



Audit™ MicroFD™ BNP Control

Cat. No. **K023/K025**
 Contents 6 x 1mL (Multi-Level) K023M-6
 6 x 0.5mL (Multi-Level) K025M-6

Lot No. Level 1 – 03211
 Level 2 – 03212

Expires 02-01-05

For In Vitro Diagnostic Use Only.

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INTENDED USE

Audit™ MicroFD™ BNP Control is a bi-level reference control consisting of human plasma based solutions. It is intended to simulate human patient plasma samples for the purpose of monitoring the precision of laboratory testing procedures for both BNP-32 and NT-proBNP assays.

SUMMARY AND PRINCIPLE

Good laboratory practices require that stable reference materials be used to verify the accuracy and precision of testing methods and techniques. Audit™ MicroFD™ BNP Control may be used as one would use human plasma to obtain the stated BNP values.

REAGENTS

Audit™ MicroFD™ BNP Control is an in vitro diagnostic control composed of a buffered bacteriostatic and fungistatic human plasma matrix.

WARNINGS AND PRECAUTIONS

Because this product is of human origin, it should be handled as though capable of transmitting infectious diseases. Each serum, plasma or whole blood donor unit used in the preparation of this material was tested by United States Food and Drug Administration (FDA) approved methods and found to be negative for antibodies to HIV and HCV and nonreactive for HBsAg. Because no test method can offer complete assurance that HIV, hepatitis B virus, and hepatitis C virus or other infectious agents are absent, this material should be handled as though capable of transmitting infectious diseases. This product may also contain other human source material for which there is no approved test. The FDA recommends such samples be handled at the Centers for Disease Control's Biosafety Level 2.

This product contains less than 0.1% sodium azide that may react with lead and copper plumbing to form potentially explosive metal azides. On disposal, flush with a large volume of water to prevent azide build-up.

Audit™ MicroFD™ BNP Control is intended solely for in vitro diagnostic use for the purpose described on the labeling. Audit™ MicroControls, Inc. shall not be liable for any unclaimed damages arising from any other usage.

STORAGE AND STABILITY

Audit™ MicroFD™ BNP Control is stored at 2-8°C and will remain stable in the unopened vial for twelve months from the date of manufacture. After opening, the contents should be used according to the instrument manufacturer's instructions and immediately returned to 2-8°C.

When used to monitor the precision of laboratory testing procedures for BNP-32 assays, it is recommended that Audit™ MicroFD™ BNP Control be used immediately (or within 8 hours after reconstitution and stored at 2-8°C).

When used to monitor the precision of laboratory testing procedures for NT-proBNP assays, Audit™ MicroFD™ BNP Control has an open vial stability of up to 5 days under the proper storage conditions. Leaving the vial uncapped, or prolonging its time at room temperature, will void this open vial stability claim. Make sure the contents of the vial are well mixed before use.

PROCEDURE

Follow the manufacturer's instructions provided for BNP procedures. Verify that the lot number on the vial matches the assay sheet. To avoid evaporation, do not leave the vial uncapped. Controls should be run:

1. daily, in conjunction with patient samples.
2. as recommended by the instrument manufacturer.
3. as required by the relevant regulatory agency.

Materials provided

- Audit™ MicroFD™ BNP Control, Multi-Level, 6 x 1.0mL or
- Audit™ MicroFD™ BNP Control, Multi-Level, 6 x 0.5mL

Materials required (but not provided)

- Distilled or deionized water

EXPECTED VALUES

The performance range for each level, based on data by combining estimates of assay variance as determined by participating laboratories using approved FDA instruments and reagents, is provided below. Average values obtained in the laboratory should fall within the performance range although the recovery may not be identical with the mean value listed. Variation between labs will be greater than the precision for any one instrument. Accuracy and precision depend on differences in equipment, reagents, supplies and techniques. Therefore, a lab must establish its own acceptable target values and ranges.

INSTRUCTIONS FOR USE

1. Remove a vial from the package, reconstitute with the appropriate amount of deionized water, dependent upon vial size, and gently swirl occasionally for 10 minutes while keeping the contents at 2-8°C. Do not shake. Do not mix mechanically.
2. Continue to mix the vial contents by gentle swirling and inversion for an additional 10 minutes, allowing the contents to be completely dissolved, while keeping the contents at 2-8°C.
3. Refer to instrument or assay instruction manual for analyzing control material.
4. After sampling, replace stopper and return to original package for maximum open vial stability at 2-8°C.

LIMITATIONS OF THE PROCEDURE

Variations in instruments and in the temperature of the testing material may result in accuracy and linearity differences. Make sure that the vial is brought to room temperature before testing. If the liquid in the vial becomes frozen, discard and use another vial, as the results will not be valid.

ORDERING INFORMATION

Product Number	Product Description	Product Packaging
K025M-6	Audit™ MicroFD™ BNP Control, Multi-Level	6 x 0.5mL
K023M-6	Audit™ MicroFD™ BNP Control, Multi-Level	6 x 1mL

Assay Values		
Level 1 (Lot No. 03211)	Biosite® Triage®	86 - 128 pg/mL
	Roche Elecsys®	170 - 256 pg/mL
	Bayer Centaur®	164 - 246 pg/mL
Level 2 (Lot No. 03212)	Biosite® Triage®	914 - 1370 pg/mL
	Roche Elecsys®	3621 - 5431 pg/mL
	Bayer Centaur®	2007 - 3011 pg/mL