

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

A. 510(k) Number:

k062737

B. Purpose for Submission:

Notification of intent to manufacture and market the devices: a group of reagents and their associated controls and calibrators for use on the ABX PENTRA 400 - ABX PENTRA CK NAC CP, ABX PENTRA Myoglobin CP, ABX PENTRA CK Control, ABX PENTRA Immuno II Control L/H, ABX PENTRA Myoglobin Cal, ABX PENTRA N Control, ABX PENTRA P Control, and ABX PENTRA Multical.

C. Measurand:

Total creatine kinase and myoglobin

D. Type of Test:

Quantitative

E. Applicant:

Horiba ABX

F. Proprietary and Established Names:

ABX PENTRA CK NAC CP
ABX PENTRA Myoglobin CP
ABX PENTRA CK Control
ABX PENTRA Immuno II Control L/H
ABX PENTRA Myoglobin Cal
ABX PENTRA N Control
ABX PENTRA P Control
ABX PENTRA Multical

G. Regulatory Information:

1. Regulation section:

21 CFR 862.1215 : Creatine phosphokinase/creatine kinase or isoenzymes test system
21 CFR 866.5680 : Myoglobin immunological test system
21 CFR 862.1150 : Calibrator
21 CFR 862.1660 : Quality control materials (assayed)

2. Classification:

Class II (Assays)
Class II (Calibrator)
Class I (Control materials), reserved

3. Product code:
CGS, NAD reduction/NADH oxidation, Cpk or isoenzymes
DDR, Myoglobin, antigen, antiserum, control
JJY, Quality control material (assayed and unassayed)
JIX, Calibrator, multi-analyte mixture
JIT, Secondary calibrator
4. Panel:
Clinical Chemistry (75)
Immunology (82)

H. Intended Use:

1. Intended use(s):
Cardiac Markers reagents, with associated calibrators and controls, are intended for use on ABX PENTRA 400 Clinical Chemistry Analyzer to measure cardiac marker analytes.

ABX PENTRA CK-NAC CP reagent with associated calibrators and controls are for quantitative in vitro diagnostic determination of the total creatine kinase in human serum and plasma based on an optimized UV test. Measurements of creatine phosphokinase and its isoenzymes are used in the diagnosis and treatment of myocardial infarction and muscle diseases such as progressive, Duchenne-type muscular dystrophy.

The ABX PENTRA CK Control is for use in quality control by monitoring accuracy and precision for the quantitative ABX PENTRA CK-NAC method.

ABX PENTRA Myoglobin CP reagent with associated calibrators and controls are for quantitative in vitro diagnostic determination of myoglobin (an oxygen storage protein found in muscle) in human serum and plasma based on a latex-enhanced immunoturbidimetric assay. Measurements of myoglobin aids in the rapid diagnosis of heart or renal disease.

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

The ABX PENTRA Immuno II Control L/H is for use in quality control by monitoring accuracy and precision.

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

The ABX PENTRA N Control is for use in quality control by monitoring accuracy and precision.

The ABX PENTRA P Control is for use in quality control by monitoring accuracy and precision.

2. Indication(s) for use:
See Intended Use above.
3. Special conditions for use statement(s):
For prescription use only
4. Special instrument requirements:
ABX PENTRA 400

I. Device Description:

All the reagents, controls and calibrators included in this submission are for use on the ABX PENTRA 400 (k052007), which is a discrete photometric benchtop clinical chemistry analyzer.

The ABX PENTRA CK NAC CP is an in vitro diagnostic assay for the quantitative determination of total creatine kinase in human serum and plasma based on an optimized UV test. The assay is composed of a bi-reagent cassette, with 26 ml and 6.5 ml compartments. Reagents are chemical solutions with additives.

The ABX PENTRA Myoglobin CP is an in vitro diagnostic assay for the quantitative determination of myoglobin in human serum and plasma based on a latex-enhanced immunoturbidimetric test. The assay is composed of a bi-reagent cassette, with 15 ml and 9.5 ml compartments. Reagents are chemical solutions with chemical additives and substances of animal origin.

The ABX PENTRA Myoglobin Cal is a liquid calibrator prepared from a dilution of purified myoglobin positive human sera. It is used for the calibration of the myoglobin assay. The assigned values are given on the vials. This calibrator is provided in five vials of 1 mL.

