

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY AND INSTRUMENT COMBINATION TEMPLATE**

A. 510(k) Number:

K052007

B. Purpose for Submission:

The submission is for clearance of the ABX Pentra 400 Clinical Chemistry Analyzer and ABX Pentra Glucose reagents and Optional I.S.E. module for Sodium, Potassium and Chloride with associated calibrators (manufactured by Roche) and controls (manufactured by Roche).

C. Measurand:

Glucose, Sodium, Potassium and Chloride

D. Type of Test:

Quantitative

E. Applicant:

HORIBA ABX

F. Proprietary and Established Names:

ABX PENTRA 400 CLINICAL CHEMISTRY ANALYZER (OPTION: I.S.E. MODULE)

G. Regulatory Information:

1. Regulation section:

21 CFR §862.1345-Glucose test system.

21 CFR §862.1665-Sodium test system.

21 CFR §862.1600-Potassium test system.

21 CFR §862.1170-Chloride test system.

21 CFR §862.1150-Calibrator.

21 CFR §862.1660-Quality control material (assayed and unassayed).

21 CFR §862.2160-Discrete Photometric Chemistry Analyzer for Clinical Use

2. Classification:

2,2,2,2,2,1 reserved, and 1 respectively

3. Product code:

CFR-HEXOKINASE, GLUCOSE

JGS-ELECTRODE, ION SPECIFIC, SODIUM

CEM-ELECTRODE, ION SPECIFIC, POTASSIUM

CGZ-ELECTRODE, ION-SPECIFIC, CHLORIDE

JIX-CALIBRATOR, MULTI-ANALYTE MIXTURE

JJY-MULTI-ANALYTE CONTROLS, ALL KINDS (ASSAYED AND UNASSAYED)

JJE-ANALYZER, CHEMISTRY (PHOTOMETRIC, DISCRETE), FOR CLINICAL USE

4. Panel:

Chemistry (75)

H. Intended Use:

1. Intended use(s):

See indications for use below

2. Indication(s) for use:

The **ABX PENTRA Glucose HK CP** is a ready-to-use reagent for use on the

ABX Pentra 400 system for quantitative in vitro diagnostic determination of glucose in serum and plasma using glucose hexokinase method by colorimetry.

The **ABX PENTRA Glucose PAP CP** is a ready-to-use reagent for use on the ABX Pentra 400 system for quantitative in vitro diagnostic determination of glucose in serum and plasma using glucose oxidase method by colorimetry.

The **ABX PENTRA Sodium – E** is an electrode for use on the I.S.E. module of the ABX Pentra 400 system for quantitative in vitro diagnostic determination of Sodium in human serum, plasma and urine.

The **ABX PENTRA Potassium – E** is an electrode for use on the I.S.E. module of the ABX Pentra 400 system for quantitative in vitro diagnostic determination of Potassium in human serum, plasma and urine.

The **ABX PENTRA Chloride – E** is an electrode for use on the I.S.E. module of the ABX Pentra 400 system for quantitative in vitro diagnostic determination of Chloride in human serum, plasma and urine.

The **ABX PENTRA 400** is a discrete photometric benchtop chemistry analyzer for clinical use.

The device is intended to duplicate manual analytical procedures by performing various steps such as pipetting, mixing, heating and measuring color intensity.

The device is intended for use in conjunction with certain materials to measure a variety of analytes.

The option of an **I.S.E.** (Ion Selective Electrode) module is intended for the quantitative determination of Sodium, Chloride, and Potassium by potentiometry using ion selective electrode.

The **ABX PENTRA Multical** is a calibrator for use in the calibration of specified quantitative Horiba ABX methods on Horiba ABX clinical chemistry analyzers.

The **ABX PENTRA Standard 1, Standard 2 and Reference** reagents are for use in the calibration of quantitative determination of sodium, potassium and chloride on ABX PENTRA 400 ISE module.

The **ABX PENTRA N Control and P Control** are for use in quality control by monitoring accuracy and precision for specified quantitative methods.

3. Special conditions for use statement(s):
For prescription use
4. Special instrument requirements:
ABX PENTRA 400 CLINICAL CHEMISTRY ANALYZER (OPTION: I.S.E. MODULE)

I. Device Description:

The **ABX PENTRA 400** is a benchtop clinical chemistry analyzer using two measuring principles absorbance and ion selective electrodes.

