CAMBRIDGE Life Sciences

Autoimmunity Reagents: Gastroenterology

AUTOZYME™ IFAB

KEY POINTS:

- **Antigen: recombinant intrinsic factor - no cross reactivity with Parietal Cell Antibodies**
- **Calibration: 6 calibrators (quantitative) or cut-off control (semi-quantitative)**
- **Dilution: 1/100 (5µl sample+ 495µl diluent)**
- **No interference from Direct and Total Bilirubin, Haemoglobin, Triglycerides, RF**
- **Serum and Plasma (EDTA, citrate, heparin) samples**
- **TMB Substrate**
- **Multiple use: microplates suitable for small and large users - no waste**

INDICATION:

Quantitative or semi-quantitative detection of antibodies to Intrinsic Factor in human sera or plasma to aid the diagnosis or pernicious anaemia in conjunction with other laboratory tests and clinical findings.

PRINCIPLE OF THE ASSAY:

The AUTOZYME™ IFAB Anti-Intrinsic Factor Antibodies Assay is a solid phase immunoassay. Detection of anti-intrinsic factor antibodies provides an important contribution to the differential diagnosis of pernicious anaemia (due to intrinsic factor deficiency) and other causes of vitamin B12 malabsorption. Indeed, other tests such as the cytomorphology of red blood cells, determination of serum vitamin B12 levels or the Schilling test are not specific enough for the diagnosis of Pernicious anaemia.
Anti-Intrinsic Factor antibodies can be detected using RIA or ELISA methods. The ability of type I auto-antibodies to prevent the binding of vitamin B12 to the intrinsic factor has allowed the development of RIA methods. ELISA methods detect type I and type II antibodies and are unaffected by the presence of high exogenous vitamin B12 levels.
The AUTOZYME™ IFAB Anti-Intrinsic Factor Antibodies Assay is an easy, rapid and sensitive method allowing the detection of total anti-intrinsic factor antibodies. The use of recombinant intrinsic factor as antigen ensures the specificity of the method.

ORDERING INFORMATION	CONFIGURATION	PART NUMBER
AUTOZYME™ IFAB Anti-Intrinsic Factor Antibodies Kit CE IVD 98/79/EC For in vitro diagnostic use and Professional Use only.	1 x Microplate 6 x 1.5mL Calibrators 1 x 1.5mL Negative Control 1 x 1.5mL Positive Control 1 x 50mL Sample Diluent 1 x 100mL Wash Buffer Conc (X20) 1 x 15mL Conjugate 1 x 15mL TMB Substrate 1 x 15mL Stop Solution	Z4396

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PERFORMANCE:

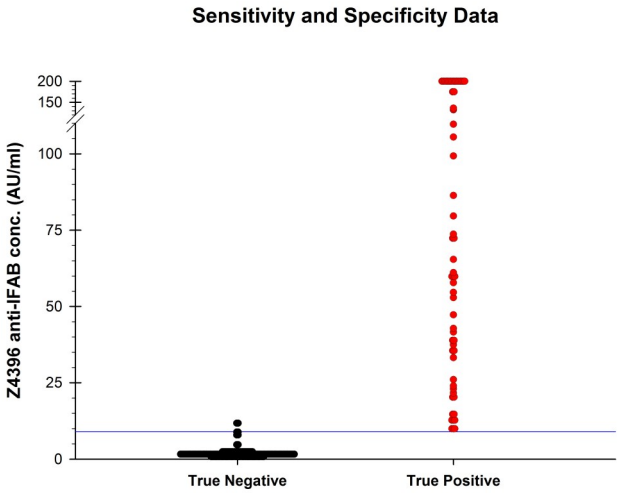
Clinical Sensitivity and Specificity

The utility of the Intrinsic Factor Antibody ELISA was evaluated by testing Pernicious anaemia patients alongside disease controls and 'normal' human sera. These results are summarised below.

