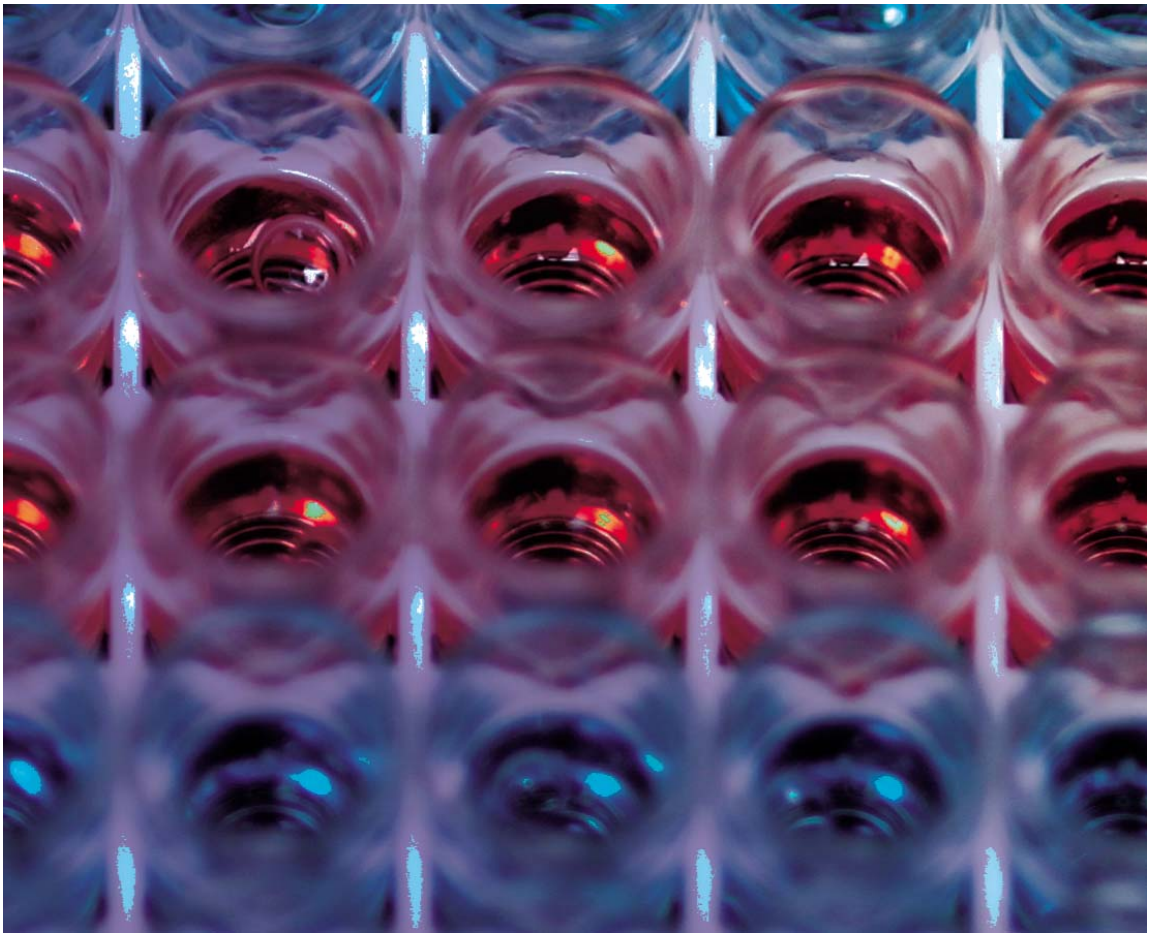

corgenix

www.corgenix.co.uk

Product Catalogue 2009

Welcome to Corgenix

We are pleased to introduce the **Corgenix 2009 Product Catalogue.**

Since the foundation of the company in 1990, Corgenix has developed and manufactures a range of unique, clinical laboratory diagnostic products suitable for use by the worldwide healthcare market. The **READS** brand of ELISA assays (**R**apid **E**LISAs **A**pplied to **A**utoimmune **D**iagnostic **S**ystems) focuses on the diagnosis and management of selected autoimmune disorders, vascular disease and thrombotic tendency using proprietary immunological technology.

Through its international headquarters based in Peterborough on the edge of the Cambridgeshire Fenlands in the United Kingdom, Corgenix continues to expand its global presence by continued enlargement and strengthening of its worldwide distribution network and the formation of strategic alliances and partnerships with people and organisations where there are common business interests.

Moreover, recognising the changing needs of the specialist customers it supplies, Corgenix is pleased to feature in 2009 the extended range of products from its European partner company, Hart Biologicals Ltd – see pages 39 - 45. Founded in August 2002 with a strategy to develop key, diagnostic assays with a particular emphasis in the area of Coagulation and Haemostasis, available through the Corgenix distribution network are products for anticoagulant drug therapy monitoring, a range of platelet function testing reagents, reagents for assessing congenital or acquired clotting factor disorders and an extensive range of quality control and reference plasmas for routine and specialised assay purposes. Hart Biologicals also offers contract manufacturing services at its facility situated in the North East of England in the United Kingdom.

For further assistance please contact us as follows, or through your local Corgenix distributor.

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an EN ISO 13485 : 2003 certified organisation

Contents Page

Cardiovascular Assays

AtherOx™ (oxLDL-β2GP1 antigen complex) ELISA

The AtherOx™ (oxLDL-β2GP1 antigen complex) ELISA detects circulating complex formed by the interaction of oxidized low-density lipoprotein cholesterol (oxLDL) with β2 glycoprotein 1 (β2GP1) in human serum or plasma. OxLDL-β2GPI complex may be used as an aid in the serologic risk assessment of atherosclerotic cardiovascular disease in individuals with systemic autoimmune diseases - Systemic Lupus Erythematosus (SLE), Systemic Sclerosis (SSc) and lupus-like disorders (Antiphospholipid Syndrome, APS), and type 2 Diabetes Mellitus (DM).

Low-density lipoprotein (LDL) is the principal form of cholesterol that accumulates in atherosclerotic plaque. The oxidative modification of LDL (oxLDL) represents an important pathogenic event in the initiation and progression of atherosclerotic lesions. Unlike unmodified or native LDL, oxLDL binds to β2-glycoprotein 1 (β2GP1) to form oxLDL-β2GP1 complexes. OxLDL-β2GP1 complexes act as a pro-inflammatory chemotactic factor for macrophages and T lymphocytes leading to the formation of foam (fat containing) cells. Both oxLDL and β2GP1 have been detected in human atherosclerotic lesions. Thus, circulating oxLDL-β2GP1 complexes have been implicated as pro-atherogenic antigens and may represent a serologic risk factor and/or a significant contributor for the development of thrombosis and atherosclerosis.

