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

**A. 510(k) Number:**

k103788

**B. Purpose for Submission:**

New device

**C. Measurand:**

Sodium, potassium, chloride, and glucose

**D. Type of Test:**

Quantitative, hexokinase method for glucose and potentiometric method for sodium, potassium, and chloride

**E. Applicant:**

HORIBA ABX

**F. Proprietary and Established Names:**

PENTRA C200,,I.S.E. Module, and ABX PENTRA Glucose HK CP

**G. Regulatory Information:**

| Product Code | Classification | Regulation Section | Panel |
|---|---|---|---|
| CFR | Class II | 21 CFR §862.1345: Glucose test system. | Chemistry (75) |
| JGS | Class II | 21 CFR §862.1665: Sodium test system. | Chemistry (75) |
| CEM | Class II | 21 CFR §862.1600: Potassium test system. | Chemistry (75) |
| CGZ | Class II | 21 CFR §862.1170: Chloride test system. | Chemistry (75) |
| JJE | Class I | 21 CFR §862.2160: Discrete Photometric Chemistry Analyzer for Clinical Use. | Chemistry (75) |

## H. Intended Use:

1. Intended use(s):

   See indications for use below

2. Indication(s) for use:

   The PENTRA C200 is a discrete photometric benchtop chemistry analyzer for use in clinical laboratories. It is not intended for use in Point of Care Settings. It duplicates manual analytical procedures by performing various steps such as pipetting, mixing, heating and measuring color intensity. The PENTRA C200 is intended for quantitative measurements of a variety of analytes: Glucose, Sodium, Potassium, and Chloride.

   ABX Pentra Glucose HK CP reagent with associated calibrators and controls are for quantitative in vitro diagnostic determination of glucose in serum and plasma using glucose hexokinase method by colorimetry. Glucose measurements are used on the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, and idiopathic hypoglycemia, and of pancreatic islet cell carcinoma.

   The I.S.E. (Ion Selective Electrode) module is intended for the quantitative determination of Sodium, Potassium and Chloride in serum, plasma, and urine by potentiometry using ion selective electrode with associated reference solution, calibrators and controls. Measurement of Sodium, Potassium and Chloride are used in diagnosis and treatment diseases involving electrolyte imbalance.

3. Special conditions for use statement(s):

   For prescription use only
   It is not intended for use in Point of Care settings

4. Special instrument requirements:

   PENTRA C200 Clinical Chemistry Analyzer

## I. Device Description:

The PENTRA C200 is a bench-top clinical chemistry analyzer using two measuring principles: absorbance and ion selective electrodes.

The instrument may be summarized as follows:

- Multi-parametric (up to 15 simultaneous tests + 3 ISE tests)
- On routine or Stat
- 90 (without ISE) to 360 tests / hour ( with ISE) (analytical cycle of 40 seconds)
- random access working on primary tubes or sample cups

- 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.

**ISE module** - PENTRA C200 includes an optional Ion Selective Electrode module which contains a sodium electrode, a potassium electrode, a chloride electrode, a reference electrode, two calibrators and two controls. The direct application is intended for serum and plasma, indirect application is intended for urine.

**Glucose reagent contains a** bi-reagent cassette, ready to use, reagent 1 (R1) and reagent 2 (R2). R1 reagent contains NAD, ATP, buffer, and sodium azide. R2 contains hexokinase, G-6-PDH, magnesium sulphate, and sodium azide.

## J. Substantial Equivalence Information:

1. Predicate device name(s):

HORIBA ABX PENTRA 400

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

k052007

3. Comparison with predicate:

For instrument and ISE: Similarities and Differences:

| | **Candidate device**<br><br>PENTRA C200 | **Predicate device (k052007)**<br><br>ABX PENTRA 400 |
|---|---|---|
| Intended Use | The PENTRA C200 is intended for quantitative measurements for Glucose, Sodium, Potassium, and Chloride. | Same |
| Instrument Type | Bench-top | Same |
| Touch Screen Interface | Yes | Same |
| I.S.E module:<br>ISE parameters<br>Methods<br><br>Sample volume in µL<br><br>Sodium Electrode | <br>Na, K, Cl<br>Direct & indirect<br><br>30 µL for 3 parameters<br><br>Glass membrane selective to | <br>Same<br>Same<br><br>60 µL for 3 parameters<br><br>Same |