The instrument may be summarized as follows:

- Multi-parametric (up to 52 simultaneous tests + 3 ISE tests)
- Patient per patient
- On routine or Stat
- 150 to 300 tests / hour (in single or bi-reaction mode) (analytical cycle of 12seconds)
- random access working on primary tubes or sample cups
- ABX PENTRA reagent cassettes are compact and ready-to-use.
- on board bar-code readers are used to identify newly loaded reagent cassettes and samples for patient identification

The ABX PENTRA 400 offers both Closed and Open channels for a multitude of parameters (clinical chemistry, DAT, TDM, plasma protein, hemostasis, optional ISE module).

ABX Pentra Glucose HK CP - Bi-reagent cassette, ready to use REAGENT 1: NAD, ATP, Buffer, Sodium azide REAGENT 2: hexokinase, G-6-PDH, Magnesium sulphate, Sodium azide.

ABX Pentra Glucose PAP CP - Single-reagent cassette, ready to use REAGENT: Phenol, 4-aminoantipyrine, glucose oxidase, peroxidase, Sodium azide, Buffer.

ABX PENTRA 400 I.S.E. MODULE -

- Sodium Electrode ABX Pentra Sodium-E: glass membrane selective to Na⁺ ions
- Potassium Electrode ABX Pentra Potassium-E: plastic membrane selective to K⁺ ions
- Chloride Electrode ABX Pentra Chloride-E: plastic membrane selective to Cl⁻ ions

J. Substantial Equivalence Information:

1. Predicate device name(s):
Roche Cobas Mira Plus/Option I.S.E module, Cobas Reagent for Glucose Rapid, Roche Calibrator for Automated Systems (C.f.a.s.) and Roche Precinorm Universal
2. Predicate 510(k) number(s):
K920402/ K963627, K801297 and K041227 respectively
3. Comparison with predicate:

	Predicate device :	Device :
Device Name	Cobas MIRA Plus	ABX PENTRA 400
Instrument Type	Tabletop analyzer	Benchtop
Separate Work Station	No	Integrated

	Predicate device :	Device :
Device Name	Cobas MIRA Plus	ABX PENTRA 400
Open/Closed reagent system	Open	Open/Closed system
Touch Screen Interface	No	Yes
I.S.E. Optional/Not optional	Optional	Optional
ISE parameters	Na, K, Cl	Na, K, Cl
Potentiometry	Direct & indirect	Direct & indirect
Sample volume in μl	Direct: 85/ Indirect: 20	60 for 3 parameters
Sodium Electrode	Glass membrane selective to Na^+ ions	Glass membrane selective to Na^+ ions
Potassium Electrode	PVC valinomycin membrane selective to K^+ ions	Plastic membrane selective to K^+ ions
Chloride Electrode	Liquid membrane selective to Cl^- ions	Plastic membrane selective to Cl^- ions
Type of samples	Serum Plasma Urine	Serum Plasma Urine
Throughput		
Without I.S.E.	132	300
With I.S.E.	200	up to 420
Parameters on board	30	52 (Mono, Bi-reagents cassettes)
Refrigerated	20	44
Non refrigerated	10	8
Sample treatment		
Sample capacity	16 tubes or 30 cups/rack	60 (6 racks of 10 samples)
Real patient sample ID	Yes	Yes
Bar-Code reader	Integrated	Integrated
Primary tube types	1, 3, 5, 7, 10 mL	1, 3, 5, 7, 10 mL
Sample volume	2 to 95 μl	2 to 95 μl
Dilution of patient sample	Yes	Yes
Fibrin detecting device	No	Yes
Disposable tips	Washable needles	Washable needles
Automatic standard curve dilution	No	Yes
Reagents		
Type of reagents	Liquid	Liquid
Disposable/Washable cuvettes	Disposable cuvettes	Disposable cuvettes
Total reaction volume	Mini: 100 μl , Maxi: 250 μl	Mini: 150 μl , Maxi: 600 μl
Maximum number of reagents per test	4	3 reagents + 5 buffers
Principles of Measurement	Spectrophotometry : Monochromatic measurement of light absorbance (Xenon (flash) lamp) Potentiometry : Direct (Serum or Plasma) and Indirect (Urine)	Spectrophotometry : Colorimetry and Turbidimetry : parallel bi-chromatic measurement of light absorbance (Tungsten halogen lamp) Potentiometry : Direct (Serum or Plasma) and Indirect (Urine)
Measurement		
Photometer type : light source	Xenon (flash)	Halogen
Type of measurement	Mono	Mono, Bi chromatic