Microwells, coated with monoclonal antibody (WB-CAL-1), are used to specifically capture complexed β2GP1. Serum or plasma samples are diluted in sample diluent containing $MgCL_2$, which allows the binding of non-dissociable oxLDL-β2GP1 complex to the wells. HRP-conjugated anti-human apolipoprotein B-100 is added to detect bound oxLDL-β2GP1 complex. TMB substrate is added to produce a colored reaction that is measured at 450nm. The concentration of oxLDL-β2GP1 complex in samples is calculated against a standard curve prepared with Cu^{2+} oxLDL-β2GP1 complex.

- **Convenient ELISA well strip or plate format**
- **60 : 60 : 30 minutes incubations**
- **Single point or Multi-level calibration**
- **Excellent Clinical Correlation**
- **High Specificity: 98% in SSc patients, 93% in APS patients**
- **Good correlation in patients with type 2 Diabetes Mellitus (DM)**

Catalogue #	Description	Pack size
11926	**AtherOx™ oxLDL-β2GP1 antigen complex ELISA**	**96 wells**

Kit contains the following reagents:

96 stabilised antibody (murine) coated breakaway microwells in frame	12 strips x 8 wells
Sample Diluent (green solution)	2 x 60 mL
Reference Solution (human oxLDL-β2GP1 complex in buffer) 100 Units	1 x 1.5 mL
Positive Control (human oxLDL-β2GP1 complex in buffer)	1 x 0.25 mL
Negative Control (human oxLDL-β2GP1 complex in buffer)	1 x 0.25 mL
HRP-Conjugated Antibody (murine) Solution (blue solution, ready to use)	1 x 15 mL
Substrate (ready to use)	1 x 15 mL
Stopping Solution (ready to use)	1 x 15 mL
Wash Concentrate (33x)	2 x 30 mL

Store at 2 - 8°C. Do Not Freeze. **For *in-vitro* diagnostic use** CE

Cardiovascular Assays

Anti-AtherOx™ Test Kits (IgG & IgM anti-oxLDL-β2GP1 antibody)

The Anti-AtherOx (IgG & IgM anti-oxLDL-β2GP1 antibody) ELISA detect antibodies to complexes formed by the interaction of oxidized low-density lipoprotein cholesterol (oxLDL) with β2-glycoprotein 1 (β2GP1) in human serum or plasma. Antibodies to oxLDL-β2GP1 may be used as an aid in the serologic risk assessment for arterial thrombosis and atherosclerotic cardiovascular disease in individuals with systemic autoimmune diseases - systemic lupus erythematosus (SLE) and lupus-like disorders (Antiphospholipid Syndrome, APS). The oxidative modification of low-density lipoprotein (oxLDL) represents an important pathogenic event in the initiation and progression of atherosclerotic lesions. In the arterial wall, oxLDL is a pro-inflammatory chemotactic factor for macrophages and immunoreactive cells. OxLDL interacts with β2GPI forming OxLDL-β2GP1 complexes, which have been implicated as pro-atherogenic antigens. Antibodies to this complex have been demonstrated in patients with systemic autoimmune diseases.

An active macrophage uptake of immune complexes containing oxLDL-β2GP1-antibody via Fc receptors has been demonstrated, a process that leads to accelerated development of foam (fat-containing) cells and atherosclerotic plaques. The premature (or accelerated) development of clinical atherosclerosis in patients with certain systemic autoimmune disorders cannot be fully explained by traditional risk factors. Oxidative stress resulting in oxLDL and complex formation with β2GP1 is common in patients with autoimmune diseases characterized by significant vascular complications.

Cu^{2+} oxidized LDL-β2GP1 complex, coated onto microwells, captures antibodies to this complex in serum or plasma samples. HRP-conjugated anti-human IgG or IgM antibodies are added to detect bound complexes. TMB substrate is added to produce a colored reaction that is measured at 450nm. Values are calculated against the standard curve, which has been prepared from diseased state serum samples. Anti-oxLDL-β2GP1antibodies are distinct from "classic" anti-β2GP1 antibodies.

Catalogue #	Description	Pack size
11854	**Anti-AtherOx™ IgG anti-oxLDL-β2GP1 antibody ELISA**	**96 wells**

Kit contains the following reagents:

96 stabilised oxLDL-β2GP1 antigen (human) coated breakaway microwells in frame	12 strips x 8 wells
Sample Diluent (green solution)	2 x 60 mL
IgG Calibrator Sera (human) (1-high, 2-moderate, 3-low)	3 x 0.25 mL
IgG Positive Control Serum (human)	1 x 0.25 mL
IgG Negative Control Serum (human)	1 x 0.25 mL
IgG anti-human (goat) HRP-Conjugate (blue solution, ready to use)	1 x 15 mL
Substrate (ready to use)	1 x 15 mL
Stopping Solution (ready to use)	1 x 15 mL
Wash Concentrate (33x)	2 x 30 mL

11855	**Anti-AtherOx™ IgM anti-oxLDL-β2GP1 antibody ELISA**	**96 wells**

Kit contains the following reagents:

96 stabilised oxLDL-β2GP1 antigen (human) coated breakaway microwells in frame	12 strips x 8 wells
Sample Diluent (green solution)	2 x 60 mL
IgM Calibrator Sera (human) (1-high, 2-moderate, 3-low)	3 x 0.25 mL
IgM Positive Control Serum (human)	1 x 0.25 mL
IgM Negative Control Serum (human)	1 x 0.25 mL
IgM anti-human (goat) HRP-Conjugate (blue solution, ready to use)	1 x 15 mL
Substrate (ready to use)	1 x 15 mL
Stopping Solution (ready to use)	1 x 15 mL
Wash Concentrate (33x)	2 x 30 mL

