AxSYM® Active-B12
(holotranscobalamin)

Measures the bio-available form of vitamin B₁₂

An early marker of changes in B₁₂ status

Direct, automated method
Laboratory Diagnosis of Vitamin B₁₂ Deficiency

For the investigation of suspected vitamin B₁₂ deficiency, measurement of serum vitamin B₁₂ is the standard test. However, the test has the following limitations:

- It measures total, not metabolically active vitamin B₁₂
- The levels are not clearly correlated with clinical symptoms
- There is a large “grey-zone” or indeterminate range between normal and abnormal levels
- Clinically significant vitamin B₁₂ deficiency can occur with total vitamin B₁₂ levels in the apparently normal range

What is Active-B₁₂ (holotranscobalamin)?

Vitamin B₁₂ (cobalamin) in serum is bound to two proteins, transcobalamin (TC) and haptocorrin (HC). The transcobalamin-cobalamin complex is called holotranscobalamin (HoloTC) or Active-B₁₂.

The much larger fraction (about 80%) of cobalamin carried by HC is considered metabolically inert because no cellular receptors exist, except on the liver.

**Active-B₁₂ contains the biologically available cobalamin because only transcobalamin-bound B₁₂ promotes the uptake of the cobalamin therein by all cells, via specific receptors.**

The markedly shorter half-life for Active-B₁₂ compared to HoloHC makes a decrease of Active-B₁₂ one of the earliest markers of cobalamin deficiency.

Recently Proposed Algorithm for B₁₂ Deficiency Subjects

Not all vitamin B₁₂ in serum is bio-available

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Clinical Studies with Active-B12 (holotranscobalamin)

Active-B12 results by vitamin B₁₂ concentration

Active-B₁₂ and total B₁₂ show good agreement at the extremes, i.e. very likely deficient or not deficient. There is an indeterminate zone between approximately 151–300 pmol/L total B₁₂ where there is likely to be misclassification of B₁₂ status if relying on total serum B₁₂ alone.

Active-B12 may be useful in earlier identification of persons at risk of developing B₁₂ deficiency.

Methods based on specific anti-TC antibodies confirm the usefulness of Active-B₁₂ for diagnosing B₁₂ deficiency. A number of studies have been published to support the contention that Active-B₁₂ would be a better indicator of early vitamin B₁₂ deficiency than total serum cobalamin.

- Active-B₁₂ levels are low in patients with biochemical signs of vitamin B₁₂ deficiency.
- Low values have been reported in both vegetarians, vegans, and in populations with a low intake of vitamin B₁₂.
- A low serum Active-B₁₂ (but not serum vitamin B₁₂) was reported in patients with Alzheimer’s disease compared to a healthy control group.
- Recent results also support that Active-B₁₂ reflects vitamin B₁₂ status independent of recent absorption of the vitamin.

AxSYM Active-B12 (holotranscobalamin) Assay

Method Comparison AxSYM to Axis-Shield Active-B₁₂ Radioimmunoassay

The AxSYM Active-B₁₂ assay is based on two well characterised binders: A monoclonal antibody to Active-B₁₂ (that does not recognize transcobalamin, TC) and a monoclonal antibody to TC.

The assay directly quantitates Active-B₁₂ and avoids the sample pre-treatment step common to all vitamin B₁₂ assays.

The new AxSYM Active-B₁₂ assay correlates well to the existing RIA method.
AxSYM Active-B12 (holotranscobalamin) Assay Characteristics

**Method**
Microparticle Enzyme Immunoassay (MEIA)

**Throughput**
Up to 45 tests/hour

**Sample Type**
Serum (including gel tubes), lithium heparin plasma (including gel tubes)

**Sample Preparation**
None

**Sample Volume**
173 µl

**Calibrators**
6, recombinant Active-B12 in buffer, liquid, ready-to-use
0, 8, 16, 32, 64, 128 pmol/l

**Controls**
2, recombinant Active-B12 in serum, liquid, ready-to-use

**Expected Values**
19.1 – 119.3 pmol/l (apparently healthy population, n = 281)

**Suggested Cut-off**
35 pmol/l

**Precision (total %CV)**
<10%

**Calibration Curve Stability**
Typically 14 days

**Limit of Detection**
≤ 1 pmol/l

**Reference Method**
Axis-Shield radio-immunoassay

### Ordering Information

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<td>AxSYM HoloTC Calibrator Kit</td>
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<td>AxSYM HoloTC Control Kit</td>
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<td>AxSYM HoloTC Assay Disk</td>
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### References


