Class 2 Device Recall Vysis CLL FISH Probe Kit

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Class 2 Device Recall Vysis CLL FISH Probe Kit

Date Initiated by Firm	August 04, 2021
Create Date	September 27, 2021
Recall Status[1]	Open[3], Classified
Recall Number	Z-2576-2021
Recall Event ID	88565[23]
Product Classification	Chronic lymphocytic leukemia fish probe kit[24] - **Product Code** OVQ[25]
Product	Vysis CLL FISH Probe Kit with the following components: Vysis LSI p53 SpectrumOrange/ATM, SpectrumGreen and LSI D13S319, SpectrumOrange/ 13q34, SpectrumAqua/CEP 12 SpectrumGreen Probes
Code Information	UDI: (01)00884999042780(10)XXXXX(17)211015(240)04N02-021; US Distribution: Part Number 04N02-021, Lot Numbers 517086, 518656; International Distribution: List/Part Numbers (Lot Number): 04N02-021 (517086, 518656), 04N02-022 (517516, 519303), 05J83-001/Part 32-191025 (517068).
Recalling Firm/ Manufacturer	Abbott Molecular, Inc. 1300 E Touhy Ave Des Plaines IL 60018-3315
For Additional Information Contact	224-361-7619
Manufacturer Reason for Recall	Potential for Vysis CLL FISH Probe Kits not detecting 13q deletions in known positive patient samples.
FDA Determined Cause [2]	Under Investigation by firm
Action	On about 08/04/2021, Abbott Molecular notified consignees via FedEx with letter titled "Urgent Field Safety Notice Molecular Diagnostics at Abbott Product: Vysis CLL FISH Probe." The letter instructed customers to discontinue use of the affected lots, discard any remaining kits on hand, complete and return the customer reply form, and notify impacted customers if the affected lots have been further distributed. Additional instructions included to review the recall notification information with your Medical Director or physicians as

	appropriate and retain the communication for future reference. Review patient results generated with the impacted lots and determine if retesting is required taking patient medical history and previous treatment into consideration.
Quantity in Commerce	186 units
Distribution	Worldwide distribution - US Nationwide distribution in the states of AZ, CA, FL, GA, IL, IN, KY, MI, MN, MA, NC, NJ, NM, NY, OH, PA, TN, TX, UT, VA, VT, WA, WI and the countries of Australia, Belgium, Brazil, Canada, China, Costa Rica, Czech Republic, Estonia, Germany, Hong Kong, Israel, Italy, Kazakhstan, Netherlands, Philippines, Poland, Saudi Arabia, Slovenia, South Africa, South Korea, Spain, United Kingdom, Uruguay.
Total Product Life Cycle	TPLC Device Report[26]

[1] A record in this database is created when a firm initiates a correction or removal action. The record is updated if the FDA identifies a violation and classifies the action as a recall, and it is updated for a final time when the recall is terminated. Learn more about medical device recalls[27].

[2] Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

[3] The manufacturer has initiated the recall and not all products have been corrected or removed. This record will be updated as the status changes.

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26. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm?id=OVQ
27. http://www.fda.gov/MedicalDevices/Safety/ListofRecalls/ucm329946.htm

Page Last Updated: 10/12/2021

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27. http://www.fda.gov/MedicalDevices/Safety/ListofRecalls/ucm329946.htm