	Predicate device :	Device :
Device Name	Cobas MIRA Plus	ABX PENTRA 400
Dimensions (HxWxD)	73 x 58 x 54 cm	100 x 65 x 57 cm
Weight	87 kg	120 kg
Calibrators	Same	Same - Horiba labeling specific
Controls	Same	Same - Horiba labeling specific

	Predicate device :	Device :
Device Name	Cobas Reagent for Glucose Rapid	ABX Pentra Glucose HK CP
Instrument	MIRA Plus	ABX PENTRA 400
Analytes	Glucose	Glucose
Method :	Enzymatic method using hexokinase coupled with glucose-6-phosphate dehydrogenase	Identical
Specimen :	Serum Plasma	Serum Plasma
Component reagent matrices	Single-reagent bottle, ready to use REAGENT : ATP, NAD, Magnesium, Hexokinase, G-6-PD, Sodium azide, Buffers, preservatives, stabilizers	Bi-reagent cassette, ready to use REAGENT 1 : NAD, ATP, Buffer, Sodium azide REAGENT 2 : hexokinase, G-6-PDH, Magnesium sulphate, Sodium azide
Format	Liquid	Liquid
Labels	-	Horiba ABX specific label
Notice	-	Horiba ABX specific notice
Packaging	Single-reagent bottle REAGENT : 2 x 100 mL	Bi-reagent cassette : REAGENT 1 : 46 mL REAGENT 2 : 12 mL
Calibrators	Same	Same - Horiba labeling specific
Controls	Same	Same - Horiba labeling specific

	Predicate device :	Device :
Device Name	Cobas Reagent for Glucose Rapid	ABX Pentra Glucose PAP CP
Instrument	MIRA Plus	ABX PENTRA 400
Analytes	Glucose	Glucose
Method :	Enzymatic method using hexokinase coupled with glucose-6-phosphate dehydrogenase	Enzymatic method using glucose oxidase coupled with peroxidase (Trinder method)
Specimen :	Serum Plasma	Serum Plasma
Component reagent matrices	Single-reagent bottle, ready to use	Single-reagent cassette, ready to use

	Predicate device :	Device :
Device Name	Cobas Reagent for Glucose Rapid	ABX Pentra Glucose PAP CP
	REAGENT : ATP, NAD, Magnesium, Hexokinase, G-6-PD, Sodium azide, Buffers, preservatives, stabilizers	REAGENT : Phenol, 4-aminoantipyrine, glucose oxidase, peroxidase, Sodium azide, Buffer
Format	Liquid	Liquid
Labels	-	Horiba ABX specific label
Notice	-	Horiba ABX specific notice
Packaging	Single-reagent bottle REAGENT : 2 x 100 mL	Single-reagent cassette : REAGENT : 99 mL
Calibrators	Same	Same - Horiba labeling specific
Controls	Same	Same - Horiba labeling specific

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

- IEC 61010-1 : safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements
- EN 61326 : standard for Electrical equipment for measurement, control and laboratory use - EMC requirements
- UL 3101 – 1 / CSA – C22.2 No. 1010-1 : Safety Requirements for Electrical Equipment for measurement, control, and laboratory use, Part 1 : General Requirements
- Guidance for Industry – Content of Premarket submissions for Software Contained in Medical Devices
- Guidance for Industry – In Vitro Diagnostics Glucose Test System
- Guidance for Industry – In Vitro Diagnostics Chloride Test System
- Guidance for Industry – In Vitro Diagnostics Sodium Test System
- Guidance for Industry – In Vitro Diagnostics Potassium Test System
- Guidance for Industry – Abbreviated 510(k) Submissions for In Vitro Diagnostic Calibrators
- Guidance for Industry – Points to Consider Guidance Document on Assayed and Unassayed Quality Control Material
- CLSI/NCCLS - EP05-A2 – Evaluation of Precision Performance of Clinical Chemistry Devices
- CLSI/NCCLS - EP06-A – Evaluation of the Linearity of Quantitative Analytical Methods
- CLSI/NCCLS - EP09-A – Method Comparison and Bias Estimation Using Patient Samples

L. Test Principle:

ABX Pentra Glucose HK CP - Enzymatic method using hexokinase coupled with glucose-6-phosphate dehydrogenase.