| | | |
|---|---|---|
| Potassium Electrode | Na+ ions<br>Plastic membrane selective to K+ ions | Same |
| Chloride Electrode | Plastic membrane selective to Cl- ions | Same |
| Type of samples | Serum, plasma, urine | Same |
| Throughput<br>Without I.S.E.<br>With I.S.E | <br>Up to 360 tests/hour<br>270 tests/hour | <br>Up to 420 tests/hour<br>180 tests/hour |
| Parameters on board | 15 cassettes + 3 ISE | 52 mono or twin cassettes + 3 ISE |
| Sample capacity<br><br><br>Sample volume<br>Dilution of patient sample<br>Fibrin detecting device | Up to 15 sample tube or cups (handling of STAT available)<br>2 to 45µL<br>Yes<br>Yes | Up to 60 (6 racks of 10 samples)<br><br>2 to 380 µL<br>Yes<br>Yes |
| Reagents:<br>Type of reagents<br>Disposable/Washable cuvettes | <br>Same<br>Same | <br>Liquid<br>Disposable cuvettes |
| Principles of Measurement | Same | Spectrophotometry : Colorimetry and Turbidimetry : parallel bi-chromatic measurement of light absorbance (tungsten halogen lamp) Potentiometry : Direct (Serum or Plasma) and Indirect (Urine) |
| Photometer type: light source<br>Type of measurement | <br>Same<br>Same | <br>Halogen<br>Mono, Bi chromatic |
| Dimensions (HxWxD) | 75.5 x 72.5 x 57 cm | 100 x 65 x 57 cm |
| Weight | 95 kg | 120 kg |

For glucose assay: Similarities and Differences:

| | **Candidate device** | **Predicate device (k052007)** |
|---|---|---|
| Intended Use | ABX Pentra Glucose HK CP reagent with associated calibrators and controls are for quantitative in vitro diagnostic determination of glucose in serum and plasma using glucose hexokinase method by colorimetry. | Same |
| Instrument | ABX PENTRA C200 | ABX PENTRA 400 |
| Analyte | Glucose | Glucose |
| Method: | Same | Enzymatic method using hexokinase coupled with glucose-6-phosphate dehydrogenase |
| Sample type: | Serum<br>Plasma (Lithium heparin, Fluoride oxalate) | Serum<br>Plasma |
| Reagent component | Same | Bi-reagent cassette, ready to use<br>REAGENT 1 : NAD, ATP, Buffer, Sodium azide<br>REAGENT 2 : hexokinase, G-6-<br>PDH, Magnesium sulphate, Sodium azide |
| Format | Same | Liquid |
| Packaging | R1-R2: (30 mL/10 mL)<br>R1-R2: (50 mL/50 mL)<br>R1-R2: (80 mL/10 mL) | Bi-reagent cassette :<br>R1 : 46 mL<br>R2 : 12 mL |
| Calibrators | Same | The ABX PENTRA Multical |
| Controls | Same | The ABX PENTRA N control and P control |

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

C28-A3: Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory
EN13640: Stability testing of in vitro diagnostic reagents, August 2002

EP05-A2: Evaluation of Precision Performance of Quantitative Measurement Methods
EP06-A: Evaluation of the Linearity of Quantitative Measurement
EP07-A2: Interference Testing in Clinical Chemistry
EP09-A2: Method Comparison and Bias Estimation Using Patient Samples
EP17-A: Protocols for Determination of Limits of Detection and Limits of Quantitation

## L. Test Principle:

There are two different measuring principles employed, potentiometry and photometry/colorimetry.

**Potentiometry** 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.

**Colorimetry** for glucose: Glucose measurement employed the hexokinase method coupled with glucose-6-phosphate dehydrogenase. The amount of absorbance change is proportional to the concentration of the glucose being present in the sample.

