



Monobind Technical Support Memo

Subject; Vitamin B12 Antibody Specificity

Date; September 2013

QUESTION:

We have a reputed customer facing some problem in Vitamin B12 CLIA kit. They are seeing a discrepancy in patient results when compared with Architect Vitamin B12.

To verify this discrepancy the customer sent 5 samples for evaluation. We ran these samples in our laboratory using 3 levels (low, medium & high) of Biorad controls. All the 3 levels result were in range but we also observed the discrepancy especially negative bias when compared with Architect Vitamin B12 results. Please find attached the data for your reference.

Additional Information: These patients were diagnosed to be Vitamin B12 deficient in past & hence were on Methylcobalmin shots. Their Vitamin B12 status was expected to be higher during testing. We would like to know whether Anti-Vitamin B12 antibodies provided in our kit can bind to only Cobalmin or also can bind to other forms such as methylcobalmin.

ANSWER:

It is to be expected that different forms of Vitamin B-12 (such as the methyl form) will be converted in the basic extraction step to the cyano form in our test (as well as others).. Cyanide is in the extraction buffer to form this stable derivative.

Since intrinsic factor is a binding protein and our assay is antibody based, differences arising from specificity are to be expected. It is apparent that the antibodies are not recognizing some analyte(s) (unknown structure(s)) while the binding protein does.

Authorized by:

A Shatla

Quality Representative

September 25, 2013