

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

A. 510(k) Number:

k071779

B. Purpose for Submission:

New device

C. Measurand:

Calibrator for urine protein

D. Type of Test:

Not applicable - calibrator

E. Applicant:

Horiba ABX

F. Proprietary and Established Names:

ABX PENTRA Urine Calibrator

G. Regulatory Information:

1. Regulation section:

21 CFR 862.1150, Calibrator

2. Classification:

Class II

3. Product code:

JIX, Calibrator, Multi-analyte mixture

4. Panel:

Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):

See Indications for Use below.

2. Indication(s) for use:

The 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 clinical chemistry analyzer.

3. Special conditions for use statement(s):

For prescription use

4. Special instrument requirements:

For use with the ABX Pentra 400

I. Device Description:

The ABX PENTRA Urine Cal is a single level human and sheep based, aqueous, buffered solution, containing protein, albumin, a1-microglobulin and Immunoglobulin G constituents.

J. Substantial Equivalence Information:

1. Predicate device name(s) :

Roche C.F.A.S.Proteins in Urine

2. Predicate K number(s):

k062319

3. Comparison with predicate:

Item	Roche CFAS urine cal	ABX PENTRA urine cal
Matrix	Liquid, ready to use	Same
Instrument	Roche analyzers	ABX PENTRA 400
Constituents	Total protein, albumin, urine/csf protein, IGG	Total protein assayed Albumin, a1 microglobulin and IGG unassayed
Closed stability	2-8°C until exp. date	12 mos. at 2-8°C
Open stability	4 weeks at 2-8°C	same

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

FDA/CDRH Guidance for Industry: Abbreviated 510(k) Submissions for In Vitro Diagnostic Calibrators

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):*

The calibrator is traceable to NIST SRM 927c

Shelf life stability was tested over a total period of 19 months. The recovery in protein content of the calibrator was assayed for 3 lots periodically over that period. The calibrator was stored within the defined temperature limits of 2-8°C. Results met the defined acceptance criteria and supported the claim for 12 month shelf life stability between 2-8°C.

Open vial stability was tested on 3 lots over a total period of 4 weeks. During this period, the open calibrator was stored at 4°C. Results met the defined acceptance criteria and supported the claim for 4 week open stability between 2-8°C.

The value assignment process consists of assaying new lots of calibrator on 6 ABX PENTRA 400 analyzers over 5 days. If the percent deviation between lowest and highest mean is less than 10%, then the target value is determined by the median of all results yielded from all analyzers.

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):

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.