Store at 2 - 8°C. Do Not Freeze. **For *in-vitro* diagnostic use** CE

Cardiovascular Assays

AspirinWorks® Urinary 11-dehydrothromboxane B_2 ELISA

Activated and aggregated platelets play a key role in the pathogenesis of cardiovascular disease. Activated platelets produce Thromboxane A2 (TxA2), a potent vasoconstrictor and inducer of platelet aggregation. TxA2 is generated by Thromboxane synthase from molecules derived from arachidonic acid by cyclooxygenase-1 (COX-1). TxA2 has a short half-life in plasma and is rapidly hydrolyzed to Thromboxane B2 (TxB2). TxB2, in turn, is metabolized to 11-Dehydro Thromboxane B2 (11dhTxB2), 11-Dehydro 2,3 din,or Thromboxane B2 (11dh2,3DTxB2, a truncated form of 11dhTxB2), and a number of other minor TxB2 metabolites which are excreted by the kidney. Thus, 11dhTxB2 is a stable metabolite of TxA2 and an *in vivo* indicator of platelet activity.
An important part of anti-platelet therapy in cardiovascular disease is aspirin (acetylsalicylic acid), which has been known for many years to have anti-platelet activity.8 Aspirin functions by acetylating and irreversibly inhibiting COX-1, thus inhibiting the production of TxA2 and its metabolites. Low dose aspirin blocks more than 95% of platelet COX-1 activity and reduces cardiovascular events by as much as 25% in patients with arterial vascular disease. However, aspirin's effectiveness varies among individuals. It has been estimated that 10-20% of aspirin users have recurrent thrombotic events. This phenomenon has been referred to as aspirin resistance and 5-57% of aspirin users may demonstrate a poor response to typical doses, depending on the measuring technique used and the population analyzed. There are a number of blood-based methods that determine an individual's response to daily aspirin therapy by measuring *ex vivo* platelet activation. These methods, however, are influenced by factors unrelated to aspirin's specific effect on the cyclooxygenase pathway including von Willebrand factor (vWF), Factor VIII, and hematocrit levels, as well as other variables involved in venipuncture. Alternatively, the measurement of stable metabolites of TxA2, such as urinary 11dhTxB2, is a means to quantitate TxA2 production by platelets and thus a direct way to analyze the effectiveness of aspirin therapy.

The AspirinWorks® Urinary 11-dehydrothromboxane B_2 ELISA represents a major advance in patient management by determining if the aspirin dosage ingested by an individual is inhibiting platelet cylcooxygenase activity through the measurement of 11dhTxB2.

For further information, see www.aspirinworks.com

Catalogue #	Description	Pack size
12136	**AspirinWorks® Urinary 11-dehydrothromboxane B_2 ELISA**	**96 wells**

Kit contains the following reagents:

96 stabilized antibody (goat) coated breakaway microwells in frame	12 strips x 8 wells
Sample Diluent (green solution)	1 x 60 mL
Reference Solution 5000 pg/mL (11dhTxB_2 in buffer)	1 x 1.75 mL
Level 1 Control, lyophilized (human urine) to be reconstituted to 0.5 mL.	1 vial
Level 2 Control, lyophilized (human urine) to be reconstituted to 0.5 mL	1 vial
Level 3 Control, lyophilized (human urine) to be reconstituted to 0.5 mL	1 vial
AP-Tracer Solution, purified 11dhTxB_2, red	1 x 10 mL
Purified anti-11dhTxB_2 antibody (murine), blue solution,	1 x 10 mL
pNPP Substrate, ready to use	1 x 23 mL
Stop Solution (0.1 M EDTA); ready to use (red cap)	1 x 15 mL
Wash Concentrate TBS/Tween 20 (20X).	2 x 50 mL
Adhesive plate sealers.	2 x

Store at 2 - 8°C. Do Not Freeze. **For *in-vitro* diagnostic use** CE

Antiphospholipid Assays

Anti-Cardiolipin Antibodies

Anti-Cardiolipin (aCL) antibodies are associated with the presence of both venous and arterial thrombosis, thrombocytopenia, and recurrent fetal loss. These autoantibodies are frequently found in patients with systemic lupus erythematosus (SLE) and other autoimmune diseases, as well as in some individuals with no apparent previous underlying disease.
The REAADS Anti-Cardiolipin ELISA are semi-quantitative, indirect enzyme linked immunosorbent assay (ELISA) tests for the detection of IgG, IgM and IgA anti-cardiolipin antibodies in human serum or plasma. The assays can be used with a single point or multi-level calibration to obtain anti-cardiolipin antibody concentrations in patient samples. Test kits for the specific semi-quantitative determination of IgG or IgM and IgA immunoglobulins are available. Assay results (in GPL, MPL or APL units) are traceable to an internationally recognised standard.

- **Convenient ELISA well strip or plate format**
- **Specific determination of IgG, IgM or IgA isotypes**
- **Single point or Multi-level calibration**
- **Short incubation time around 40 minutes at room temperature**
- **Easily automated, instrumentation protocols available**
- **Excellent Clinical Correlation**
- **High Specificity: 97% for IgG, 96% for IgM, 95% for IgA aCL antibodies**
- **High Sensitivity: Clear distinction between positive and negative results**

Catalogue #	Description	Pack size
023-001	**REAADS IgG/IgM Anti-Cardiolipin ELISA**	**96 wells**
023-002	**REAADS IgG/IgM Anti-Cardiolipin ELISA**	**288 wells**

Kit contains the following reagents (volumes may vary depending on kit size and configuration):

96 stabilised beef heart Cardiolipin coated breakaway microwells in frame	12 strips x 8 wells
Sample Diluent (green solution) (ready to use)	1 x 60 mL
aCL IgG Human Serum Calibrators (1-high, 2-moderate, 3-low)	3 x 0.25 mL
aCL IgM Human Serum Calibrators (1-high, 2-moderate, 3-low)	3 x 0.25 mL
aCL IgG Positive Human Serum Control	1 x 0.25 mL
aCL IgM Positive Human Serum Control	1 x 0.25 mL
Normal Human Serum Control	1 x 0.25 mL
anti-human IgG (goat) HRP-Conjugate (blue solution, ready to use)	1 x 15 mL
anti-human IgM (goat) HRP-Conjugate (red solution, ready to use)	1 x 15 mL
Substrate (ready to use)	1 x 15 mL
Stopping Solution (ready to use)	1 x 15 mL
Wash Concentrate (33x)	2 x 30 mL

026-001	**REAADS IgA Anti-Cardiolipin ELISA**	**96 wells**
026-006	**REAADS IgA Anti-Cardiolipin ELISA**	**288 wells**

Kit contains the following reagents (volumes may vary depending on kit size and configuration):

96 stabilised beef heart Cardiolipin coated breakaway microwells in frame	2 strips x 8 wells
Sample Diluent (green solution) (ready to use)	1 x 60 mL
aCL IgA Human Serum Calibrators (1-high, 2-moderate, 3-low)	3 x 0.25 mL
aCL IgA Positive Human Serum Control	1 x 0.25 mL
Normal Human Serum Control	1 x 0.25 mL
anti-human IgA (goat) HRP-Conjugate (orange solution, ready to use)	1 x 15 mL
Substrate (ready to use)	1 x 15 mL
Stopping Solution (ready to use)	1 x 15 mL
Wash Concentrate (33x)	2 x 30 mL

Store at 2 - 8°C. Do Not Freeze. **For *in-vitro* diagnostic use** CE

Antiphospholipid Assays

Anti-Phosphatidylserine

Elevated serum levels of anti-phospholipid (aPS) antibodies are associated with an increased risk for recurrent arterial and venous thrombotic events, thrombocytopenia and fetal loss. These are the main clinical manifestations of Antiphospholipid Syndrome. Phosphatidylserine is found in the membranes of platelets and endothelial cells, which participate in the coagulation cascade. Due to its physiological role, testing for autoantibodies directed towards phosphatidylserine provides not only more relevant results, but also additional information to assess the risk of thrombosis.

