Abbott
1300 E. Touhy Ave.
Des Plaines, IL 60018

Abbott

Urgent Field Safety Notice
Molecular Diagnostics at Abbott
Product: Vysis CLL FISH Probe
Vysis LSI p53 Spectrumürange/ATM SpectrumGreen and
LSI D13S319 Spectrumürange/13q34 SpectrumAqua/
CEP 12 SpectrumGreen Probes
List/Part Number: 04No2-021, 04No2-022, 05J83-001/32-191025
Lot Numbers: 517086, 518656, 517516, 517068
Unique Device Identifiers (UDis):
(01)00884999042780(10)517086(17)211015(240)04No2-021
(01)00884999042780(10)518656(17)220419(240)04No2-021
(01)00884999045101(10)517516(17)220112(240)04No2-022
(01)00884999012622(10)517068(17)230219(240)05J83-001

August 4, 2021

Dear Abbott Customer,

This letter contains important information regarding Vysis CLL FISH Probe Kit, List 04No2-022 Lot 517516, Vysis CLL FISH Probe Kit List 04No2-021 Lots 517086 and 518656 and Vysis LSI p53 Spectrumürange/ATM SpectrumGreen and LSI D13S319 Spectrumürange/13q34 SpectrumAqua/CEP 12 SpectrumGreen Probes List 05J83-001/Part 32-191025 Lot 517068. These kit lots contain the same bulk probe mixture. Please review this information carefully.

Background

Abbott has received 9 reports of the Vysis CLL FISH Probe Kits not detecting 13q deletions in known positive patient samples. The D13S319 probe target contained within the probe mixture is intended to hybridize to chromosome location 13q14.3.

Potential Impact

Prognosis of CLL is determined by presence or absence of TP53/Immunoglobulin Heavy-Chain Variable (IGHV), del (uq), del (17P), and del (13q). The impacted probe mix may not detect 13q deletion of the D13S319 region leading to incorrect results. A false negative result means that presence of a 13q deletion in a patient specimen is not detected. This false negative result can lead clinicians to incorrectly evaluate a patient's prognosis.

Treatment is usually determined by disease stage, as well as presence or absence of mutation (del (17P)/TP53) which is also part of the FISH product, but the detection of this mutation **is not affected** by this recall.

Necessary Actions

Please discontinue use of these lots and discard any remaining kits.

Please complete and return the customer reply form.

This recall is to be carried out at the user/ customer level. If these lots have been further distributed by your facility, please notify any additional impacted customers.

Please review this information with your Medical Director or physicians as appropriate and retain this communication for future reference. Please review patient results generated with the impacted lots and determine if retesting is required taking patient medical history and previous treatment into consideration.

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(01)00884999012622(10)517068(17)230219(240)05J83-001

If you have any questions regarding this communication, please contact your local Molecular Diagnostics at Abbott representative . We apologize for any inconvenience this may have caused your laboratory.

Sincerely

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Quality Assurance
Molecular Diagnostics at Abbott