ABX Pentra Glucose PAP CP - Enzymatic method using glucose oxidase coupled with peroxidase (Trinder method).

ABX PENTRA 400 I.S.E. MODULE for Sodium Potassium and Chloride - Electrical potential measured between the reference electrode flowed by a reference solution and the specific selective electrode flowed by the sample. Slopes of the electrodes are determined with two standard solutions of known concentrations and stored by the instrument.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

ABX PENTRA Glucose HK CP

Repeatability (within-run precision)

3 specimens of low, medium and high concentration and 2 controls are tested 20 times

	Mean value mg/dL	CV %
Normal control	96.90	0.66
Pathological control	251.90	0.81
Specimen 1	31.15	1.18
Specimen 2	94.35	0.52
Specimen 3	253.45	0.74

Reproducibility (total precision)

2 specimens of low and high levels and 2 controls are tested in duplicate for 20 days (2 series per day) according to the recommendations found in the NCCLS, EP5-A protocol.

	Mean value mg/dL	CV %
Normal control	98.18	2.00
Pathological control	252.88	1.19
Specimen 1	99.86	2.03
Specimen 2	273.38	1.48

ABX PENTRA Glucose PAP CP

Repeatability (within-run precision)

	Mean value mg/dL	CV %
Normal control	89.36	0.41
Pathological control	230.53	0.40
Specimen 1	42.76	0.62
Specimen 2	111.47	0.30
Specimen 3	296.22	0.49

Reproducibility (total precision)

	Mean value mg/dL	CV %
Normal control	90.20	1.23
Pathological control	235.44	1.12
Specimen 1	107.18	1.44
Specimen 2	298.97	1.05

ABX PENTRA Sodium – E

Repeatability (within-run precision)

Two control levels were tested in 2 runs, 20 times per run

	Mean value mmol/l	CV %
Normal control	136.04	0.17
	137.74	0.24
Pathological control	159.81	0.44
	159.81	0.27

2 serum specimens are tested 10 times

	Mean value mmol/l	CV %
Serum specimen 1	146.45	0.12
Serum specimen 2	151.21	0.09

2 plasma specimens are tested 10 times

	Mean value mmol/l	CV %
Plasma specimen 1	144.36	0.26
Plasma specimen 2	143.95	0.23

2 urine specimens are tested 10 times

	Mean value mmol/l	CV %
Urine specimen 1	95.61	1.09
Urine specimen 2	163.17	0.79

Reproducibility (total precision)

2 controls are tested in duplicate for 20 days (2 series per day) according to the recommendations found in the NCCLS, EP5-A protocol.

	Mean value mmol/l	CV %
Normal control	138.60	0.69
Pathological control	157.58	0.92

ABX PENTRA Potassium - E

Repeatability (within-run precision)

Two control levels were tested in 2 runs, 20 times per run

	Mean value mmol/l	CV %
Normal control	3.75	0.29
	3.81	0.64
Pathological control	6.81	0.65
	6.86	0.49

2 serum specimens are tested 10 times

	Mean value mmol/l	CV %
Serum specimen 1	4.14	0.47
Serum specimen 2	4.99	0.42

2 plasma specimens are tested 10 times

	Mean value mmol/l	CV %
Plasma specimen 1	4.35	0.46
Plasma specimen 2	4.26	0.40

2 urine specimens are tested 10 times

	Mean value mmol/l	CV %
Urine specimen 1	45.40	1.67
Urine specimen 2	67.32	1.51

Reproducibility (total precision)

2 controls are tested in duplicate for 20 days (2 series per day) according to the recommendations found in the NCCLS, EP5-A protocol

	Mean value mmol/l	CV %
Normal control	3.82	1.28
Pathological control	6.76	1.56

ABX PENTRA Chloride – E**Repeatability (within-run precision)**

Two control levels were tested in 2 runs, 20 times per run

	Mean value mmol/l	CV %
Normal control	89.25	0.26
	91.04	0.32
Pathological control	119.81	0.40
	117.56	0.51