The ABX PENTRA CK Control is a lyophilized assayed control prepared from a bovine serum albumin with chemical additives and material of biological origin. It has to be used for the quality control of the creatine kinase assay. The assigned values are given in the enclosed annex. This calibrator is provided in 4 vials of 3 mL.

The ABX PENTRA Immuno II Control L/H is a lyophilized assayed control prepared from a stabilized pool of human sera. It has 2 levels (Low and High) to be used for the quality control of the myoglobin assay. The assigned values are given in the enclosed annex. Each level of this control is provided in one vial of 3 mL.

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 given in the enclosed annex, 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. All products derived from blood are prepared exclusively from the blood of donors tested individually and shown by FDA-approved methods to be free from HBsAg and antibodies to HCV and HIV.

The ABX PENTRA N Control and ABX PENTRA P Control are quality control products consisting of lyophilized human serum with chemical additives and materials of biological origin added as required to obtain given component levels. The assigned values of the control components are given in the enclosed annexes, ensuring control of the appropriate HORIBA ABX methods on the ABX PENTRA 400 analyzer. Each control is provided in ten vials of 5 ml. All products derived from blood are prepared exclusively from the blood of donors tested individually and shown by FDA-approved methods to be free from HBsAg and antibodies to HCV and HIV.

J. Substantial Equivalence Information:

1. Predicate device name(s):
Roche CK NAC Reagent Set, Beckman Coulter ACCESS Myoglobin Reagent, Pointe Scientific CK-MB Control Set Level I/Level II, Bio-Rad Liquicheck Cardiac Markers Control Level 2, Beckman Coulter ACCESS Myoglobin Calibrators, ABX Pentra Multical and ABX Pentra N Control.
2. Predicate 510(k) number(s):
k834502, k021229, k954074, k961828, k021229, k060854
3. Comparison with predicate:

	Predicate device (k834502):	Device :
Device Name	CK NAC	ABX Pentra CK NAC CP
Manufactured by	Roche, USA	HORIBA ABX, France
Instrument	COBAS MIRA	ABX PENTRA 400
Analytes	Creatine Kinase	Total Creatine Kinase
Method :	Optimized UV test	Optimized UV test
Specimen :	Serum	Serum and plasma
Number of tests	-	125 tests
Sample volume	4.4 µL/test	8 µL/test
Detection limit	-	8 U/L
Precision	CV Total < 1.6%	CV Total < 4.65%
Measuring range	-	8 U/L – 1500 U/L
Upper linearity limit	2000 U/L	1500 U/L, and with automatic post-dilution: 4500 U/L
Calibration stability	-	8 days
Closed reagent stability	Until the expiration date when stored at 2-8°C after reconstitution:	18 months at 2-8°C

	Predicate device (k834502):	Device :
Device Name	CK NAC	ABX Pentra CK NAC CP
Open reagent stability	6 days at 2-8C 24 hours at 15-25°C	on-board stability (refrigerated area): 64 days

	Predicate device (k021229):	Device :
Device Name	ACCESS Myoglobin Reagent	ABX Pentra Myoglobin CP
Manufactured by	BECKMAN COULTER Inc.	HORIBA ABX, France
Instrument	ACCESS Immunoassay systems (Access II analyzer)	ABX PENTRA 400
Analytes	Myoglobin	Myoglobin
Method :	Paramagnetic particle and chemiluminescent immunoassay.	Latex-enhanced immunoturbidimetric assay.
Specimen :	Serum and plasma	Serum and plasma
Number of tests	100 tests	100 tests
Sample volume	20 µL/test	14 µL/test
Detection limit	< 1 µg/L (ng/mL)	6.7 µg/L (ng/mL)
Precision	CV Total < 4.54%	CV Total < 5.24%
Measuring range	13.8 µg/L – 3650.9 µg/L	20.4 µg/L – 500 µg/L
Upper linearity limit	4000 µg/L	500 µg/L, and with automatic post-dilution: 2500 µg/L
Calibration stability	56 days	21 days
Closed reagent stability	Until the expiration date when stored at 2-10°C	12 months at 2-8°C
Open reagent stability	Open pack: 56 days at 2-10°C	On-board stability (refrigerated): 35 days

	Predicate device (k954074):	Device :
Device Name	CK-MB Control Set Level I , Level II	ABX Pentra CK Control
Manufactured by	POINTE SCIENTIFIC, INC. AALTO SCIENTIFIC, INC,	HORIBA ABX, France
Instrument	COBAS MIRA Plus	ABX PENTRA 400
Method :	Single parameter control by monitoring the performances of CK-MB determination with Creatine Kinase-MB Reagent Set	Bi-parameter control by monitoring accuracy and precision for the quantitative Methods as specified in the enclosed value sheet. Concentrations and activities are mostly in the normal or at the normal/pathological threshold.