The REAADS IgG/IgM and IgA Anti-Phosphatidylserine ELISA test kits are indirect, semi-quantitative enzyme-linked immunosorbent assay (ELISA) tests for the detection of antibodies against phosphatidylserine. Each assay uses a single point or multi-level calibration to obtain IgG or IgM and IgA anti-phosphatidylserine antibody concentrations in patient samples.

- **Convenient ELISA well strip or plate format**
- **IgG, IgM and IgA isotypes available**
- **Single point or Multi-level calibration**
- **Short incubation time around 40 minutes at room temperature**
- **Easily automated, instrumentation protocols available**
- **Excellent Clinical Performance**
- **High Specificity: 96% for both IgG and IgM and 95% for IgA aPS antibodies**
- **High Sensitivity: Clear discrimination between Primary APS and SLE**

Catalogue #	Description	Pack size
030-001	**REAADS IgG/IgM Anti-Phosphatidylserine ELISA**	**96 wells**
030-002	**REAADS IgG/IgM Anti-Phosphatidylserine ELISA**	**288 wells**

Kit contains the following reagents (volumes may vary depending on the kit size and configuration):

96 Phosphatidylserine (porcine brain) coated breakaway microwells in frame	12 strips x 8 wells
Sample Diluent (green solution) (ready to use)	1 x 60 mL
aPS IgG Human Serum Calibrators (1-high, 2-moderate, 3-low)	3 x 0.25 mL
aPS IgM Human Serum Calibrators(1-high, 2-moderate, 3-low)	3 x 0.25 mL
aPS IgG Positive Human Serum Control	1 x 0.25 mL
aPS IgM Positive Human Serum Control	1 x 0.25 mL
Normal Human Serum Control	1 x 0.25 mL
anti-human IgG (goat) HRP-Conjugated Antibody (blue solution) (ready to use)	1 x 15 mL
anti-human IgM (goat) HRP-Conjugated Antibody (red solution) (ready to use)	1 x 15 mL
Substrate (ready to use)	1 x 15 mL
Stopping Solution (ready to use)	1 x 15 mL
Wash Concentrate (33x)	2 x 30 mL

10206	**REAADS IgA Anti-Phosphatidylserine ELISA**	**96 wells**
10497	**REAADS IgA Anti-Phosphatidylserine ELISA**	**288 wells**

Kit contains the following reagents (volumes may vary depending on the kit size and configuration):

96 Phosphatidylserine (porcine brain) coated breakaway microwells in frame	12 strips x 8 wells
Sample Diluent (green solution) (ready to use)	1 x 60 mL
aPS IgA Human Serum Calibrators (1-high, 2-moderate, 3-low)	3 x 0.25 mL
aPS IgA Positive Human Serum Control	1 x 0.25 mL
Normal Human Serum Control	1 x 0.25 mL
anti-human IgA (goat) HRP-Conjugated Antibody (orange solution)	1 x 15 mL
Substrate (ready to use)	1 x 15 mL
Stopping Solution (ready to use)	1 x 15 mL
Wash Concentrate (33x)	2 x 30 mL

Store at 2 - 8°C. Do Not Freeze. **For *in-vitro* diagnostic use** CE

Anti-β2 Glycoprotein 1

Anti-phospholipid antibodies are a heterogeneous group of antibodies that bind to several anionic phospholipids. Most autoimmune anti-phospholipid antibodies require serum cofactors for optimal binding. β2 Glycoprotein 1 (β2GPI) is a protein cofactor with natural anticoagulant properties and has an affinity for negatively-charged phospholipids. Antibodies directed against B2GPI have been shown to be associated with thrombosis in individuals with systemic lupus erythematosus (SLE) and lupus-like disorders (antiphospholipid syndrome). The presence of both anti-phospholipid and anti-β2GP1 antibodies shows a better correlation with the clinical manifestations of antiphospholipid syndrome than either of these antibodies occurring separately.

The REAADS IgG, IgM and IgA anti-β2GPI kits are indirect enzyme linked immunosorbent assay (ELISA) for the semi-quantitation of anti-β2GP1 antibodies in human serum. The assays use separate single point or multi-level calibrations to obtain anti-β2GP1 antibody concentrations in G, M or A units.

- **Convenient ELISA well strip or plate format**
- **Specific determination of IgG, IgM or IgA isotypes using colour coded reagents**
- **Single point or Multi-level calibration**
- **Easily automated, instrumentation protocols available**
- **Excellent Clinical Correlation**
- **High Specificity: 100% for IgG, 93% for IgM, and 96% for IgA anti-B2 GP1 antibodies**
- **High Sensitivity: Clear distinction between positive and negative results**

Catalogue #	Description	Pack size
037-001	**REAADS IgG Anti-β2 Glycoprotein 1 ELISA**	**96 wells**
	Kit contains the following reagents:	
	96 stabilized β2GP1 (from human serum) coated breakaway microwells in frame	12 strips x 8 wells
	Sample Diluent (blue-green solution) (ready to use)	1 x 60 mL
	β2GP1 IgG Human Serum Calibrators (1-high, 2-moderate, 3-low)	3 x 0.25 mL
	β2GP1 IgG Positive Human Serum Control	1 x 0.15 mL
	Normal Human Serum Control	1 x 0.15 mL
	anti-Human **IgG** (goat) HRP-Conjugate (blue solution, ready to use)	1 x 15 mL
	One Component Substrate Solution (ready to use)	1 x 15 mL
	Stopping Solution (ready to use)	1 x 15 mL
	Wash Concentrate (33x)	2 x 30 mL
038-001	**REAADS IgM Anti-β2 Glycoprotein 1 ELISA**	**96 wells**
	Kit contains the following reagents:	
	96 stabilized β2GP1 (from human serum) coated breakaway microwells in frame	12 strips x 8 wells
	Sample Diluent (blue-green solution) (ready to use)	1 x 60 mL
	β2GP1 IgM Human Serum Calibrators (1-high, 2-moderate, 3-low)	3 x 0.25 mL
	β2GP1 IgM Positive Human Serum Control	1 x 0.15 mL
	Normal Human Serum Control	1 x 0.15 mL
	anti-Human **IgM** (goat) HRP-Conjugate (blue solution, ready to use)	1 x 15 mL
	One Component Substrate Solution (ready to use)	1 x 15 mL
	Stopping Solution (ready to use)	1 x 15 mL
	Wash Concentrate (33x)	2 x 30 mL
039-001	**REAADS IgA Anti-β2 Glycoprotein 1 ELISA**	**96 wells**
	Kit contains the following reagents:	
	96 stabilized β2GPI (from human serum) coated breakaway microwells in frame	12 strips x 8 wells
	Sample Diluent (blue-green solution) (ready to use)	1 x 60 mL
	β2GP1 IgA Human Serum Calibrators (1-high, 2-moderate, 3-low)	3 x 0.25 mL
	β2GP1 IgA Positive Human Serum Control	1 x 0.15 mL
	Normal Human Serum Control	1 x 0.15 mL
	anti-Human **IgA** (goat) HRP-Conjugate (blue solution, ready to use)	1 x 15 mL
	One Component Substrate Solution (ready to use)	1 x 15 mL
	Stopping Solution (ready to use)	1 x 15 mL
	Wash Concentrate (33x)	2 x 30 mL