2 serum specimens are tested 10 times

	Mean value mmol/l	CV %
Serum specimen 1	108.94	0.30
Serum specimen 2	116.70	0.23

2 plasma specimens are tested 10 times

	Mean value mmol/l	CV %
Plasma specimen 1	111.71	0.38
Plasma specimen 2	110.43	0.36

2 urine specimens are tested 10 times

	Mean value mmol/l	CV %
Urine specimen 1	104.66	2.12
Urine specimen 2	154.34	2.08

Reproducibility (total precision)

2 controls are tested in duplicate for 20 days (2 series per day) according to the recommendations found in the NCCLS, EP5-A protocol.

	Mean value mmol/l	CV %
Normal control	89.98	1.21
Pathological control	121.99	1.12

b. Linearity/assay reportable range:

The reagent linearity is determined according to the recommendations found in the NCCLS, EP6-A protocol.

ABX PENTRA Glucose HK CP

Low linearity: 1.98 mg/dL

High linearity: 900 mg/dL, with automatic post-dilution: 2700 mg/dL.

ABX PENTRA Glucose PAP CP

Low linearity: 1.80 mg/dL

High linearity: 432 mg/dL, with automatic post-dilution: 1296 mg/dL.

ABX PENTRA Sodium – E

Serum / Plasma:	Low linearity:	110 mmol/l
	High linearity:	200 mmol/l
Urine:	Low linearity:	80 mmol/l
	High linearity:	300 mmol/l

ABX PENTRA Potassium – E

Serum / Plasma:	Low linearity:	1.4 mmol/l
	High linearity:	10 mmol/l
Urine:	Low linearity:	2 mmol/l
	High linearity:	150 mmol/l

ABX PENTRA Chloride – E

Serum / Plasma:	Low linearity:	85 mmol/l
	High linearity:	200 mmol/l
Urine:	Low linearity:	70 mmol/l
	High linearity:	300 mmol/l

- c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*
Subject of K801297 and K041227 for the ABX PENTRA Multical and ABX PENTRA N & P Controls.

ABX PENTRA Standard 1, Standard 2 and Reference solutions are made from weighed raw materials, so that electrolyte concentrations remain the same from lot to lot:

ABX Pentra Standard 1 and Standard 2 component concentrations:

	ABX Pentra Standard 1	ABX Pentra Standard 2
Na+	120 mmol/l	200 mmol/l
K+	4 mmol/l	7 mmol/l
Cl-	100 mmol/l	150 mmol/l

ABX Pentra Reference component concentration:

	ABX Pentra Reference
KCl	1.5 mol/l

Pentra 400 ISE module calibration stabilities and control values have been tested during the ABX Pentra 400 Standard 1, Standard 2 and Reference reagent life time. Its closed stability is validated on 18 months, its on board stability is validated on 1 month.

- d. *Detection limit:*

ABX PENTRA Glucose HK CP

1.98 mg/dL

ABX PENTRA Glucose PAP CP

1.80 mg/dL

ABX PENTRA ISE

Not Applicable

- e. *Analytical specificity:*

ABX PENTRA Glucose HK CP

Haemoglobin: No significant influence is observed up to 500 mg/dL

Triglycerides: No significant influence is observed up to 613 mg/dL (as Intralipid®, representative of lipemia)

Total Bilirubin: No significant influence is observed up to 36 mg/dL

Direct Bilirubin: No significant influence is observed up to 36 mg/dL

ABX PENTRA Glucose PAP CP

Haemoglobin: No significant influence is observed up to 460 mg/dL

Triglycerides: No significant influence is observed up to 613 mg/dL (as Intralipid®, representative of lipemia)

Total Bilirubin: No significant influence is observed up to 8.19 mg/dL

Direct Bilirubin: No significant influence is observed up to 5.63 mg/dL

ABX PENTRA Sodium – E

Haemoglobin: No significant influence is observed up to 10 g/l

Triglycerides: No significant influence

Total Bilirubin: No significant influence

Direct Bilirubin: No significant influence

ABX PENTRA Potassium - E

Haemoglobin: No significant influence is observed up to 1 g/l

Triglycerides: No significant influence

Total Bilirubin: No significant influence

Direct Bilirubin: No significant influence

ABX PENTRA Chloride – E

Haemoglobin: No significant influence is observed up to 10 g/l

Triglycerides: No significant influence

Total Bilirubin: No significant influence

Direct Bilirubin: No significant influence

Drugs: Acetylsalicylic acid and probenecid acid falsely increase chloride concentrations. 2.6 mmol/l acetylsalicylic acid concentration falsely increases the chloride concentration of around 10%.