	Predicate device (k954074):	Device :
Device Name	CK-MB Control Set Level I , Level II	ABX Pentra CK Control
Biological additives	Human derived isoenzymes	CK-MM (Human origin) CK-MB (porcine brain origin)
Controlled molecules	CK-MB: the exact control values are given on the vial label.	Total Creatine Kinase (CK-NAC): the exact control values are given in the enclosed annex.
Theoretical values and confidence intervals	<ul style="list-style-type: none"> - The assay value and range are established using the manufacturer's CK-MB reagent. - The assigned values and range are indicated on the vial label. - The values are lot-specific. 	<ul style="list-style-type: none"> - The assigned values are determined by calibration 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. - The assigned values are lot-specific.
Closed stability	Until the expiration date when stored at 2-8°C	18 months at 2-8°C
Components stability after reconstitution of the calibrator	At 2 – 8°C : 7 days	At 15 - 25°C : 24 hours At 2 - 8°C : 3 days

	Predicate device (k961828):	Device :
Device Name	Liquicheck Cardiac Markers Control, level 2	ABX Pentra Immuno II Control L/H
Manufactured by	Bio-Rad	HORIBA ABX, France
Instrument	ACCESS Immunoassay systems (Access II analyzer)	ABX PENTRA 400
Method :	Quality control by monitoring the precision of laboratory testing procedures listing in the package insert	Quality control by monitoring accuracy and precision for the quantitative methods as specified in the enclosed value sheet.
Controlled molecules	Myoglobin, Troponin I, Troponin T, CK Total, LD-1 isoenzyme, CK-MB isoenzyme. The exact control values are given in the notice.	Myoglobin, Ferritin. The exact control values are given in the enclosed annex.
Assigned values	<ul style="list-style-type: none"> - The assigned values are determined by calculating the mean value obtained from replicate analyses. - The assay values are listed in the notice enclosed in the kit. 	<ul style="list-style-type: none"> - The assigned values specified are determined by calculating the mean value obtained from multiple determinations. - The assigned values are indicated in the notice enclosed in the kit.

	Predicate device (k961828):	Device :
Device Name	Liquicheck Cardiac Markers Control, level 2	ABX Pentra Immuno II Control L/H
Closed stability	- The values are lot specific 2 years at -20°C to -10°C	- The assigned values for both Low and High controls are lot-specific 24 months at 2-10°C
Open stability	Stability of Myoglobin, Troponin I, Troponin T: At 2 to 8°C : 10 days Stability of Total CK, CK-MB, LD-1: At 2 to 8°C : 20 days	2 weeks at 2-10°C 3 months at -20°C

	Predicate device (k021229):	Device :
Device Name	ACCESS Myoglobin Calibrators	ABX Pentra Myoglobin Cal
Manufactured by	BECKMAN COULTER Inc.	HORIBA ABX, France
Instrument	ACCESS Immunoassay systems (Access II analyzer)	ABX PENTRA 400
Method :	Calibration of ACCESS Myoglobin assay	Calibration of HORIBA ABX Myoglobin methods
Calibrated molecules	Myoglobin	Myoglobin
Format	Liquid	Liquid
Calibration value	- Assigned by procedure traceable to the manufacturer's working calibrators and based on prEN ISO 17511. - The exact assigned values are indicated on each vial or on calibration card (5 levels: approximately 50, 200, 800, 2000 and 4000 ng/mL)	- Determined using primary calibration with in-house calibrator adjusted to nephelometric method. - The assigned values are indicated on each vial (5 levels: 0, 62.5, 125, 250 and 500 ng/mL)
Closed stability	Up to the expiration date at -20°C	12 months at 2-10°C
Open stability	60 days at 2-10°C	7 weeks at 2-10°

ABX Pentra Multical and ABX Pentra N Control: Addition of creatine kinase.