## M. Performance Characteristics (if/when applicable):

1. Analytical performance:

*a. Precision/Reproducibility:*

A precision study was performed to assess the with-run precision and total precision of the PENTRA C200 system by replicate measurements of controls materials and human samples (Serum, lithium heparin plasma, and urine). The precision study was performed in duplicates, twice a day, for twenty days. The precision results were summarized below:

For glucose (serum): within-run precision (N=20)

| | Mean value | CV% |
|---|---|---|
| | mg/dL | |
| Serum control 1 | 91 | 0.76 |
| Serum control 2 | 244 | 0.75 |
| Serum sample 1 | 40 | 1.81 |
| Serum sample 2 | 88 | 0.51 |
| Serum sample 3 | 314 | 0.61 |

For glucose (serum): total precision (N=80)

| | Mean value | CV% |
|---|---|---|
| | mg/dL | |
| Serum control 1 | 93 | 1.99 |
| Serum control 2 | 246 | 1.60 |
| Serum sample 1 | 41 | 1.81 |
| Serum sample 2 | 86 | 1.58 |
| Serum sample 3 | 304 | 1.40 |

For sodium (serum and plasma): within-run precision (N=20)

| | Mean value mmol/L | CV% |
|---|---|---|
| Serum control 1 | 137.57 | 0.13 |
| Serum control 2 | 152.62 | 0.15 |
| Serum sample 1 | 105.40 | 0.57 |
| Serum sample 2 | 144.87 | 0.18 |
| Serum sample 3 | 176.81 | 0.14 |
| Plasma sample 1 | 117.12 | 0.18 |
| Plasma sample 2 | 143.50 | 0.15 |
| Plasma sample 3 | 176.71 | 0.13 |

For sodium (urine): within-run precision (N=20)

| | Mean value mmol/L | CV% |
|---|---|---|
| Urine control 1 | 101.04 | 2.22 |
| Urine control 2 | 179.11 | 1.28 |
| Urine sample 1 | 77.16 | 2.46 |
| Urine sample 2 | 114.73 | 1.50 |
| Urine sample 3 | 231.60 | 0.79 |

For sodium (serum): total precision (N=80)

| | Mean value mmol/L | CV% |
|---|---|---|
| Serum control 1 | 130.02 | 0.88 |
| Serum control 2 | 148.49 | 1.10 |
| Serum sample 1 | 107.85 | 0.80 |
| Serum sample 2 | 138.93 | 0.62 |
| Serum sample 3 | 151.11 | 0.78 |

For sodium (urine): total precision (N=80)

| | Mean value mmol/L | CV% |
|---|---|---|
| Urine control 1 | 76.96 | 4.39 |
| Urine control 2 | 158.07 | 2.88 |
| Urine sample 1 | 119.65 | 4.91 |
| Urine sample 2 | 141.62 | 3.14 |

For potassium (serum and plasma): within-run precision (N=20)

| | Mean value mmol/L | CV% |
|---|---|---|
| Serum control 1 | 3.58 | 0.25 |
| Serum control 2 | 6.29 | 0.35 |
| Serum sample 1 | 3.56 | 0.85 |
| Serum sample 2 | 4.17 | 0.55 |
| Serum sample 3 | 5.15 | 0.85 |
| Plasma sample 1 | 2.37 | 0.57 |
| Plasma sample 2 | 3.96 | 0.70 |
| Plasma sample 3 | 7.16 | 0.75 |

For potassium (urine): within-run precision (N=20)

| | Mean value mmol/L | CV% |
|---|---|---|
| Urine control 1 | 32.70 | 0.88 |
| Urine control 2 | 68.96 | 0.81 |
| Urine sample 1 | 26.90 | 1.03 |
| Urine sample 2 | 99.56 | 0.91 |
| Urine sample 3 | 207.59 | 0.42 |

For potassium (serum): total precision (N=80)

| | Mean value mmol/L | CV% |
|---|---|---|
| Serum control 1 | 3.56 | 0.87 |
| Serum control 2 | 6.43 | 1.07 |
| Serum sample 1 | 4.02 | 0.86 |
| Serum sample 2 | 4.65 | 0.73 |
| Serum sample 3 | 4.79 | 0.85 |

