

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

A. 510(k) Number:

k092570

B. Purpose for Submission:

New device

C. Measurand:

Calibrator material for urine protein

D. Type of Test:

Not applicable-calibrator material

E. Applicant:

Horiba ABX

F. Proprietary and Established Names:

ABX PENTRA TPU Cal

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
JIT	Class II	21 CFR 862.1150	Chemistry (75)

H. Intended Use:

1. Intended use(s):

See indications for use below.

2. Indication(s) for use:

ABX PENTRA Urine Cal is a calibrator for use in the calibration of the quantitative method: ABX PENTRA Urinary Proteins CP on ABX Pentra 400 clinical chemistry analyzer as specified on the vials.

3. Special conditions for use statement(s):

For Prescription Use

4. Special instrument requirements:

For use with the ABX Pentra 400 Analyzer

I. Device Description:

The ABX PENTRA TPU Cal is a liquid calibrator based on a buffered aqueous solution, containing human serum. The assigned values of the calibrator components are given on the calibrator vials, ensuring optimal calibration of the appropriate HORIBA ABX methods on the ABX PENTRA 400 analyzer. This calibrator is provided in three vials of 3 mL.

All human source materials were tested and found to be negative for HIV ½, HBsAg, and HCV.

J. Substantial Equivalence Information:

1. Predicate device name(s)

ABX PENTRA Urine Calibrator

2. Predicate K number(s):

k071779

3. Comparison with predicate:

Similarities and Differences		
Item	(Predicate Device)- ABX PENTRA Urine Calibrator (k071779)	(Candidate Device)-ABX PENTRA TPU Cal
Intended Use	ABX PENTRA Urine Cal is a calibrator for use in the calibration of the quantitative method: ABX Pentra Urinary Proteins CP on Horiba ABX Pentra 400 Analyzer	ABX PENTRA TPU calibrator is used to calibrate total proteins in urine measurement with reagent ABX Pentra Urinary Proteins CP on ABX Pentra 400 Analyzer
Analyte	Urine total protein, albumin, Immunoglobulin G, α1-Microglobulin	Urine total protein
Instrument	ABX Pentra 400	Same

Reagent	ABX Pentra Urinary Proteins CP	Same
Number of Calibrator Levels	One	Same
Format	Material of biological and chemical additives in a buffered solution	Buffered aqueous solution containing human serum
Packaging	3 vials of 1 mL, liquid, ready to use	3 vials of 3 mL, liquid, ready to use
Calibration Value	Value is lot specific	The value is constant and equals 1300 mg/L \pm 4%
Stability	Closed: 12 months at 2-8 °C Open: 4 weeks at 2-8 °C	Closed: 24 months at 2-8 °C Open: 9 weeks at 2-8 °C

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

EN 13640 Stability Testing of In-Vitro Diagnostic Reagents

EN 980 Symbols for use in the Labeling of Medical Devices

L. Test Principle:

Not applicable

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Not applicable

b. Linearity/assay reportable range:

Not applicable

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

Traceability:

The ABX PENTRA TPU calibrator is traceable to NIST SRM 927d

Stability:

Real-time stability study was performed to evaluate the shelf-life and open-vial stability of the calibrator. Recovery of the controls and the optical control measurements were performed with 3 lots of calibrators at regular intervals over a period of 25 months. The calibrator was stored within the defined temperature limits of 2-8 °C. Acceptance criteria and protocol were provided and found to be acceptable to support the claim for 24 month shelf life stability between 2-8°C. Open vial stability was tested on 3 lots over a total period of 189 days. During this period, the open calibrator was stored between 2-8°C. Results met the defined acceptance criteria and supported the claim for 9 week open-vial stability between 2-8°C.

Assigned Value:

The ABX PENTRA TPU calibrator is value assigned using an internal procedure by testing the master calibrator material multiple times on multiple days. The calibration of the assay is verified by testing the NIST SRM 927d material and checking acceptable recovery of the NIST material. Each new lot of calibrator material is verified by assaying the new calibrator material with ABX Pentra Urinary Proteins CP reagent on the ABX PENTRA 400 Analyzer and checking if the value is within acceptable limits. The calibrator value is constant for all lots with an expected value of 1300 mg/L. Acceptance criteria and protocol for assigning the value were provided and found to be acceptable

d. Detection limit:

Not applicable

e. Analytical specificity:

Not applicable

f. Assay cut-off:

Not applicable

2. Comparison studies:*a. Method comparison with predicate device:*

Not applicable

b. Matrix comparison:

Not applicable

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):*

4. Clinical cut-off:

Not applicable

5. Expected values/Reference range:

Not applicable

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.