Store at 2 - 8°C. Do Not Freeze. **For *in-vitro* diagnostic use** CE

Antiphospholipid Assays

Anti-Prothrombin

Several plasma proteins associated with the coagulation system and with strong phospholipid binding properties have been identified as antiphospholipid cofactors. Antibodies to prothrombin, one of these plasma proteins, have been reported in patients with antiphospholipid syndrome (APS). Testing for these antibodies is proposed to be included in the serologic evaluation of antiphospholipid antibodies. Clinically, elevated serum levels of these anti-prothrombin (aPT) antibodies are associated with an increased risk for APS, characterised by recurrent arterial or venous thrombosis, thrombocytopenia and/or fetal loss. High serum or plasma levels of aPT antibodies may add valuable information in the laboratory assessment of antiphospholipid antibodies.
The REAADS IgG and IgM anti-Prothrombin kits are indirect enzyme linked immunosorbent assay (ELISA) used to detect antibodies against human prothrombin. Each assay uses a single point or multi-level calibration to obtain IgG or IgM anti-prothrombin antibody concentrations in patient serum.

- **Convenient ELISA well strip or plate format**
- **Specific determination of IgG or IgM**
- **Single point or Multi-level calibration**
- **Short incubation time around 40 minutes at room temperature**
- **Easily automated, instrumentation protocols available**
- **Objective, accurate, reproducible**
- **High Specificity: 95% for IgG, 97% for IgM aPT antibodies using serum and plasma**
- **High Sensitivity: Demonstrated elevated levels in patients with SLE and APS**

Catalogue #	Description	Pack size
10238	**REAADS IgG anti-Prothrombin ELISA**	**96 wells**

Kit contains the following reagents:

96 stabilised Prothrombin (human) coated breakaway microwells in frame	12 strips x 8 wells
Sample Diluent (blue-green solution) (ready to use)	1 x 60 mL
aPT IgG Human Serum Calibrators (1-high, 2-moderate, 3-low)	3 x 0.25 mL
aPT IgG Positive Human Serum Control	1 x 0.15 mL
Normal Human Serum Control	1 x 0.15 mL
anti-human IgG (goat) HRP-Conjugated Antibody Solution (blue solution) (ready to use)	1 x 15 mL
One-Component Substrate Solution (ready to use)	1 x 15 mL
Stopping Solution (ready to use)	1 x 15 mL
Wash Concentrate (33x)	2 x 30 mL

10240	**REAADS IgM Anti-Prothrombin ELISA**	**96 wells**

Kit contains the following reagents:

96 stabilised Prothrombin (human) coated breakaway microwells in frame	12 strips x 8 wells
Sample Diluent (blue-green solution) (ready to use)	1 x 60 mL
aPT IgM Human Serum Calibrators (1-high, 2-moderate, 3-low)	3 x 0.25 mL
aPT IgM Positive Human Serum Control	1 x 0.15 mL
Normal Human Serum Control	1 x 0.15 mL
anti-Human IgM HRP-Conjugate (red solution) (ready to use)	1 x 15 mL
One-Component Substrate Solution (ready to use)	1 x 15 mL
Stopping Solution (ready to use)	1 x 15 mL
Wash Concentrate (33x)	2 x 30 mL

Store at 2 - 8°C. Do Not Freeze. **For *in-vitro* diagnostic use** CE

Autoimmune Assays

Anti-Nuclear Antibodies (ANA)

Antinuclear antibodies (ANA) are a group of auto-antibodies against various cell nuclear antigens. Some of them are considered to be quite useful as disease markers, primarily for diagnostic screening and also to monitor the course of various connective tissue diseases.

Because of the high correlation of positive antinuclear antibodies with SLE, a negative ANA essentially rules out this disease. Although antibodies specific to DNA have a high correlation with SLE, antibodies to a number of other nuclear antigens appear to be of diagnostic and/or prognostic significance in diseases such as Progressive Systemic Sclerosis, Mixed Connective Tissue Disease, Sjögren's Syndrome, and Polymyositis, making ANA testing useful not only for SLE, but as a general screening tool for connective tissue diseases.

The REAADS ANA kit is an enzyme linked immunosorbent assay (ELISA), which detects disease specific anti-nuclear antibodies frequently observed in the serum of patients with autoimmune diseases using a mixture of recombinant and native purified nuclear antigens. The test is simple to use, many samples can be examined in a short period of time, the use of breakaway wells conserves reagents and the results are expressed in objective unit values.

- **Detects autoantibodies to specific nuclear antigens, including RNP, Sm, SSA, SSB, Scl-70, Jo-1, CENP-B, Ribosomal P, DNA and Histones**
- **Excellent correlation with specific autoantibody ELISA test kits**
- **Improved specificity compared to immunofluorescent assays (IFA)**
- **Results are reported in semi-quantitative units, eliminating subjective interpretation required with IFA**
- **Easy to use procedure can be automated allowing for a large number of specimens to be screened in a short period of time**

Catalogue #	Description	Pack size
10876	**REAADS ANA ELISA**	**96 wells**

Kit contains the following reagents:

96 antigen coated breakaway microwells, with recombinant purified proteins, Jo-1, RNP, SS-A, SS-B, CENPB, Ribosomal P; *in vitro* transcribed U1 RNA; Native, purified SS-A, Sm, Scl-70, ssDNA and dsDNA in frame	12 strips x 8 wells
Sample Diluent (ready to use)	2 x 50 mL
Calibrator 1 (ready to use)	1 x 1.5 mL
Calibrator 2 (ready to use)	1 x 1.5 mL
Positive Control	1 x 0.2 mL
Negative Control	1 x 0.2 mL
Conjugated Reagent (101x) (HRP conjugated goat anti-human immunogloblin)	1 x 0.3 mL
Conjugate Diluent (ready to use)	1 x 24 mL
Substrate Solution (ready to use)	1 x 20 mL
Stop Solution (ready to use)	1 x 20 mL
Wash Concentrate (10x)	1 x 100 mL

Store at 2 - 8°C. Do Not Freeze. **For *in-vitro* diagnostic use** CE

Anti-double-stranded DNA Antibodies (anti-dsDNA)

Antibodies directed against deoxyribonucleic acid (DNA) were first detected in the serum of patients with systemic lupus erythematosus (SLE) in the late 1950s. The presence of anti-dsDNA autoantibodies is one of the four highly specific serologic markers included in the 1982 American Rheumatism Association (now the American College of Rheumatology) revised criteria for the classification of SLE. The detection of elevated levels of anti-dsDNA antibodies and decreased serum levels of complement component C3 have been found to be 100% specific for SLE.