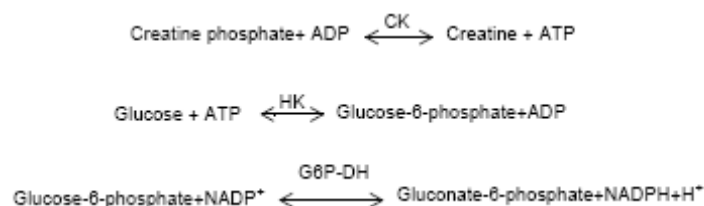
K. Standard/Guidance Document Referenced (if applicable):

- 1) Valtec protocol for evaluation of device performance: Vassault et al., Ann. Biol. Clin., 1986, (44), 686-745).

- 2) CLSI EP5-A2, Evaluation of Precision Performance of Quantitative Measurement Methods.
- 3) CLSI EP6-A, Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach.
- 4) CLSI EP9-A2, Method Comparison and Bias Estimation Using Patient Samples.
- 5) CLSI EP17-A, Protocols for Determination of Limits of Detection and Limits of Quantitation.

L. Test Principle:

For total creatine kinase, the reagents supplied cause a chemical reaction which produces an amount of gluconate-6-phosphate+NADPH+H⁺ which is proportional to the amount of creatine kinase in the sample.



For myoglobin, the method used in this assay is a turbidimetric immunoassay. When an antigen-antibody reaction occurs between Mb in a sample and anti-Mb antibody which has been sensitized to latex particles, agglutination results. This agglutination is detected as an absorbance change, with the magnitude of the change being proportional to the quantity of Mb in the sample. The actual concentration is then determined by interpolation from a calibration curve prepared from calibrators of known concentration.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:
 - a. *Precision/Reproducibility:*

Within Run:

For the CK NAC (total CK) reagent, within-run precision was determined using 2 controls (ABX PENTRA N and P Controls) and 3 serum specimens of low, medium and high concentrations were tested 20 times in a single run for each sample (in accordance with the Valtec guideline (Vassault et al., Ann. Biol. Clin., 1986, (44), 686-745). Results are described below.

In U/L	N Control	P Control	Sample 1	Sample 2	Sample 3
Mean	166	474	46	115	347
SD	2	4	1	1	3
%CV	1.2	0.92	2.54	1.14	0.79

For the Myoglobin reagent, within-run precision was determined using 2 controls (Immuno II Control L/H) and 3 serum specimens of low, medium and high concentrations tested 20 times in a single run for each sample (in accordance with the Valtec guideline (Vassault et al., Ann. Biol. Clin., 1986,

(44), 686-745). Results are described below.

In ng/mL	L Control	H Control	Sample 1	Sample 2	Sample 3
Mean	66.9	207.4	27.9	46.7	330.3
SD	1.0	2.4	1.2	1.7	1.8
%CV	1.53	1.18	4.26	3.56	0.54

Between Run:

For the CK NAC reagent, between-run precision NCCLS (CLSI) EP-5A was followed using two serum specimens of low & high levels and 2 controls tested in duplicate for 20 days, two series per day (for a total of 80). Results are described below.

In U/L		N Control	P Control	Sample 1	Sample 2
Between Run	Mean	162	489	81	311
	SD	3.7	8.34	2.26	3.62
	%CV	2.28	1.78	2.76	1.13
Total	SD	4.14	11.71	3.78	8.12
	%CV	2.56	2.50	4.65	2.61

For the Myoglobin reagent, between-run precision NCCLS (CLSI) EP-5A was followed using two serum specimens of low & high levels and 2 controls tested in duplicate for 20 days, two series per day (for a total of 80). Results are described below.

