. 166.

ABX PENTRA Phosphorus CP

Serum/Plasma:	27 - 45	mg/L
	2.7 – 4.5	mg/dL
	0.87 – 1.45	mmol/L

Reference :
Endres, D.B., Rude, R.K., Mineral and bone metabolism. Tietz Fundamentals of Clinical Chemistry, Burtis, C.A. et Ash-wood, E.R. (W.B. Saunders eds. Philadelphia USA), (2001), 795.

ABX PENTRA Urea CP

In Serum / Plasma	Urea		**BUN**
	[mg/dl]	[mmol/l]	**[mg/dl]**
Adults:			
Global	17-43	2.8-7.2	**7.9-20.2**
Women <50 years	15-40	2.6-6.7	**7.3-18.8**
Women >50 years	21-43	3.5-7.2	**9.8-20.2**
Men <50 years	19-44	3.2-7.3	**9.0-20.5**
Men >50 years	18-55	3.0-9.2	**8.4-25.8**
Children:			
1-3 years	11-36	1.8-6.0	**5.1-16.8**
4-13 years	15-36	2.5-6.0	**7.0-16.8**
14-19 years	18-45	2.9-7.5	**8.1-21.1**

Reference:
Thomas L. Clinical Laboratory Diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 374-377.

ABX PENTRA Uric Acid CP

Serum, plasma:

Women : 26 - 60 mg/L
2.6 - 6 mg/dL
155 – 357 µmol/l

Men : 35 - 72 mg/L
3,5 - 7,2 mg/dL
208 - 428 µmol/L

Reference : Tietz, N.W., Clinical guide to laboratory tests. 3ème Ed., (W.B. Saunders eds. Philadelphia USA), (1995), 268.

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.