Cut-Off = 9 AU/ml

		True Status	
		Positive	Negative
Z4396	Positive	61	2
	Negative	0	147

Sensitivity = 100.0%
Specificity = 98.7%
Agreement = 99.0%
PPV = 96.8%
NPV = 100.0%



Precision

Samples run am + pm over 20 days					
Sample		**Kit Positive**	**NHS**	**Low Positive**	**High Positive**
Mean (AU/mL)		**38.66**	**3.57**	**20.33**	**71.21**
Repeatability	**SD**	1.23	0.15	0.49	1.40
	%CV	**3.2**	**4.3**	**2.4**	**2.0**
Between Day	**SD**	0.82	0.45	0.86	3.68
	%CV	**2.1**	**12.6**	**4.2**	**5.2**
Between Run	**SD**	3.64	0.61	0.92	3.46
	%CV	**9.4**	**17.1**	**4.5**	**4.9**
Total	**SD**	3.75	0.77	1.35	5.24
	%CV	**9.7**	**21.6**	**6.6**	**7.4**

Imprecision (n = 20 replicates)			
Sample	**Kit Negative**	**Kit Positive**	**Low Positive**
Mean (AU/mL)	**3.28**	**40.54**	**18.88**
SD	0.25	1.86	0.56
%CV	**7.7**	**4.6**	**3.0**
Sample	**NHS**	**Low Positive**	**High Positive**
Mean (AU/mL)	**2.47**	**21.80**	**74.57**
SD	0.25	0.81	3.04
%CV	**8.9**	**3.7**	**4.1**

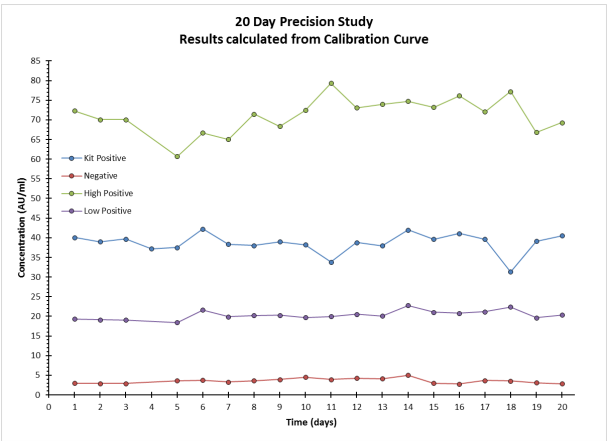
NEQAS Performance

Sample	Target	Z4396 AU/ml	Agreement
206A	Negative	0.6	✓
206B	**Positive**	**14.2**	✓
206C	Negative	1.7	✓
207A	**Positive**	**32.2**	✓
207B	Negative	1.2	✓
207C	Negative	1.4	✓
208A	Negative	2.1	✓
208B	Negative	2.2	✓
208C	**Positive**	**10.1**	✓
213A	Negative	1.0	✓
213B	**Positive**	**31.7**	✓
213C	Negative	1.3	✓
214A	**Positive**	**43.0**	✓
214B	Negative	2.7	✓
214C	Negative	0.8	✓
215A	**Positive**	**82.0**	✓
215B	Negative	1.1	✓
215C	Negative	1.4	✓
216A	Negative	1.3	✓
216B	**Positive**	**67.4**	✓
216C	Negative	2.4	✓
217A	Negative	2.2	✓
217B	**Positive**	**48.1**	✓
217C	Negative	1.6	✓
218A	Negative	2.9	✓
218B	**Positive**	**74.3**	✓
218C	Negative	1.0	✓

Interference

Interferent	Concentration
Ascorbic Acid	200.0µmol/L
Total Bilirubin (unconjugated)	225.0mg/L (385µmol/L)
Direct Bilirubin (conjugated)	300.0mg/L (513µmol/L)
Haemoglobin	5.0g/L (77.6µmol/L)
Triglycerides	10.0 g/L (11.3mmol/L)
Intralipids	1% (w/v)
Rheumatoid Factor	100U/mL

No significant interference observed.



Measuring Range

0.3 - 200 AU/mL
LoD: The limit of detection (LoD) was determined based on 60 replicates of the blank and 10 replicates each of 6 low-level (NHS) samples.