In ng/mL		L Control	H Control	Sample 1	Sample 2
Between Run	Mean	67.5	201.2	58.8	389.3
	SD	1.66	5.02	1.65	10.00
	%CV	2.47	2.49	2.81	2.57
Total	SD	2.99	10.55	2.46	17.08
	%CV	4.43	5.24	4.18	4.39

b. Linearity/assay reportable range:

Linearity for CK NAC was assessed for non-post dilution samples in accordance with CLSI EP6-A. Samples used for this study were in house preparations of CK aqueous solution. Two different studies with ten different levels of total CK (each tested 4 times except for lowest dilution of the low level study which was sampled twice) were prepared based on the dilution of the highest concentration solution level with a solution near the low limit of detection resulting in a range of samples from 8.48 to 147 U/L and 81.38 to 1510 U/L. The linearity of the CK NAC assay was evaluated by comparing observed versus expected values across the expected range. A linear regression analysis was performed on the data and plotted. The sponsor's acceptable bias for recovery of the samples is $\pm 8\%$. The observed linearity across the 8.48 to 147 U/L range has a slope of 0.993, and an intercept of 0.5558. The observed linearity across the 81.38 to 1510 U/L range has a slope

of 0.9995, and an intercept of 0.3936. The assay range was demonstrated to be linear from 8.48 to 1510 U/L. The sponsor will claim a range of 8 (the detection limit) to 1500 U/L. Recovery of post dilution serum samples was also assessed comparing manual versus automatic dilution by the PENTRA 400. Five serum samples were each tested 4 times and ranged from 1610 to 4263 U/L. The sponsor's acceptable bias for recovery of the samples is $\pm 10\%$. The data supports the sponsor's claim of a post dilution limit of 4500 U/L.

Linearity for Myoglobin was assessed for non-post dilution samples in accordance with CLSI EP6-A. Samples used for this study were human serum. Eleven different levels of myoglobin (each tested 4 times) were prepared based on the dilution of the highest concentration solution level with a solution near the low limit of detection resulting in a range of samples from 48 to 482.6 ng/mL. The linearity of the assay was evaluated by comparing observed versus expected values across the expected range. A linear regression analysis was performed on the data and plotted. The sponsor's acceptable bias for recovery of the samples is $\pm 10\%$. The observed linearity across the reportable range has a slope of 0.9998, and an intercept of 0.0667. The assay range was demonstrated to be linear from 48 to 482.6 ng/mL. The sponsor will claim a range of 20.4 (the lowest value of the comparison study) to 500 ng/mL (the value of the highest calibrator). The lower values of 20.4 to 48 were found to be acceptable for the claimed range as the predicate device included this range in its claim and the sponsor showed equivalence at these levels. Recovery of post dilution serum samples was also assessed comparing manual versus automatic dilution by the PENTRA 400. Seven samples were each tested 4 times and ranged from 513.9 to 2301.1 ng/mL. The sponsor's acceptable bias for recovery of the samples is $\pm 10\%$. The data supports the sponsor's claim of a post dilution limit of 2500 ng/mL.

- c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*
Real time stability at 8°C was investigated for Myoglobin calibrator. Recovery of the values for the calibration points in Myoglobin was assayed for 3 lots periodically over a period of 18 months. The closed stability study was performed over a period providing data to support the sponsor's claim of closed stability between 2 - 10°C for 12 months. Real time stability studies after opening were performed. Recovery of the values for the calibration points in Myoglobin was assayed for 1 lot periodically over a period of 7 weeks, providing data supporting a stability period of 7 weeks at 8°C.

Real time stability at 8°C was investigated for Immuno II Control L/H. Recovery of the values in Myoglobin and Ferritin for the Low and High controls was assayed for 3 lots during 27 to 29 months. The closed stability study was performed over a period providing data to support the sponsor's claim of closed stability of 27 months at 8°C. Stability after reconstitution and storage frozen at -20°C was investigated for Immuno II Control L/H.

Stability studies after reconstitution were performed providing data supporting a stability of 3 months at -20°C for ABX Pentra Immuno II Control L/H after reconstitution and a closed stability of 24 months between 2 - 10°C.

For ABX PENTRA N Control & ABX PENTRA P Control traceability, the values of the ABX PENTRA Controls are assigned from the ABX PENTRA calibrator, reagents and analyzers. The target value is determined by the median of results from 150 measurements/parameters. Confidence range is determined as the calculated range in percent which is based on the experimental results from the previous target value trials. The range declared in the target value sheet is equal to the assigned value +/- 3 standard deviations (3 SD).

For ABX Pentra Multical traceability, the ABX Pentra Multical is prepared from reference materials. Commercial calibrators are standardized by means of a master lot which is stored at -80°C. Two controls are used to ensure that the calibration values of the master lot, as well as the entire measurement system (calibrator, reagent, and analyzer), remain stable during the storage period. The target value is determined by the median of results from 150 measurements/parameters.

