

June 2015



Important Product Information

Product Name	List Number	Lot number
i-STAT PT/INR Cartridges	03P89-24	All lots from S15007 to S15026 inclusive and All lots from T15037A to T15076A inclusive

Dear Abbott Point of Care Customer,

This letter contains important information regarding PT/INR star outs (***) as reported by the product name, list number and lot numbers noted above. The issue that has been observed relates only to the frequency of PT/INR star outs. **PT/INR results, when reported, are within the expected performance of the assay.**

Our records show that your facility is an i-STAT[®] PT/INR cartridge user of the product lots associated with this communication. Please review the information below as it may apply to cartridges in use at your facility.

BACKGROUND

The i-STAT[®] PT/INR cartridge, a prothrombin time test, is useful for monitoring patients receiving oral anticoagulation therapy such as Coumadin or warfarin.

The i-STAT System automatically runs a comprehensive set of quality checks of analyzer and cartridge performance each time a sample is tested. This internal quality system will suppress results if the analyzer or cartridge does not meet certain internal specifications. It is typical for the system to suppress a very small percentage of results in normal operation given the stringency of these specifications. Stars appear in place of results on the handheld display if the analyzer detects that the sensor's signal is uncharacteristic.

Through a combination of internal studies and customer reports, Abbott Point of Care Inc. (APOC) has determined that certain lots of i-STAT[®] PT/INR cartridges may generate a higher than typical number of PT/INR star outs.

There is no impact on user safety. There is a potential to delay the generation of patient results for PT/INR due to the star outs. When results are generated they are within the expected performance of the assay. Abbott Point of Care made the decision to communicate this information to the potentially affected marketplace. This communication was not performed to reduce risk to health.

RECOMMENDED ACTIONS

Cartridges can continue to be used for patient testing. If you repeatedly observe the condition where cartridges from the lots listed above display star outs and would like credit, please indicate on the customer reply form.

If you have forwarded any cartridges to another facility, please provide a copy of this letter to them.

ADDITIONAL INFORMATION

If you have any questions regarding this information, please contact your local Abbott representative.

We appreciate your understanding in this matter and thank you for your continued support of Abbott and Abbott products.

APOC2015-002

i-STAT is a registered trademark of the Abbott Group of Companies in various jurisdictions.