

P20180904-1

September 4, 2018

Product Notification  
PATHFAST Type-D / PATHFAST hs-cTnI

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 issue observed by us:

With regard to the use of PATHFAST Type-D in combination with new PATHFAST hs-cTnI (Product No. PF1241-K), probably due to a software issue, the print-out as 0.000 without unit have been reported. The result obtained as 0.000 without unit is not correct.

We, therefore, strongly request you NOT to use the new hs-cTnI (Product No. PF1241-K) in combination with PATHFAST Type-D until the problem is solved. If you obtained such a result, please measure the sample again with PATHFAST cTnI (Product No. PF1011-K) or other IVDs to confirm the result.

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



**Example of print-out using both PATHFAST Type-D and PATHFAST hs-cTnI**

Image of a correct print out  
(concentration with a unit)

Image of an incorrect print out  
(concentration without a unit)

-----  
DATE:03/09/2018 15:40  
SAMPLE ID:  
LANE: 1

-----  
DATE:03/09/2018 15:40  
SAMPLE ID:  
LANE: 1

hs-cTnI

hs-cTnI

70.6 ng/L

0.000

REMARK:DF  
TYPE: WB (40.0 %)  
SAMPLE: PATIENT

REMARK:DF  
TYPE: WB (40.0 %)  
SAMPLE: PATIENT

INSTRUMENT SERIAL: 1509D2539  
PROGRAM VERSION: 4.0.5  
OPERATOR ID: USER1  
REAGENT LOT: 1241910042  
CALIBRATED ON: 03/09/2018  
-----

INSTRUMENT SERIAL: 1509D2542  
PROGRAM VERSION: 4.0.5  
OPERATOR ID: USER1  
REAGENT LOT: 1241910042  
CALIBRATED ON: 03/09/2018  
-----

P20180905-1

September 5, 2018

Product Notification  
PATHFAST Type-D / PATHFAST hs-cTnI

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 issue observed by us:

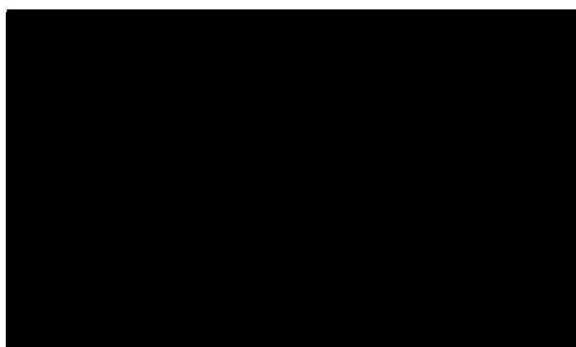
In the previous notification (P20180904-1), we requested NOT to use the combination of PATHFAST Type-D and the new PATHFAST hs-cTnI (Product No. PF1241-K).

As a result of the further investigation, we confirmed that only the combination of Ver.4.0.5 Type-D and the new PATHFAST hs-cTnI (Product No. PF1241-K) caused the problem.

Ver.4.0.2, Ver.4.0.3 and Ver.4.0.4 Type-D with the new PATHFAST hs-cTnI parameter upgraded with ITEM PARAMETER DATA SHEET according to the procedure of "6-10. NEW REGISTRATION" on PATHFAST operator's manual can be used without any problems.

For Ver.4.0.5 Type-D, a software patch to resolve the problem will be released soon.

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



Q&A

Q1: Do Items other than hs-cTnl work correctly on Ver.4.0.5 Type-D?

A1: Yes.

Q2: Does hs-cTnl work correctly on Type-B and Type-C?

A2: Yes.

Q3: How to downgrade from Ver.4.0.5 to Ver.4.0.3?

A3: We do not recommend it. Because the parameters installed at factory will be cleared.

Q4: How to upgrade hs-cTnl parameter into PATHFAST?

A4: Refer to "6-10. NEW REGISTRATION" on PATHFAST operator's manual.

There are two types of ITEM PARAMETER DATA SHEET, one is for Type-A, B and C and the other is for Type-D.

Please use correct ITEM PARAMETER DATA SHEET.