

P20180412-1

April 23, 2018

Urgent Field Safety Notice
PATHFAST Recall

Dear Valued PATHFAST Customers:

LSI Medience Corporation takes the safety and the wellbeing of its patients, customers and clients extremely seriously. This is why we would like to inform you today about a quality related incident observed by us:

With regard to the PATHFAST reagent lots of CKMB, Myoglobin and NTproBNP manufactured between March 2, 2017 and March 26, 2018, we found that several reagent cartridges had a tiny pinhole on the aluminum seal at the well position of alkaline phosphatase labeled antibody reagent (hereafter ALP reagent) which was generated during the filling process. Although, no safety related incident was reported to us as a result of this quality issue, **the appropriate result may not be obtained, in case the reagent leaked through the pinhole.** Since it is, and has always been, our top priority not to compromise the safety or the health of our clients, customers and patients in any respect, we met the decision to conduct a recall:

[Product recall]:

LSIM would ask each local distributor to kindly take the following actions.

- Inform customers to stop using the products in **Appendix A** by forwarding this Field Safety Notice.
- Collect confirmation form with customer's signature in order to confirm that the customers have received this notice, even if there is no remaining reagent of the corresponding products.
- Collect and check quantity of the remaining reagent (including opened box).
- Destroy all collected reagents with appropriate manner.
- Fill out and send scrap certificate (attached in page 3) to LSIM.

For the recalled products, we are manufacturing the replacement lots urgently. The details will be

P20180412-1

shared by LSIM person in charge.

Further we have conducted a sampling test of the cartridges in all our inventory, but no pinholes on the well were confirmed except for the recalled products.

However, we would like customers to pay close attention when using the products in **Appendix B**, to the following points, just in case.

- Please do not use the reagent cartridges which have leakage or trace of leakage on the aluminum seal of the ALP reagent well position (where the aluminum seal is colored in red and the item name is printed) .
- Please inform us immediately when you find such reagent cartridges.

Notwithstanding the above, we want to assure you that we have undertaken all the necessary steps to make sure that there is no danger to our patients, clients and customers.

Please contact us if you have any questions or concerns about these products. We shall be more than happy to discuss them with you.

Sincerely,



Toru Murakumo
General Manager
Quality Assurance Department
LSI Medience Corporation

SCRAP CERTIFICATE

We certificate the following reagents have been collected, destroyed and scrapped.

Product name	Lot	Number of kits scrapped	Reason for scrap
PATHFAST Myo	N762		Recall notified
PATHFAST Myo	S864		Recall notified
PATHFAST CK-MB	A768		Recall notified
PATHFAST CK-MB	O769		Recall notified
PATHFAST CK-MB	S871		Recall notified
PATHFAST NTproBNP	T767		Recall notified
PATHFAST NTproBNP	O768		Recall notified
PATHFAST NTproBNP	B769		Recall notified

DATE : _____

SIGNATURE: _____

COMPANY: _____

P20180412-1

Appendix A) Recalled products

Product No.	Product Name	Lot No.	Expiration
PF1021-K	PATHFAST Myo	N762	Sep. 2018
PF1021-K	PATHFAST Myo	S864	Jan. 2019
PF1031-K	PATHFAST CK-MB	D767	Mar. 2018
PF1031-K	PATHFAST CK-MB	A768	May. 2018
PF1031-K	PATHFAST CK-MB	O769	Aug. 2018
PF1031-K	PATHFAST CK-MB	S871	Jan. 2019
PF1061-K	PATHFAST NTproBNP	T767	Nov. 2018
PF1061-K	PATHFAST NTproBNP	O768	Jan. 2019
PF1061-K	PATHFAST NTproBNP	B769	Apr. 2019

Appendix B) Products which need to pay attention

Product No.	Product Name	Lot	Expiration
PF1021-K	PATHFAST Myo	T761	Jun. 2018
PF1021-K	PATHFAST Myo	E763	Dec. 2018
PF1031-K	PATHFAST CK-MB	E770	Dec. 2018