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--IMPORTANT NOTICE--

**Thyroglobulin Assay
Interference from Biotin**

Contacts:

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Effective Date: Immediately

Members should notify ordering providers of the following:

Specimens from patients who are undergoing biotin therapy and/or ingesting biotin supplements may contain high levels of biotin. The higher biotin concentration in these specimens interferes with the biotin-streptavidin assay design of the Access Thyroglobulin assay. Beckman Coulter, the manufacturer of the thyroglobulin assay used at CPAL, has confirmed the potential of falsely decreased thyroglobulin results through interference testing. This testing demonstrated that interference occurred with samples that contained 100 ng/mL of biotin which is greater than the maximum biotin concentration observed in the normal healthy population. Results of that testing are shown below in Table 1.

Table 1: Investigation Results on the Access Thyroglobulin Assay

		100 ng/mL Biotin		
Assay	Analyte Level	Expected Concentration	Observed Concentration	% Interference
Thyroglobulin ng/mL	Low	15.3	9.6	-37
	High	90.7	61.6	-32

Conclusions:

There is potential for the Access Thyroglobulin immunoassay to exhibit interference from biotin. Interpret results in light of the total clinical presentation of the patient, including: symptoms, clinical history, data from additional tests, and other appropriate information.

References:

1. Urgent Medical Device Recall: Beckman Coulter Access Thyroglobulin Reagent; May 2017.