Antibodies against native, or double stranded DNA (dsDNA) are found almost exclusively in patients with SLE, while antibodies against denatured, or single stranded DNA (ssDNA) can also be detected in patients with SLE as well as in patients with many other diseases, including rheumatic diseases and chronic infections. The serum level of anti-dsDNA antibodies in patients with SLE correlate significantly with the level of disease activity, particularly when there is renal involvement. Therefore, the test for anti-dsDNA antibodies is useful for monitoring disease activity and the progress of therapy in patients with SLE.

The REAADS anti-dsDNA ELISA kit is an enzyme linked immunosorbent assay (ELISA), which measures specifically and with high sensitivity anti-dsDNA antibodies present in the sera. The ELISA method offers advantages over other assays (e.g. the PHA; passive hemagglutination, the Crithidia luciliae immunofluorescence assay and the Farr radioimmunoassay) in areas of sensitivity, specificity, objectivity and efficiency.

- **Detects IgG and IgM anti-dsDNA antibodies in human serum or plasma**
- **Highly sensitive and specific for the detection of anti-dsDNA autoantibodies associated with the diagnosis of SLE**
- **Results are reported in either IU/mL (International Units, standardized against the World Health Organization (WHO) reference preparation) or AU/mL (Arbitrary Units that are traceable to the Centers of Disease Control (CDC) reference preparation)**
- **40 minute total incubation time, assay can be easily automated minimizing result turnaround time**

Catalogue #	Description	Pack size
022-001	**REAADS anti-dsDNA ELISA**	**96 wells**

Kit contains the following reagents:

96 stabilised dsDNA (from calf thymus) coated breakaway microwells in frame	12 strips x 8 wells
Sample Diluent (green solution) (ready to use)	1 x 60 mL
Calibrator Serum	1 x 0.25 mL
Positive Control Serum	1 x 0.25 mL
Normal Control Serum	1 x 0.25 mL
anti-Human IgG/IgM HRP Conjugate (red solution) (ready to use)	1 x 15 mL
Substrate Solution (ready to use)	1 x 15 mL
Stop Solution (ready to use)	1 x 15 mL
Wash Concentrate (33x)	12 x 30 mL

Store at 2 - 8°C. Do Not Freeze. **For *in-vitro* diagnostic use** CE

Anti-SS-A/Ro Antibodies

Anti-SS-A/Ro antibody, one of the anti-ENA (extractable nuclear antigen) antibodies, is observed with high frequency in the sera of patients with Sjögren's syndrome (SjS). In 1975 Alspaugh and Tan et al. reported that anti-SS-A antibodies and anti-SS-B antibodies were highly specific for SjS. Later, it was confirmed that the anti-SS-A antibodies and anti-SS-B antibodies were identical with anti-Ro antibodies and anti-La antibodies respectively, which had already been reported by Reichlin et al. Now the terms anti-SS-A/Ro antibodies and anti-SS-B/La antibodies are generally used. Anti-SS-A/Ro antibodies are reported to be present in more than 70 % of cases of systemic lupus erythematosus (SLE) overlap syndrome, sicca syndrome and mixed connective tissue disease (MCTD) overlap syndrome etc. in SjS. This antibody is also reported to be present in 30-50 % of other cases of collagen diseases overlap syndrome, and in more than 70 % of SLE without sicca syndrome.

The REAADS anti-SS-A kit is an enzyme linked immunosorbent assay (ELISA) test, which measures specifically and with high sensitivity anti-SS-A/Ro antibody present in the serum.

- **Highly purified SS-A/Ro protein is used as the antigen therefore the test is highly specific**
- **The results are expressed as quantitative values (Unit/mL) therefore any changes in anti-SS-A/Ro values can be monitored**
- **Many samples can be examined in a short period of time in an easy-to-use operation**
- **Convenient ELISA well strip or plate format**

Catalogue #	Description	Pack size
10870	**REAADS anti-SS-A ELISA**	**96 wells**

Kit contains the following reagents:

96 purified recombinant SS-A/Ro protein coated breakaway microwells in frame	12 strips x 8 wells
Sample Diluent (ready to use)	2 x 50 mL
Calibrator 1 (ready to use)	2 x 1.5 mL
Calibrator 2 (ready to use)	2 x 1.5 mL
Positive Control	1 x 0.2 mL
Negative Control	1 x 0.2 mL
HRP Conjugated goat anti-human immunoglobulins (ready to use)	1 x 15 mL
Substrate Solution (ready to use)	1 x 20 mL
Stop Solution (ready to use)	1 x 20 mL
Wash Concentrate (10x)	1 x 100 mL

Store at 2 - 8°C. Do Not Freeze. **For *in-vitro* diagnostic use** CE

Anti-SS-B/La Antibodies

Anti-SS-B/La antibody, one of the anti-ENA (extractable nuclear antigen) antibodies, is observed with high frequency in the sera of patients with Sjögren's syndrome (SjS). In 1975 Alspaugh and Tan et al. reported that anti-SS-A antibodies and anti-SS-B antibodies were highly specific for SjS. Later, it was confirmed that the anti-SS-A antibodies and anti-SS-B antibodies were identical with anti-Ro antibodies and anti-La antibodies respectively, which had already been reported by Reichlin et al. Now the terms anti-SS-A/Ro antibodies and anti-SS-B/La antibodies are generally used. Anti-SS-B/La antibodies are frequently associated with anti-SS-A/Ro antibodies, and cases in which anti-SS-B/La alone is detected are rare. In recent reports, anti-SS-B/La antibodies were observed in 47.5 % of SjS sicca syndrome cases but infrequently observed in other types of SjS and collagen diseases without sicca syndrome.

The REAADS anti-SS-B kit is an enzyme linked immunosorbent assay (ELISA), which measures specifically and with high sensitivity anti-SS-B/La antibody present in the serum.

