



Product Correction

Urgent - Immediate Action Required

To Lab Technician
 Cc: Chairman Medical Board and relevant Head of Departments

Date Issued November 8, 2019

Product

Product Name	List Number (LN)*	Lot Number	Expiration Date	UDI Number
ARCHITECT CRP Vario	6K26-30	80401Y600	30NOV2019	(01)00380740010485 (17)191130(10)80401Y600
		80517Y600	31JAN2020	(01) 00380740010485 (17)200131(10)80517Y600
		80621Y600	31MAR2020	(01) 00380740010485 (17)200331(10)80621Y600
		90078Y600	31MAY2020	(01)00380740010485 (17)200531(10)90078Y600
		90287Y600	30SEP2020	(01)00380740010485 (17)200930(10)90287Y600
		90460Y600	31OCT2020	(01)00380740010485 (17)201031(10)90460Y600
	6K26-31	80524Y600	31JAN2020	(01)00380740158491 (17)200131(10)80524Y600
		90229Y600	31JUL2020	(01) 00380740158491 (17)200731(10)90229Y600
	6K26-41	80402Y600	30NOV2019	(01)00380740010492 (17)191130(10)80402Y600
		80518Y600	31JAN2020	(01)00380740010492 (17)200131(10)80518Y600
		80502Y600	31JAN2020	(01)00380740010492 (17)200131(10)80502Y600
		80623Y600	30APR2020	(01)00380740010492 (17)200430(10)80623Y600
		90079Y600	31MAY2020	(01)00380740010492 (17)200531(10)90079Y600
		90288Y600	31JUL2020	(01)00380740010492 (17)200731(10)90288Y600
		90204Y600	31JUL2020	(01)00380740010492 (17)200731(10)90204Y600
		90319Y600	31AUG2020	(01)00380740010492 (17)200831(10)90319Y600
		90193Y600	31AUG2020	(01)00380740010492 (17)200831(10)90193Y600

Product continued

Product Name	List Number (LN)*	Lot Number	Expiration Date	UDI Number
ARCHITECT CRP Vario	6K26-41	90461Y600	31OCT2020	(01)00380740010492 (17)201031(10)90461Y600
	6K26-42	80503Y600	31JAN2020	(01)00380740158507 (17)200131(10)80503Y600
		90230Y600	31JUL2020	(01)00380740158507 (17)200731(10)90230Y600
Alinity c CRP Vario Reagent Kit	07P5620	80400Y600	30NOV2019	(01)00380740130107 (17)191130(10)80400Y600
		80622Y600	31MAR2020	(01)00380740130107 (17)200331(10)80622Y600
		90318Y600	31JUL2020	(01)00380740130107 (17)200731(10)90318Y600
		90210Y600	31JUL2020	(01)00380740130107 (17)200731(10)90210Y600
		90386Y600	31AUG2020	(01)00380740130107 (17)200831(10)90386Y600
		90192Y600	31AUG2020	(01)00380740130107 (17)200831(10)90192Y600
		90553Y600	31OCT2020	(01)00380740130107 (17)201031(10)90553Y600
		90459Y600	31OCT2020	(01)00380740130107 (17)201031(10)90459Y600

*Note: Some list numbers are not available in all countries.

Explanation

The purpose of this letter is to inform you that Abbott has received the attached Field Safety Notice from SENTINEL DIAGNOSTICS, the manufacture of the ARCHITECT CRP Vario assay and Alinity c CRP Vario Reagent Kit. Sentinel has confirmed that the EDTA specimen collection tube type (Dipotassium and Tripotassium) did not meet the sample storage stability claim listed in the package insert and is no longer appropriate for use. Based upon this testing, the specimen storage information is being revised.

Patient Impact

Please refer to the attached Sentinel Field Safety Notice.

Necessary Actions

- Please review the attached Sentinel Field Safety Notice and follow the required actions.
- Complete and return the Customer Reply Form.

Contact Information

If you or any of the health care providers you serve have any questions regarding this information, U.S. Customers please contact Customer Service at 1-877-4ABBOTT (available 24 hours a day, 7 days a week). Customers outside the U.S., please contact your local area Customer Service.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online (<http://www.fda.gov/MedWatch/report.htm>), by mail (<http://www.fda.gov/MedWatch/getforms.htm>), by phone (1-800-332-1088), or by fax (1-800-FDA-0178).

If you have experienced any patient or user injury associated with this Field Action, please immediately report the event to your local area Customer Service.