

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

A. 510(k) Number:

k092749

B. Purpose for Submission:

New Device

C. Measurand:

Quality control material for parathyroid hormone (PTH) determinations

D. Type of Test:

Not applicable

E. Applicant:

Microgenics Corporation, Thermo Fisher Scientific Specialty Diagnostics Division

F. Proprietary and Established Names:

Liquid Assayed PTH Control

G. Regulatory Information:

1. Regulation section:

21 CFR§862.1660

2. Classification:

Class I (Reserved)

3. Product code:

JJX - Quality control material (assayed and unassayed)

4. Panel:

Chemistry (75)

H. Intended Use:

1. Intended use(s):

MAS® PTH Control is intended for use in the clinical laboratory as a consistent test sample of known concentration for monitoring assay conditions in many Parathyroid hormone (PTH) determinations. Include PTH Control with patient serum specimens when assaying for Parathyroid hormones. Assay values are provided for the specific systems listed. The user can compare observations with expected ranges as a means of assuring consistent performance of reagent and instrument.

Moni-Trol® PTH Control is intended for use in the clinical laboratory as a consistent test sample of known concentration for monitoring assay conditions in many Parathyroid hormone (PTH) determinations. Include PTH Control with patient serum specimens when assaying for Parathyroid hormones. Assay values are provided for the specific systems listed. The user can compare observations with expected ranges as a means of assuring consistent performance of reagent and instrument.

2. Indication(s) for use:

Same as intended use above.

3. Special conditions for use statement(s):

For prescription use only

4. Special instrument requirements:

Roche Cobas 6000; Roche Elecsys; Roche Modular E170; Siemens Immulite

I. Device Description:

The MAS® PTH Control and Moni-Trol® PTH Control are liquid stable control materials prepared from human serum. Components of the controls which are derived from human source material have been tested using FDA accepted methods and found non-reactive for Hepatitis B Surface antigen (HBsAg), Hepatitis C (HCV), HIV-1 and HIV-2. Analyte levels are adjusted with various pure chemicals and preparations from human tissue or bodily fluids. Preservatives and stabilizers are added to maintain product integrity. Three levels of control are available and are provided ready to use. Each kit will contain 6 vials each: 2 vials of Level 1, 2 vials of Level 2, and 2 vials of Level 3. Each vial contains 3 mLs.

The MAS and Moni-Trol products are the same.

J. Substantial Equivalence Information:

1. Predicate device name(s):
Liquichek™ Specialty Immunoassay Control
2. Predicate 510(k) number(s):
k04310
3. Comparison with predicate:
Similarities:

	Predicate Device, K043108 Bio-Rad Liquichek™ Controls	Proposed new device K092749 MAS® PTH Control and Moni-Trol® PTH Control
Intended Use	For use as quality control serum to monitor the precision of laboratory testing procedures listed in the package insert.	MAS® PTH and Moni-Trol ® PTH Control are intended for use in the clinical laboratory as a consistent test sample of known concentration for monitoring assay conditions in many Parathyroid hormone (PTH) determinations. Include PTH Control with patient serum specimens when assaying for Parathyroid hormones. Assay values are provided for the specific systems listed. The user can compare observations with expected ranges as a means of assuring consistent performance of reagent and instrument.

Description of device	This product is prepared from human serum with added constituents, chemicals, stabilizers, and preservatives.	This product is a liquid stable control material prepared from human serum. Analyte levels are adjusted with various pure chemicals and preparations from human tissue or bodily fluids. Preservatives and stabilizers are added to maintain product integrity.
Matrix	Human Serum	Same
Form	Liquid	Same
Open Vial Stability	30 days at 2-8°C with exceptions	30 days when stored tightly capped at 2-8°C
Analytes	Anti-Tg Anti-TPO C-Peptide Erythropoietin Intact PTH IGF-I Osteocalcin 25-OH Vitamin D	PTH

Differences:

	Predicate Device, K043108 Bio-Rad Liquichek™ Controls	Proposed new device, K092749 MAS® PTH Control and Moni-Trol® PTH Control
Storage Condition	-20°C to -70°C until expiration date on the label	-25°C to -15°C until expiration date on the label
Closed Vial Stability	30 days at 2-8°C with exceptions	90 days when stored tightly capped at 2-8°C
Levels and targets	Level 1: ~30 pg/mL Level 2: ~200 pg/mL Level 3: ~600 pg/mL (estimated from value assignment data in BioRad PI)	Level 1: 15 pg/mL Level 2: 200 pg/mL Level 3: 400 pg/mL

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

None were referenced.

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 stability studies were performed using the Roche COBAS PTH reagents on the Roche Elecsys 2010 analyser. All studies that were performed were done so using three lots of the control material.

Open vial stability:

Three lots of PTH control, each lot at three different levels were used. For each lot and level vials were opened on day 0, stored at 5°C, and tested at different time points for up to 42 days.

The recommended claim based on the data is 30 days at 2 - 8°C.

Closed vial stability:

Three lots of PTH control, each lot at three different levels were used. For each lot and level, unopened vials were stored at 5°C, and tested at multiple time points for up to 90 days.

The recommended claim based on the data is 90 days at 2 - 8°C.

Shelf-Life stability:

The Arrhenius model was applied using stress data to establish the frozen - 20°C shelf life claim. Three lots, each lot at three different levels were used for the study. For each lot and level, product was stressed at elevated temperatures of 41°C and 37°C for 14 days, and 25°C for 28 days. Multiple time points were tested and point of failure was determined by linear regression. The recommended claim based on the data is 24 months frozen at -20°C.

Value assignment:

Value assignment ranges are established 20% around the mean. Control ranges are provided as guidelines until the laboratory has established its own statistical limits. The values are based on replicate assays of representative samples by participating laboratories in accordance with established protocol. Twenty replicates per level per analyte over a period of 10 days were run on 4 instruments. Means established by individual laboratories should fall within the corresponding acceptable range. It is recommended that each laboratory establish its own means and acceptable ranges and use those provided only as guides.

- 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.