- **Recombinant SS-B/La protein is used as antigen and any other ENA protein is excluded therefore the test is highly specific**
- **The results are expressed as quantitative values (Unit/mL) therefore any changes of anti-SS-B/La values can be monitored**
- **Many samples can be examined in a short period of time in an easy-to-use operation**
- **Convenient ELISA well strip or plate format**

Catalogue #	Description	Pack size
10871	**REAADS anti-SS-B ELISA**	**96 wells**

Kit contains the following reagents:

96 purified recombinant SS-B/La protein coated breakaway microwells in frame	12 strips x 8 wells
Sample Diluent (ready to use)	2 x 50 mL
Calibrator 1 (ready to use)	2 x 1.5 mL
Calibrator 2 (ready to use)	2 x 1.5 mL
Positive Control	1 x 0.2 mL
Negative Control	1 x 0.2 mL
HRP Conjugated goat anti-human immunoglobulins (ready to use)	1 x 15 mL
Substrate Solution (ready to use)	1 x 20 mL
Stop Solution (ready to use)	1 x 20 mL
Wash Concentrate (10x)	1 x 100 mL

Store at 2 - 8°C. Do Not Freeze. **For *in-vitro* diagnostic use** CE

Anti-Sm Antibodies

Anti-Sm antibody is an antinuclear antibody named after a patient's name "Smith" who suffered from systemic lupus erythematosus (SLE). This autoantibody reacts with ENA (extractable nuclear antigen). Anti-Sm antibody is detected in 10-30% of SLE patients, and is rarely detected in other diseases. Therefore, it can serve as a marker for SLE and has a diagnostic value. The presence of Anti-Sm was adopted as a marker for the diagnosis of SLE by the 1982 revised-criteria for the classification of SLE by the American College of Rhematology (ACR). It was reported that anti-Sm is observed at a high titre in the active period and at a low titre in the non-active period of SLE. Raynaud phenomena and nephropathy are reported to occur in SLE patients tested positive for anti-Sm more frequently than in patients tested negative for anti-Sm.

The REAADS anti-Sm kit is an enzyme linked immunosorbent assay (ELISA), which measures specifically and with high sensitivity anti-Sm antibody present in the serum.

- **Highly purified Sm protein is used as antigen therefore the test is highly specific**
- **The results are expressed as quantitative values (Unit/mL) and therefore any changes of anti-Sm values can be monitored**
- **Many samples can be examined in a short period of time in an easy-to-use operation**
- **Convenient ELISA well strip or plate format**

Catalogue #	Description	Pack size
10868	**REAADS anti-Sm ELISA**	**96 wells**

Kit contains the following reagents:

96 purified native Sm protein coated breakaway microwells in frame	12 strips x 8 wells
Sample Diluent (ready to use)	2 x 50 mL
Calibrator 1 (ready to use)	2 x 1.5 mL
Calibrator 2 (ready to use)	2 x 1.5 mL
Positive Control	1 x 0.2 mL
Negative Control	1 x 0.2 mL
HRP Conjugated goat anti-human immunoglobulins (ready to use)	1 x 15 mL
Substrate Solution (ready to use)	1 x 20 mL
Stop Solution (ready to use)	1 x 20 mL
Wash Concentrate (10x)	1 x 100 mL

Store at 2 - 8°C. Do Not Freeze. **For *in-vitro* diagnostic use** CE

Anti-RNP Antibodies

RNP antibodies are ENA (extractable nuclear antigen) antibodies, present with high frequency in the sera of patients with collagen diseases such as SLE and mixed connective tissue disease (MCTD). Mixed connective tissue disease is a clinical disease combining features of SLE, Progressive Systemic Sclerosis (PSS) and Polymyositis/Dermatomyositis (PM/DM). The presence of RNP antibodies in the sera of patients is essential for diagnosis of MCTD. RNP antibodies, when present alone at high levels, are diagnostic of MCTD. Lower levels of anti-RNP, in conjunction with other autoantibodies may be observed in PSS, Sjögren's Syndrome (SS) and Rheumatoid Arthritis (RA). Among the methodologies available to detect anti-ENA's are Immunoblot, Double Immunodiffusion (DID), Immunoprecipitation (IPP) and Enzyme-linked Immunosorbent Assay (ELISA). The ELISA tests are specific, sensitive, and due to their objectivity and rapidity, suitable for testing samples from patients with suspected connective tissue diseases.

The REAADS anti-RNP kit is an enzyme linked immunosorbent assay (ELISA), which uses recombinant protein for the solid phase antigen and therefore measures specifically and with high sensitivity anti-RNP antibodies present in the serum of patients with certain connective tissue diseases.

- **Increased Sensitivity – detects additional autoantibodies compared to ELISA's using RNP only**
- **Increased Specificity – recombinant proteins and peptides used as coated antigens providing a high degree of specificity**
- **Detects antibodies which recognize the structural configuration of U1 snRNP complex**
- **Detects anti-U1 RNP autoantibodies independently from anti-Sm antibodies**
- **Correctly coincides with double immunodiffusion and immunoprecipitation assays**

Catalogue #	Description	Pack size
10869	**REAADS anti-RNP ELISA**	**96 wells**

Kit contains the following reagents:

96 purified recombinant RNP protein coated breakaway microwells in frame	12 strips x 8 wells
Sample Diluent (ready to use)	2 x 50 mL
Calibrator 1 (ready to use)	2 x 1.5 mL
Calibrator 2 (ready to use)	2 x 1.5 mL
Positive Control	1 x 0.2 mL
Negative Control	1 x 0.2 mL
HRP Conjugated goat anti-human immunoglobulins (ready to use)	1 x 15 mL
Substrate Solution (ready to use)	1 x 20 mL
Stop Solution (ready to use)	1 x 20 mL
Wash Concentrate (10x)	1 x 100 mL

Store at 2 - 8°C. Do Not Freeze. **For *in-vitro* diagnostic use** CE

Anti-Scl-70 Antibodies

Anti-Scl-70 antibody, one of the anti-ENA (extractable nuclear antigen) antibodies, is seen in the sera of patients with progressive systemic sclerosis (PSS). First discovered by Tan et al. (1975), it was confirmed that the antigen of anti-Scl-70 antibody is identified with topoisomerase I, one of the nuclear enzymes, and is therefore, also called anti-topoisomerase I antibody. The presence of anti-Scl-70 antibody and anticentromere antibody in the sera of patients is essential for diagnosis of PSS. PSS is classified as two types; diffuse scleroderma and limited scleroderma. The anti-Scl-70 antibodies are observed specifically in the former, and the anti-centromere antibodies are observed specifically in the latter. Therefore, detection of these antibodies is useful for classification of PSS.

The REAADS anti-Scl-70 kit is an enzyme linked immunosorbent assay (ELISA), which measures specifically and with high sensitivity anti-Scl-70 antibody present in the serum.

