Abbott Diagnostics Division
Lisnamuck, Longford, Co.
Longford, Ireland

Urgent Field Safety Notice

Product Correction

Immediate Action Required

To : Chairman Medical Board/ Head of Departments".

Date Issued April 28, 2017

Product

Product Name	List Number	Kit Configuration	Lot Numbers	UDI Number
ARCHITECT Free T4 Reagent	7K65-29	100 Test Kit	65349UI00	N/A
			65349UI01	N/A
			68194UI00	N/A
			68194UI01	N/A
			68196UI00	N/A
			68196UI01	N/A
			71292UI00	N/A
			71292UI01	N/A
			71374UI00	N/A
			71374UI01	N/A
	7K65-34	2000 Test Kit	65415UI00	N/A
			68241UI01	N/A
			70273UI01	N/A
			71339UI00	N/A
			73200UI01	N/A
			74137UI00	N/A
	7K65-39	500 Test Kit	65415UI01	N/A
			68241UI00	N/A
			70273UI00	N/A
			71339UI01	N/A
			73200UI00	N/A
			74137UI01	N/A

Explanation

This Product Correction letter is being issued to provide you with information regarding a change of measuring interval for the ARCHITECT Free T4 assay list numbers 7K65-29, 7K65-34 and 7K65-39.

Recent data generated by Abbott have determined that the measuring interval is 0.40 ng/dL to 5.00 ng/dL. Measuring interval is defined as the range of values in ng/dL which meets the limits of acceptable performance for both imprecision and linearity.

The current measuring interval for list numbers 7K65-29, 7K65-34 and 7K65-39 is 0.40 ng/dL to 6.00 ng/dL. A new FT4 assay file and updated package insert will be created reflecting the new measuring interval of 0.40 ng/dL to 5.00 ng/dL to be used with list numbers 7K65-29, 7K65-34 and 7K65-39.

Availability of the new assay file will be forthcoming.

Patient Impact	There is no impact to patient results with values between 0.40 ng/dl and 5.0 ng/dl. Only the measuring interval between 5.00 – 6.00 ng/dL is affected. Other ARCHITECT Free T4 assay list numbers 7K65-27, 7K65-32 and 7K65-35 are not impacted by this change.
Necessary Actions	• Patient sample results between 5.00 ng/dL and 6.00 ng/dL should be reported as >5.00 ng/dL. • Please review this letter with your laboratory's management for potential impact specific to your laboratory procedures such as internal ranges. If you have forwarded the product listed above to other laboratories, please inform them of this Product Correction and provide to them a copy of this letter. Please retain this letter for your laboratory records.
Contact Information	We regret the inconvenience this situation is causing you. If you or any of the health care providers you serve have any questions regarding this information, please contact your local area Customer Service Representative.