For potassium (urine): total precision (N=80)

| | Mean value mmol/L | CV% |
|---|---|---|
| Urine control 1 | 28.75 | 1.72 |
| Urine control 2 | 62.84 | 1.64 |
| Urine sample 1 | 31.15 | 1.54 |
| Urine sample 2 | 106.05 | 1.67 |
| Urine sample 3 | 61.37 | 2.87 |

For chloride (serum and plasma): within-run precision (N=20)

| | Mean value mmol/L | CV% |
|---|---|---|
| Serum control 1 | 89.54 | 0.26 |
| Serum control 2 | 116.25 | 0.23 |
| Serum sample 1 | 81.02 | 0.96 |
| Serum sample 2 | 109.52 | 0.51 |
| Serum sample 3 | 145.23 | 0.76 |
| Plasma sample 1 | 83.76 | 0.74 |
| Plasma sample 2 | 110.78 | 0.63 |
| Plasma sample 3 | 143.57 | 0.55 |

For chloride (urine): within-run precision (N=20)

| | Mean value mmol/L | CV% |
|---|---|---|
| Urine control 1 | 98.64 | 2.74 |
| Urine control 2 | 176.08 | 1.71 |
| Urine sample 1 | 81.86 | 2.35 |
| Urine sample 2 | 148.30 | 2.13 |
| Urine sample 3 | 174.52 | 1.26 |

For chloride (serum): total precision (N=80)

| | Mean value mmol/L | CV% |
|---|---|---|
| Urine control 1 | 85.88 | 1.20 |
| Urine control 2 | 113.36 | 1.55 |
| Serum sample 1 | 83.26 | 0.99 |
| Serum sample 2 | 104.72 | 0.96 |
| Serum sample 3 | 115.32 | 0.88 |

For chloride (urine): total precision (N=80)

| | Mean value mmol/L | CV% |
|---|---|---|
| Urine control 1 | 98.26 | 4.59 |
| Urine control 2 | 172.06 | 1.56 |
| Urine sample 1 | 116.68 | 4.02 |
| Urine sample 2 | 169.16 | 3.12 |

*b. Linearity/assay reportable range:*

A linearity study was performed according to the recommendations found in the CLSI EP6-A guideline. Serum or urine samples containing the target analytes (glucose, sodium, potassium, and chloride) in different concentrations were prepared. Each sample was run in four replicates per level. The observed values were plotted against the expected values and an appropriate line fitted by standard linear regression. Results were summarized in the tables below:

Table 1: Serum samples

| | Sodium (serum) | Potassium (serum) | Chloride (serum) | Glucose (serum) |
|---|---|---|---|---|
| Correlation (r) | 0.9997 | 0.9996 | 0.9995 | 0.9999 |
| Slope | 1.0273 | 0.9630 | 1.0210 | 0.9160 |
| Intercept | - 2.753 | 0.1613 | -2.1902 | 2.7394 |
| Range tested | 79.4-204.1 (mmol/L) | 1.01-10.13 (mmol/L) | 67.3-173.0 (mmol/L) | 1.5-933 mg/dL |
| Levels tested | 9 | 10 | 10 | 13 |

Table 2: Urine samples

| | Sodium (urine) | Potassium (urine) | Chloride (urine) |
|---|---|---|---|
| Correlation (r) | 0.9996 | 0.9996 | 0.9915 |
| Slope | 0.9979 | 0.9982 | 0.9585 |
| Intercept | 0.3203 | -1.0224 | 12.2347 |
| Range | 57.6-329.9 mmol/L | 21.48-261.53 (mmol/L) | 41.87-366.32 mmol/L |
| Levels tested | 10 | 10 | 10 |