For the ABX PENTRA N Control, ABX PENTRA P Control, and ABX PENTRA Multical, protocols and acceptance criteria for open and closed stability of the controls and calibrators were described and found to be acceptable.

d. Detection limit:

The detection limit for the CK NAC was determined by measuring 30 measurements of saline water (NaCl 0.9 g/L) + 4.65 SD. The limit of detection for the CK NAC assay was determined to be 8 U/L.

Because the measurement of saline water is not possible with the normal application of the Myoglobin assay (no results available when sample concentration is lower than the calibration curve), usual measurement of MDL (30 measurements of saline water) is not possible. For the specific proteins the Minimum Interpretation Limit (MIL) is used. Like MDL, MIL is the lower concentration that could be distinguished from 0, concentration calculated using the rate absorbency measurement of known concentration's samples and saline water. The limit of detection for the Myoglobin assay was determined to be 6.7 ng/mL.

e. Analytical specificity:

For CK NAC: In accordance with the Valtec guideline, the tested interferants were added to base serum at two different CK concentrations (normal and high). The base serum with each substance was then serially diluted with the same base serum and saline to adjust CK concentration. Hemoglobin up to 55

μmol/l (97 mg/dL), total bilirubin up to 125 μmol/L (7.3 mg/dL), direct bilirubin up to 100 μmol/l (5.9 mg/dL) and triglycerides (as Intralipid®, representative of lipemia) up to 7 mmol/L (612.5 mg/dL) do not interfere with CK determination by this test.

For Myoglobin: Substances were added to the base serum at two different myoglobin concentrations (normal and high). The base serum with each substance was then serially diluted with the same base urine serum and saline to adjust myoglobin concentration. Hemoglobin up to 195 μmol/l (336 mg/dL), total bilirubin up to 500 μmol/L (29.3 mg/dL), direct bilirubin up to 500 μmol (29.3 mg/dL) and triglycerides (as Intralipid®, representative of lipemia) up to 7 mmol/L (612.5 mg/dL) do not interfere with myoglobin determination by this test. The sponsor also determined a prozone effect for the Myoglobin assay to occur at 1374 ng/mL with dilution being effective in overcoming the effect.

- f. *Assay cut-off:*
Not applicable.

2. Comparison studies:

a. *Method comparison with predicate device:*

A total of 175 serum and plasma samples were run using the CK NAC reagents on the PENTRA 400 and a reference method. Samples ranged from 8.0 to 1408 U/L. Diluted or spiked samples (59) were used to cover the range of the assay. Linear regression analysis gave the following relationship: Device = 1.056(Predicate) – 2.253; r = 0.9967.

A total of 90 serum and plasma samples were run using the Myoglobin reagents on the PENTRA 400 and a reference method. Clinical non-spiked samples ranged from 20.4 to 484 ng/mL. Linear regression analysis gave the following relationship: Device = 0.920(Predicate) + 22.251; r = 0.9876.

b. *Matrix comparison:*

The sponsor demonstrated equivalence of CK NAC results in serum and Lithium Heparin plasma samples by using 42 clinical samples spanning a range of 29 to 1197 U/L. Linear regression showed a slope of 0.96 and an intercept of 1.04, and a correlation coefficient of 0.999.

The sponsor demonstrated equivalence of Myoglobin results in serum and Lithium Heparin plasma samples by using 69 clinical samples spanning a range of 19 to 236 ng/mL. Linear regression showed a slope of 1.01 and an intercept of 2.12, and a correlation coefficient of 0.9959.

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:
The reference range for CK NAC is indicated to be:
Adults:
Women < 145 U/L
Men < 171 U/L

Reference:
IFCC Primary Reference Procedures for the Measurement of Catalytic Activity
Concentrations of Enzymes at 37°C; Part 2 ; Clin Chem Lab Med 2002; 40(6) :
635-642.

The reference range for Myoglobin is indicated to be:
70 – 110 ng/mL (µg/L)

Reference :
Thomas L. Clinical Laboratory Diagnostics. 1st ed. Frankfurt: TH-Books
Verlagsgesellschaft; 1998. p. 106.

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.