



PBM

Cardiac Marker Control Set

Level 1
Level 2

REF LSC-301

LOT 160122

IVD



2018-02-24

INTENDED USE

PBM Cardiac Marker Control Set is a reference control consisting of human serum based solutions. It is intended to simulate human patient serum samples for the purpose of monitoring the performance of Cardiac Markers assays: CK-MB, Myoglobin, and Troponin I. These external controls compliment the internal procedural control provided in each test device of the LifeSign MI® cardiac markers.

SUMMARY AND PRINCIPLE

Good laboratory practices require that stable reference materials be used to verify the performance of testing methods and techniques. PBM Cardiac Marker Controls should be used as one would use human serum to obtain the stated values.

REAGENTS

PBM Cardiac Marker Control Set is an in vitro diagnostic control composed of a buffered bacteriostatic and fungistatic human serum matrix. PBM Cardiac Marker Control Set is a lyophilized product manufactured according to standard quality control procedures.

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 and found to be negative for antibodies to HIV and HCV and noreactive 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.

PBM Cardiac Marker Controls is intended solely for in vitro diagnostic use for the purpose described on the labeling. PBM shall not be liable for any unclaimed damages arising from any other usage.

STORAGE AND STABILITY

PBM Cardiac Marker Control Set is stored at 2-8°C and will remain stable in the unopened vial until the expiration date. After opening, the contents should be used according to the test device manufacturer's instructions and immediately returned to 2-8°C.

When used to monitor the precision of laboratory testing procedures for Cardiac Markers assays, PBM Cardiac Marker Controls has a reconstituted stability of up to 8 hours 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.

MATERIALS PROVIDED

PBM Cardiac Marker Control Set, 2 x 1 mL (after reconstitution)

PROCEDURE

Follow the manufacturer's instructions provided for Cardiac Markers 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. as recommended by the instrument manufacturer.
2. as required by the relevant regulatory agency.

INSTRUCTIONS FOR USE

1. Remove a vial from the package and reconstitute with 1 mL of deionized water.
2. Allow the vial to sit at room temperature for 5 minutes.
3. Occasionally swirl for 15 minutes, or until all visible material is dissolved. Do not shake. Do not mix mechanically. Avoid getting any undissolved material on the sides of the vial or the stopper.
4. When all visible solid material is dissolved, invert several times to dissolve any material on the stopper.
5. Swirl occasionally for at least 5 minutes.
6. Use immediately or return to 2-8°C. Allow the control set to equilibrate to room temperature prior to reuse.
7. The vial should remain stored at 2-8°C at all times. If additional sampling is necessary, the time outside of 2-8°C storage should be minimized.

RESULTS

Each level of PBM Cardiac Marker Control Set contains CK-MB, Myo, and TnI to yield the following results using the LifeSign MI® cardiac markers.

Analyte	Level 1	Level 2
Myoglobin	Negative	Positive
CK-MB	Negative	Positive
Troponin I	Negative	Positive

LIMITATIONS OF THE PROCEDURE

PBM Cardiac Marker Control Set should not be used past the expiration date. 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.

Dispose of any discarded materials in accordance with the requirements of your local waste management authorities.

ORDERING INFORMATION

PRODUCT NUMBER	PRODUCT DESCRIPTION	PRODUCT PACKAGING
LSC-301	PBM Cardiac Marker Controls	2 x 1 mL

Distributed by PBM/LifeSign - U.S. customers only please call (800) 526-2125.

Manufactured by Aalto Scientific, Ltd. for PBM



Catalog Number



For In Vitro Diagnostic Use



Use By YYYY-MM-DD:



Lot Number



2 - 8°C
Temperature Limit



Reconstitute With