Results of the study support the sponsor claims for the following measuring ranges:

| Analyte | Measuring range |
|---|---|
| | |
| Glucose (serum) | 5 – 900 mg/dL |
| Sodium (serum) | 90 – 190 mmol/L |
| Sodium (urine) | 60 – 280 mmol/L |
| Potassium (serum) | 2 – 9.5 mmol/L |
| Potassium (urine) | 25 – 250 mmol/L |
| Chloride (serum) | 70 – 170 mmol/L |
| Chloride (urine) | 70 – 280 mmol/L |

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

Traceability of all the analytes:

| Analyte | Traceability |
|---|---|
| Sodium | Gravimetric method using standard materials |
| Potassium | Gravimetric method using standard materials |
| Chloride | Gravimetric method using standard materials |
| Glucose | Reference material: NIST SRM 965a |

The ABX Pentra Multical is the calibrator used for calibration for the glucose assay and has been previously cleared (k052007). The ABX Pentra Standard 1 and 2 are calibrators used for calibration for the sodium, potassium, and chloride assays and have been previously cleared (k052007).

The glucose assay has a calibration stability of 20 days. The glucose reagent has a shelf-life of 36 months (when stored at 2 to 8$^{o}$C) and an on-board (refrigerated) stability of 39 days. Protocols and acceptance criteria has been provided and were found to be adequate.

*d. Detection limit:*

See linearity study in M.2.b. above.

In addition, the sponsor performed a limit of detection study for the glucose assay according to a modified protocol based on the CLSI EP17-A guideline. Limit of blank (LoB) was determined by testing 90 times of a blank sample on 3 different instruments. Limit of detection (LoD) was determined by testing four low serum samples 20 times on one instrument. Limit of quantitation

(LoQ) was determined by testing three low samples 5 times on three instruments over 5 days. LoQ is defined as the lowest concentration where total precision is < 10 %CV. The sponsor determined that for the glucose assay, the LoB is 0.72 mg/dL, LoD is 1.08 mg/dL, and LoQ is 4.9 mg/dL.

The sponsor claims for the following measuring ranges:

| Analyte | Measuring range |
|---|---|
| | |
| Glucose (serum) | 5 – 900 mg/dL |
| Sodium (serum) | 90 – 190 mmol/L |
| Sodium (urine) | 60 – 280 mmol/L |
| Potassium (serum) | 2 – 9.5 mmol/L |
| Potassium (urine) | 25 – 250 mmol/L |
| Chloride (serum) | 70 – 170 mmol/L |
| Chloride (urine) | 70 – 280 mmol/L |

*e. Analytical specificity:*

A study of common interfering substances was conducted and evaluated following recommendations by CLSI EP7A2. Two sample pools were prepared at the following target concentrations:

| Analyte | Target Concentrations | |
|---|---|---|
| | Low level | High level |
| Glucose (serum) | 90 mg/dL | 234 mg/dL |
| Sodium (serum) | 120 mmol/L | 150 mmol/L |
| Sodium (urine) | 80 mmol/L | 150 mmol/L |
| Potassium (serum) | 2 mmol/L | 6 mmol/L |
| Potassium (urine) | 60 mmol/L | 150 mmol/L |
| Chloride (serum) | 90 mmol/L | 110 mmol/L |
| Chloride (urine) | 100 mmol/L | 200 mmol/L |

Various concentrations of interfering substances were spiked into the serum and urine sample pools. The sponsor states that interferences are considered to be non- significant if the bias between the spiked and non-spiked samples is within ± 10%. Results are summarized in the following:

I. Glucose (serum):

Hemoglobin: No significant interference observed up to 603 mg/dL
Triglycerides: No significant interference observed up to 10,500 mg/dL
Total Bilirubin: No significant interference observed up to 24.4 mg/dL
Direct Bilirubin: No significant interference observed up to 37.7 mg/dL

Protein: No significant interference observed up to 12 g/dL
Intralipid: No significant interference observed up to 640 mg/dL
Acetylsalicyclic acid: No significant interference observed up to 65 mg/dL
Bicarbonate: No significant interference observed up to 40 mmol/L

