Abbott Laboratories
100 Abbott Park Road
Abbott Park, IL 60064-6081

Product Correction

Immediate Action Required

Date Issued December 19, 2017

Product

Product Name	List Number (LN)	Lot Number	Expiration Date	UDI Number
Hemoglobin A1c (HbA1c) Reagent	4P52-21	50007UQ10	02JAN2018	(01)00380740103149(17)180102 (10)50007UQ10(240)4P5221
		50030UQ10		(01)00380740103149(17)180102 (10)50030UQ10(240)4P5221
		50031UQ10		(01)00380740103149(17)180102 (10)50031UQ10(240)4P5221
		50279UQ12	28FEB2018	(01)00380740103149(17)180228 (10)50279UQ12(240)4P5221
		50280UQ12		(01)00380740103149(17)180228 (10)50280UQ12(240)4P5221
		50281UQ12		(01)00380740103149(17)180228 (10)50281UQ12(240)4P5221
		50282UQ12		(01)00380740103149(17)180228 (10)50282UQ12(240)4P5221
		50613UQ02	05MAY2018	(01)00380740103149(17)180505 (10)50613UQ02(240)4P5221
		50614UQ02		(01)00380740103149(17)180505 (10)50614UQ02(240)4P5221
		50615UQ02	12MAY2018	(01)00380740103149(17)180512 (10)50615UQ02(240)4P5221
		50616UQ02		(01)00380740103149 (17)180512 (10)50616UQ02(240)4P5221
		50884UQ04	02JUL2018	(01)00380740103149 (17)180702 (10)50884UQ04(240)4P5221
		51177UQ06	11SEP2018	(01)00380740103149 (17)180911 (10)51177UQ06(240)4P5221
		51457UQ08	07NOV2018	(01)00380740103149 (17)181107 (10) 51457UQ08(240)4P5221

Explanation	The purpose of this Product Correction letter is to inform you Fetal Hemoglobin (HbF) interference occurs at a level lower than what is stated in the HbA1c reagent package insert. The package insert states that the HbA1c assay is susceptible to interference effects from HbF at > 20%, while the most current data shows interference from HbF at > 5%. HbA1c results are invalid for patients with abnormal amounts of HbF, including those with known Hereditary persistence of Fetal hemoglobin. In healthy adults, approximately 95% of Hb is HbA, with small amounts (<3.5%) of HbA2 and HbF present[1]. Although the update to the HbF interference impacts all in-date lots of 4P52-21 reagent inventory listed above, the updated claim is not driven by a process or formulation change. Additional updates to the HbA1c reagent package insert are forthcoming and will be communicated to you in an upcoming letter.
Patient Impact	Falsely depressed results could occur when the HbF variant level in patient samples is > 5%. This negative % difference with HbF was found to be proportional in magnitude to the % HbF present in the sample.
Necessary Actions	• Please review this letter with your Medical Director. • Take the information above into consideration when using the HbA1c reagent 4P52-21. • Complete and return the Customer Reply Form. • Please retain this letter for your laboratory records. • If you have forwarded any of the products listed above to other laboratories, please inform them of this Product Correction and provide to them a copy of this letter.
Contact Information	If you or any of the health care providers you serve have any questions regarding this information, please contact your local area Customer Service.

[1] Clarke GM and Higgins TN. Laboratory Investigation of Hemoglobinopathies and Thalassemias: Review and Update. Clinical Chemistry 46:8(B) 1284-1290 (2000)