



## Document Information:

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# SPECIFICATION

for

## Vitamin B 12 II

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### Part 1 (PT1)

Appearance	clear solution
pH	5.1 – 5.9

### Part 2 (PT2)

Appearance	clear solution
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### Part 3 (M)

Appearance	brown suspension
Streptavidine coated micro particles	648 - 792 µg/ml

### Part 4 (R1)

Appearance	clear solution
pH	5.3 – 5.7
Ruthenium labeled recombinant porcine intrinsic factor	proved by performance test

### Part 5 (R2)

Appearance	clear solution
pH	6.8 – 7.2
Biotinylated vitamin B12	proved by performance test

### Performance test

### Recovery of Vitamin B 12 II in (based on assigned value)

PreciControl Varia Level 0	67 – 133 %
PreciControl Varia Level 1	67 – 133 %
PreciControl Varia Level 2	61 – 139 %

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All products derived from human blood are prepared exclusively from the blood of donors tested individually and shown to be free from HBsAg and antibodies to HCV and HIV. The testing methods used assays approved by the FDA or cleared in compliance with the European Directive 98/79/EC, Annex II, List A.