II. Sodium, potassium, and chloride (serum)

Hemoglobin: No significant interference observed up to 200 mg/dL The sponsor included a limitation in the labeling that hemolyzed samples should not be used.
Triglycerides: No significant interference observed up to 740 mg/dL
Total Bilirubin: No significant interference observed up to 19.9 mg/dL
Urea: No significant interference observed up to 258 mg/dL
Protein: No significant interference observed up to 12 g/dL
Acetylsalicyclic acid: No significant interference observed up to 65 mg/dL
L-Glutathione reduced: No significant interference observed up to 92.2 mg/dL
Methyl Dopa: No significant interference observed up to 16.9 mg/dL
Lithium: No significant interference observed up to 118 mg/dL
Bicarbonate: No significant interference observed up to 50 mmol/L

For sodium (serum):
Ammonium Nitrate: No significant influence observed up to 40 mmol/L
Ammonium Bromide: No significant influence observed up to 37.5 mmol/L
Probenecid: No significant influence observed up to 2100 µmol/L

For potassium (serum):
Ammonium Nitrate: No significant influence observed up to 40 mmol/L
Ammonium Bromide: No significant influence observed up to 37.5 mmol/L.
Probenecid: Significant interference observed from 500 µmol/L

For chloride (serum):
Probenecid: No significant influence observed up to 1200 µmol/L
Ammonium Nitrate: Significant interference observed from 0.2 mmol/L
Ammonium Bromide: Significant interference observed from 1.25 mmol/L

III. Sodium, potassium, and chloride (urine)

Hemoglobin: No significant interference observed up to 1000 mg/dL
Total Bilirubin: No significant interference observed up to 8.8 mg/dL
Urea: No significant interference observed up to 3600 mg/dL

Protein: No significant interference observed up to 0.2 g/dL
Ascorbic Acid: No significant interference observed up to 60 mg/dL
Boric acid: No significant interference observed up to 867 mg/dL

Based on the significant interference substances identified above, the sponsor states the following in their limitations section in the labeling of the sodium, potassium and chloride:

1. Do not use hemolyzed samples.
2. Do not use samples containing Probenecid acid, ammonium nitrate and ammonium bromide.

*f. Assay cut-off:*

Not Applicable

2. Comparison studies:

*a. Method comparison with predicate device:*

Method comparison studies were conducted following CLSI EP9-A2. This study was conducted for glucose (serum), chloride (serum, plasma, and urine), potassium (serum, plasma and urine), and sodium (serum, plasma, and urine). Plasma samples were collected from lithium heparin plasma samples. The method comparison studies were performed on the ABX Pentra C200 and compared to the predicate device (ABX Pentra 400). Left over clinical laboratory serum, plasma, and urine samples covering the measuring range were analyzed in duplicate and a singlet set of data were used for linear regression analysis. To cover the high and low ends of the measuring range, some specimens were spiked with stock solutions and others were diluted with saline (glucose samples) and DI water (sodium, potassium, and chloride samples). Deming regression results were summarized in the table below:

Summary of test results using Deming Regressions are as follows:

| Analyte | Sample type | Slope | Intercept | r | N | Sample range tested |
|---|---|---|---|---|---|---|
| | | | | | | |
| Glucose (mg/dL) | serum | 0.98 | 0.248 | 0.9920 | 103 | 7.02-821.52 mg/dL |
| Sodium (mmol/L) | serum | 0.96 | 6.42 | 0.9909 | 129 | 103.4-166.5 mmol/L |
| | plasma | 1.05 | -5.32 | 0.9989 | 132 | 93.4-165.9 mmol/L |
| | urine | 1.01 | -2.20 | 0.9946 | 101 | 67.64-273.61 mmol/L |
| Potassium (mmol/L) | serum | 1.01 | -0.06 | 0.9989 | 122 | 2.52-8.32 mmol/L |
| | plasma | 1.01 | -0.09 | 0.9992 | 125 | 2.24-9.47 mmol/L |
| | urine | 1.02 | -0.27 | 0.9987 | 159 | 25.22-226.70 mmol/L |
| Chloride (mmol/L) | serum | 0.96 | 3.74 | 0.9980 | 170 | 74.37-166.92 mmol/L |
| | plasma | 1.04 | -4.17 | 0.9984 | 131 | 71.15-144.56 mmol/L |
| | urine | 1.04 | -5.63 | 0.9933 | 112 | 73.05-262.46 mmol/L |