f. Assay cut-off:

Not Applicable

2. Comparison studies:

a. Method comparison with predicate device:

ABX PENTRA Glucose HK CP

103 patient samples are correlated with a commercial reagent taken as reference according to the recommendations found in the NCCLS, EP9-A2 protocol.

The equation for the allometric line obtained is (in mg/dL):

$$Y = 0.93 x + 2.70 \text{ with a correlation coefficient } r^2 = 0.9958.$$

ABX PENTRA Glucose PAP CP

103 patient samples are correlated with a commercial reagent taken as reference according to the recommendations found in the NCCLS, EP9-A2 protocol.

The equation for the allometric line obtained is:

$$Y = 0.98 x + 0.72 \text{ with a correlation coefficient } r^2 = 0.9974.$$

ABX PENTRA Sodium – E

The equation for the allometric line obtained on serum (N=100) is:

$$Y = 0.98 x + 2.64 \text{ with a correlation coefficient } r^2 = 0.9991.$$

The equation for the allometric line obtained on plasma (N=100) is:

$$Y = 0.97 x + 4.77 \text{ with a correlation coefficient } r^2 = 0.9960.$$

The equation for the allometric line obtained on urine (N=103) is:

$$Y = 1.00 x + 1.00 \text{ with a correlation coefficient } r^2 = 0.9851.$$

ABX PENTRA Potassium - E

The equation for the allometric line obtained on serum (N=100) is:

$$Y = 1.00 x + 0.00 \text{ with a correlation coefficient } r^2 = 0.9988.$$

The equation for the allometric line obtained on plasma (N=100) is:
 $Y = 1.00 x + 0.00$ with a correlation coefficient $r^2 = 0.9977$.

The equation for the allometric line obtained on urine (N=103) is:
 $Y = 1.03 x - 0.72$ with a correlation coefficient $r^2 = 0.9753$.

ABX PENTRA Chloride – E

The equation for the allometric line obtained on serum and plasma (N=152) is:
 $Y = 1.09 x - 10.60$ with a correlation coefficient $r^2 = 0.9651$.

The equation for the allometric line obtained on urine (N=103) is:
 $Y = 0.99 x + 2.64$ with a correlation coefficient $r^2 = 0.9730$.

b. Matrix comparison:

ABX PENTRA Glucose HK CP

Slope = 1.02 intercept = -2.55 $r^2 = 0.988$, N=42 on serum verses plasma Heparin-Lithium

ABX PENTRA Glucose PAP CP

Slope = 1.01 intercept = -2.11 $r^2 = 0.990$, N=43 on serum verses plasma Heparin-Lithium

See method comparison for I.S.E.

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:

Literature reference

N. Instrument Name:

ABX PENTRA 400 CLINICAL CHEMISTRY ANALYZER (OPTION: I.S.E. MODULE)

O. System Descriptions:

1. Modes of Operation:

Routine or Stat random access

2. Software:

FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types:

Yes X or No _____

3. Specimen Identification:

Real patient sample bar-code ID

4. Specimen Sampling and Handling:

Primary tubes or sample cups

5. Calibration:

Calibration modes: Factor, Slope average, Linear regression, Linear interpolation, LOGIT/LOG4, LOGIT/LOG5, EXPONENT5

6. Quality Control:

The Quality Control allows the user to check the quality of measurements performed by the instrument. Statistical analyses of the control results are performed. These statistical analyses consist in calculating the average, the standard deviation and the coefficient of variation of the measurement over a defined period. They can be carried out over the following periods:

- the current Worklist
- a specific month
- a specific year.

The Quality Control is done by reviewing either the results and statistical analyses of a selected control for each test controlled with this control or the results and statistical analyses of all controls used for a selected test.

P. Other Supportive Instrument Performance Characteristics Data Not Covered In The “Performance Characteristics” Section above:

None

Q. Proposed Labeling:

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

R. Conclusion:

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