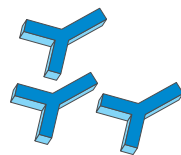


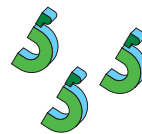
- Random access assay for the detection of intrinsic factor antibodies and as an aid in the diagnosis of pernicious anemia
- Convenient – the only fully automatic intrinsic factor Ab assay available; use on any system in the Access family
- Detection of intrinsic factor Ab may eliminate the need for further testing, such as the radioactive Schillings test
- 14-day calibration stability
- Imprecision: <8%

2 step
competitive
binding
technique



Sample containing
intrinsic factor
antibodies

+



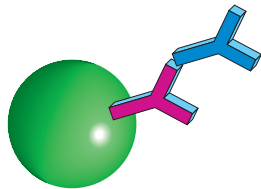
Porcine intrinsic factor –
alkaline phosphatase
conjugate

→



Incubate at =36.5°C
for 20 minutes

→

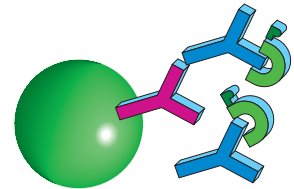


Paramagnetic particles
coated with goat anti-
mouse IgG/anti-intrinsic
factor MAb complexes

→



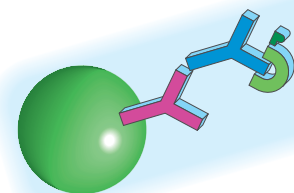
Incubate at =36.5°C
for 5 minutes



Competitive binding

→

Wash
3 times



+

Add
substrate

→

Incubate
5 minutes

Dioxetane-P



Dioxetane



Read light

Signal produced is inversely proportional to the Intrinsic Factor Antibody concentration in the sample



Intrinsic Factor Ab

Pernicious Anemia

Vitamin B₁₂ deficiency affects the general population, but particularly elderly people. Pernicious anemia is characterized by vitamin B₁₂ deficiency, megaloblastic anemia, neuropathy and gastritis with intrinsic factor autoantibodies.

Although pernicious anemia is clinically expressed as a disease of the blood, it is the end stage of an autoimmune disease that results in the destruction of gastric mucosa. The first of two autoimmune processes that lead to the condition is the depletion of intrinsic factor-producing gastric parietal cells. The second process occurs when autoantibodies block binding sites on intrinsic factor required for vitamin B₁₂ absorption.

The presence of circulating autoantibodies to intrinsic factor is very specific for pernicious anemia. The combination of megaloblastic anemia, low serum vitamin B₁₂ and the presence of serum antibodies to intrinsic factor is essentially diagnostic of pernicious anemia. The detection of intrinsic factor antibodies may eliminate the need for further testing, such as the Schillings test.

Expected Values

1. Each laboratory should establish its own reference ranges to assure proper representation of specific populations.
2. Sera from 200 apparently health male and female subjects were assayed to establish expected values. A non-parametric estimate at the 99% confidence level yield the following ranges:

Results	Interpretation	Comment
<1.20 AU/mL	Negative	Results are considered negative for the detection of intrinsic factor antibody. Samples with ratios less than the negative cutoff are reported as <i>negative</i> .
≥1.20 to <1.53 AU/mL	Equivocal	Results that are above the negative cutoff and below the positive cutoff are regarded as equivocal and are reported as <i>equivocal</i> .
≥1.53 AU/mL	Positive	Results are considered positive for the detection of intrinsic factor antibody and are reported as <i>positive</i> .

Characteristics

Sample Type/Size	Serum or plasma (heparin)/55 µL
Time to First Result	35 minutes
Calibrator Levels	S ₀ = 1.0 AU/mL
Expected Values	0.93 to <1.20 AU/mL
Open Pack Stability	56 days
Calibration Stability	14 days
Imprecision	< 8% CV

Ordering Information

Access® Intrinsic Factor Ab - 2 packs of 50 tests/pack	387992
Access® Intrinsic Factor Ab Calibrators - 2 vials of 4 mL/vial	387993
Access® Intrinsic Factor Ab QC - 2 levels; 3 vials of 4 mL/vial, each level	387999

