



August 2024

IMPORTANT PRODUCT INFORMATION – PRODUCT SUPPLY DISRUPTION

Product Name	List Number
<i>i-STAT Total β-hCG</i> cartridge	05P58-25

Dear Valued Abbott Customer,

This letter contains important information regarding the *i-STAT*[®] *Total β -hCG* cartridge, list number 05P58-25, noted above. If you use this cartridge, your facility is impacted, and further action is required.

This communication is to inform you that Abbott has experienced a challenge which has impacted our ability to supply the *i-STAT Total β -hCG* cartridge and there currently is no inventory of the *i-STAT Total β -hCG* cartridge available for distribution.

BACKGROUND

The *i-STAT Total β -hCG* test is an *in vitro* diagnostic test for the quantitative and qualitative determination of β -hCG in venous whole blood or plasma samples using the *i-STAT 1* analyzer. The test is intended to aid early pregnancy detection.

Abbott has identified through internal quality control testing that lots of the *i-STAT Total β -hCG* cartridges do not meet all required release testing performance specifications, and therefore, these lots were not released for distribution. As a result, there is no inventory of the *i-STAT Total β -hCG* cartridge available for distribution. Abbott is working to address the supply of the *i-STAT Total β -hCG* cartridge; however, the timing is uncertain as to when the cartridge will be available again.

All distributed cartridge lots have met the required release testing performance specifications, are unaffected by this issue, and can continue to be used until their expiration date. As all previously distributed product is unaffected by this issue, this communication is not being done to reduce risk to health. The purpose of this communication is for awareness that the *i-STAT Total β -hCG* cartridge is not currently available so alternative methods may be put in place.

RECOMMENDED ACTIONS

As Abbott Point of Care has no substitute for the *i-STAT Total β -hCG* cartridge, we recommend facilities using the *i-STAT Total β -hCG* cartridge transition to an alternate testing method for pregnancy detection, while we continue to work to address the supply disruption.

For facilities that do not have an alternative test method available in their facility or laboratory and are looking to obtain one, please contact your Abbott representative or your distributor of Abbott products for available options.

Please confirm receipt and understanding of this communication by responding to the business reply card included with this letter. If you have forwarded any *i-STAT Total β -hCG* cartridges to another facility, we request that you please provide a copy of this letter to them.

ADDITIONAL INFORMATION

All orders for the *i-STAT β -hCG* Control fluids and *i-STAT β -hCG* Calibration Verification materials will be reviewed to ensure the materials are still required.

If you have any questions regarding this information, please contact your local Abbott Point of Care Support services representative, local Abbott Point of Care Technical Support via oustechsvc@apoc.abbott.com or visit the Abbott Point of Care website www.globalpointofcare.abbott.

Abbott understands the inconvenience this may create for your facility and is committed to supporting you through this transition. We appreciate and thank you for your continued support of Abbott and Abbott products.

APOC2024-002

i-STAT is a registered trademark of Abbott.
Alere is a registered trademark of Abbott.