*b. Matrix comparison:*

Anticoagulated plasma and serum were evaluated to demonstrate equivalency of these matrices for measurement of glucose, sodium, potassium, and chloride. The following anticoagulants were tested in the study: lithium heparin and fluoride oxalate for the glucose assay and lithium heparin for the sodium, potassium and chloride assays. Matched samples for serum and plasma were collected for each comparison. All samples were assayed in duplicate over several days on the PENTRA C200. Results of the study are summarized in the following tables:

Glucose serum vs. Lithium heparin plasma

| | |
|---|---|
| Number of samples | 40 |
| Slope | 1.0460 |
| Intercept | -0.36158 |
| R | 0.999 |
| Sample range tested | 47.52-821.9 mg/dL |

Glucose serum vs fluoride oxalate plasma

| | |
|---|---|
| Number of samples | 49 |
| Slope | 0.9963 |
| Intercept | -0.8242 |
| R | 0.999 |
| Sample range tested | 59.04-787.50 mg/dL |

Sodium serum vs lithium heparin plasma

| | |
|---|---|
| Number of samples | 26 |
| Slope | 1.0162 |
| Intercept | -2.5289 |
| R | 0.975 |
| Sample range tested | 128.20-141.30 mmol/L |

Potassium serum vs lithium heparin plasma

| | |
|---|---|
| Number of samples | 26 |
| Slope | 0.9829 |
| Intercept | 0.0307 |
| R | 0.999 |
| Sample range tested | 3.33-9.06 mmol/L |

Chloride serum/lithium heparin plasma

| | |
|---|---|
| Number of samples | 26 |
| Slope | 1.0166 |
| Intercept | -1.8639 |
| R | 0.993 |
| Sample range tested | 93.55-110.95 mmol/L |

The sponsor determined that lithium heparin is an acceptable anticoagulant for sodium, potassium, chloride and glucose. In addition, fluoride oxalate is also acceptable for glucose measurement.

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:

**Glucose**[1]
Serum:70 – 115 mg/dL

**Chloride** [2], [3]
Serum:101 – 110 mmol/L
Urine:110-250 mmol/24h

**Potassium** [2], [3]
Serum:3.7 – 5.5 mmol/L
Urine:25 – 125 mmol/24h

**Sodium** [2], [3]
Serum: 136 – 145 mmol/L
Urine: 40-220 mmol/24h

1. Thomas L., Clinical Laboratory Diagnostics: Use and Assessment of Clinical Laboratory Results. 1st ed and Frankfurt: TH Books Verlagsgesellschaft; 1998 p.132

2. Tietz, Fundamentals of Clinical Chemistry, 4th ed., p.983-990

3. Tietz, Fundamentals of Clinical Chemistry, 5th ed., p. 970-1009

**N. Instrument Name:**

PENTRA C200

**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:
   ISE calibration is stable for 8 hours and needs to be calibrated at the beginning of each day and every 8 hours.

6. Quality Control:
   At least two levels of controls should be assayed daily and after a calibration. In the labeling the sponsor states that the user should follow the state, local and state guidelines for testing quality control materials.

**P. Other Supportive Instrument Performance Characteristics Data Not Covered In The "Performance Characteristics" Section above:**

A dilution study was provided to show that the instrument can automatically diluted sample with a dilution factor of 3. Six serum samples (spiked) with glucose concentrations range from 900 mg/dL to 2700 mg/dL were manually diluted X3 and assayed on the Pentra C200 instrument. Results were compared with the automatic dilution protocol of the Pentra C200 instrument. Results showed that the instrument can automatically dilute the serum samples accurately.

An ambient temperature study on the Pentra C200 was performed to demonstrate that ambient temperature between 15 to 30$^{o}$C will not have a significant impact on the performance (ISE and glucose) of the Pentra C200. The study protocol and acceptance criteria was found to be adequate.

**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.