Alberta Health Services

Laboratory Bulletin

Date: **May 29, 2012**

To: **<u>Central Zone - Former DTHR Sites; South Zone - Former CHR Sites</u>: Physicians, Laboratories**

From: **AHS Laboratory Services**

Re: **Vitamin B12 – Interference from Intrinsic Factor Blocking Antibodies**

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Key Messages:

Siemens Healthcare Diagnostics has issued a device recall letter for the reagent used for Vitamin B12 testing. Siemens has confirmed that the presence of an Intrinsic Factor Blocking Antibody in some patients can result in a false and significant elevation in the Vitamin B12 results obtained from the Siemens Dimension Vista analyzer.

The laboratories in Red Deer (testing for former DTHR) and Lethbridge (testing for former CHR) have used the Siemens Vista analyzer for the determination of Vitamin B12 since the implementation of the Vista analyzers in July 2009 and December 2009, respectively.

Vitamin B12 testing on the Vista analyzers was suspended in Red Deer and Lethbridge during the afternoon of May 10, 2012.

Vitamin B12 testing for the former DTHR sites is being referred to Edmonton.

The laboratory in Lethbridge is working to implement Vitamin B12 testing on a different analytical system. Until ready, urgent test requests for Vitamin B12 are being referred to Calgary.

Action Required:

1. Review the attached letter for physicians and healthcare providers from Siemens Healthcare Diagnostics.

2. Consider the criteria listed in this letter when determining whether to retest patients.

Inquiries and feedback may be directed to:
Red Deer - Dr. Allison Venner – 403-406-5633, allison.venner@albertahealthservices.ca
Lethbridge – Dr. Michael Wendelboe – 403-388-6095, michael.wendelboe@albertahealthservices.ca

This bulletin has been reviewed and approved by:
Dr. James Wesenberg, AHS Provincial Medical/Scientific Director, Laboratory Services

SIEMENS

May 2012

Dear Physician or Healthcare Provider:

Siemens Healthcare Diagnostics has issued an urgent device recall letter for **all** lots of the Dimension Vista® Vitamin B12 assay.

Siemens Healthcare Diagnostics has confirmed that the presence of Intrinsic Factor Blocking Antibody (IFBA) in some patients can result in a false and significant elevation in the reported concentration of vitamin B12 on the Dimension Vista® System. All vitamin B12 results obtained from the Dimension Vista® System are impacted by this issue, starting in **January 2008.**

In order to assist you in the management of your patients Siemens Healthcare Diagnostics has provided this letter to the laboratories that have utilized this assay.

This issue only affects patients with Intrinsic Factor Blocking Antibodies (IFBA). This issue does not pertain to patients who do not have IFBA or who have a demonstrated deficiency for vitamin B12.

Siemens Healthcare Diagnostics recommends that the following criteria be considered when determining whether to retest patients:

- Patients who have tested positive for intrinsic factor blocking antibodies and have had a vitamin B12 value within or above the expected normal range
- Patients who have demonstrated clinical signs of vitamin B12 deficiency either a macrocytic anemia or neurologic signs compatible with vitamin B12 deficiency
- Patients who have undergone an evaluation for reversible dementia and have demonstrated a normal or elevated vitamin B12 value
- Patients presumptively diagnosed with erythroblastic leukemia or refractory anemia after bone marrow biopsy
- Patients who have undergone bariatric or other gastric surgery in which you are monitoring compliance with vitamin supplements
- Patients who were initially vitamin B12 deficient who are receiving only oral supplements of vitamin B12 therapy and not parenteral injections, especially if adherence to dosing is an issue

Your clinical judgment should guide you on whether retesting is required for an individual patient and if it is on a routine or more urgent basis.

In addition to retesting vitamin B12 there are alternate plasma biochemical parameters such as methylmalonic acid and homocysteine that would also both be elevated in a B12 deficiency. These can help you determine vitamin B12 status in your patient. Elevated methylmalonic acid and homocysteine are indicative of a vitamin B12 deficiency. Elevated homocysteine in the absence of a methylmalonic acid elevation is more likely indicative of folate deficiency.

With these and any patients with delayed diagnosis of vitamin B12, vigilance is appropriate to prevent the potential for misclassification of anemia, development of neurologic disorders and delay in screening for gastric malignancy in those patients with pernicious anemia.

Siemens Healthcare Diagnostics appreciates your understanding and shares your commitment to the patients that are under your care. We are working with your laboratory provider to assist them in obtaining alternate vitamin B12 tests.