- **Recombinant Scl-70 protein is used as antigen and any other ENA protein is excluded therefore the test is highly specific**
- **The results are expressed as quantitative values (Unit/mL) and therefore any changes of anti-Scl-70 values can be monitored in detail**
- **Many samples can be examined in a short period of time in an easy-to-use operation.**
- **Convenient ELISA well strip or plate format**

Catalogue #	Description	Pack size
10872	**REAADS anti-Scl-70 ELISA**	**96 wells**

Kit contains the following reagents:

96 purified recombinant Scl-70 protein coated breakaway microwells in frame	12 strips x 8 wells
Sample Diluent (ready to use)	2 x 50 mL
Calibrator 1 (ready to use)	2 x 1.5 mL
Calibrator 2 (ready to use)	2 x 1.5 mL
Positive Control	1 x 0.2 mL
Negative Control	1 x 0.2 mL
HRP Conjugated goat anti-human immunoglobulins (ready to use)	1 x 15 mL
Substrate Solution (ready to use)	1 x 20 mL
Stop Solution (ready to use)	1 x 20 mL
Wash Concentrate (10x)	1 x 100 mL

Store at 2 - 8°C. Do Not Freeze. **For *in-vitro* diagnostic use** CE

Anti-Jo-1 Antibodies

Anti-Jo-1 antibodies were first reported by Nishikai et al, and known to be detected in the serum from the patients with Polymyositis (PM) and Dermatomyositis (DM). Anti-Jo-1 antibodies are one of the anti-ENA antibodies, and the corresponding antigen appeared to be histidyl-tRNA synthetase. Polymyositis and Dermatomyositis are considered to be the typical diseases which result in inflammatory myopathies, and immunologic abnormalities have been implicated in the pathogenesis of these disorders, but details have not been revealed. Since this antibody was found in 20-30% patients with PM/DM, and in 30-40% of patients with PM, particularly in more than 60% of patients with PM combined with interstitial lung disease, and rarely found in the other collagen diseases, it is regarded as a marker for PM/DM. In recent studies, it was reported that the quantity of this antibody varied in proportion to disease activity. That is why anti-Jo-1 antibodies are also expected to indicate an effect of treatment.

The REAADS anti-Jo-1 kit in an enzyme linked immunosorbent assay (ELISA), which measures specifically and with high sensitivity anti-Jo-1 antibodies present in the serum.

- **Detects anti-Jo-1 antibodies using recombinant purified histidyl tRNA synthetase protein**
- **Highly sensitive and specific for polymyositis and dermatomyositis**
- **Excellent correlation compared to double immunodiffusion method (DID)**
- **Results are reported in semi-quantitative units, eliminating subjective interpretation required with immunodiffusion methods**
- **Easy to use procedure can be automated allowing for a large number of specimens to be screened in a short period of time**

Catalogue #	Description	Pack size
10873	**REAADS anti-Jo-1 ELISA**	**96 wells**

Kit contains the following reagents:

96 purified recombinant Jo-1 protein coated breakaway microwells in frame	12 strips x 8 wells
Sample Diluent (ready to use)	2 x 50 mL
Calibrator 1 (ready to use)	2 x 1.5 mL
Calibrator 2 (ready to use)	2 x 1.5 mL
Positive Control	1 x 0.2 mL
Negative Control	1 x 0.2 mL
HRP Conjugated goat anti-human immunoglobulins (ready to use)	1 x 15 mL
Substrate Solution (ready to use)	1 x 20 mL
Stop Solution (ready to use)	1 x 20 mL
Wash Concentrate (10x)	1 x 100 mL

Store at 2 - 8°C. Do Not Freeze. **For *in-vitro* diagnostic use** CE

Anti-Centromere Antibodies

Anti-centromere antibody (ACA) was first reported in 1980 by Moroi et al, and is known to be detected in the serum from the patients with the CREST syndrome of scleroderma and PBC. Earnshaw et al designated the antigens which are recognised by ACA, CENP (CENtromere Protein) -A (17 kd), CENP-B (80 kd) and CENP-C (140 kd) according to the molecular weight. They also identified four different epitopes in the CENP-B antigen from a study with affinity-eluted antibodies. In 1987, they cloned the CENP-B cDNA and clarified three independent epitopes on CENP-B that were targets of auto-antibodies. Furthermore, they established an enzyme linked immunosorbent assay (ELISA) using a cloned fusion protein, c-term CENP-B, as antigen. The fusion protein included the c-terminal 147 amino acids and carried the major epitope of CENP-B. Therefore, that ELISA test had much higher sensitivity and specificity than immunofluorescence on the detection of ACA.

The REAADS anti-Centromere kir is an enzyme linked immunosorbent assay (ELISA), which measures specifically and with high sensitivity anti-Centromere antibodies present in the serum.

- **Recombinant CENP-B protein is used as antigen providing a high degree of specificity**
- **The results are expressed as quantitative values (Unit/mL) enabling changes of anti-CENP-B can be monitored**
- **Many samples can be examined in a short period of time in an easy-to-use operation**
- **Convenient ELISA well strip or plate format**

Catalogue #	Description	Pack size
10884	**REAADS anti-Centromere ELISA**	**96 wells**

Kit contains the following reagents:

96 purified recombinant Cent-B protein coated breakaway microwells in frame	12 strips x 8 wells
Sample Diluent (ready to use)	2 x 50 mL
Calibrator 1 (ready to use)	2 x 1.5 mL
Calibrator 2 (ready to use)	2 x 1.5 mL
Positive Control	1 x 0.2 mL
Negative Control	1 x 0.2 mL
HRP Conjugated goat anti-human immunoglobulins (ready to use)	1 x 15 mL
Substrate Solution (ready to use)	1 x 20 mL
Stop Solution (ready to use)	1 x 20 mL
Wash Concentrate (10x)	1 x 100 mL

Store at 2 - 8°C. Do Not Freeze. **For *in-vitro* diagnostic use** CE

Anti-Mitochondria Antibodies

Primary biliary cirrhosis (PBC) is an autoimmune liver disease named in 1950 by Ahrens et al. PBC is a disease caused by chronic inflammation of thin bile duct of the liver, making it difficult for the bile to flow, and the bile remains in the liver. Anti Mitochondrial antibodies occur frequently in patients with PBC and their presence constitutes one of the diagnostic criteria of the disease. Berg et al. classified corresponding antigen to AMA into M1-M9 and found anti M2 antibody is the most specific antibody to PBC. In 1988, it was reported by Gershwin, et al. that main corresponding antigen to anti M2 antibody is E2 component of pyruvate dehydrogenase complex (PDC). It is further reported that subunit (BCOADC-E2, OGDC-E2) of the enzyme which belongs to 2-acid dehydrogenase complex is also a corresponding antigen to M2 antibodies, and reported by Motegi et al. that antibodies which react only to one of them is present in approximately 5-6 % of sera from patient with PBC.

The REAADS anti-Mitochondria kit is an enzyme linked immunosorbent assay (ELISA), which measures specifically with high sensitivity anti-Mitochondria M2 antibody present in the serum.

- **Detects anti-mitochondrial antibodies specific to the M2 antigen using recombinant protein components of pyruvate dehydrogenase complex (PDC-E2)**
- **Highly sensitive and specific for primary biliary cirrhosis**
- **Improved sensitivity and specificity compared to immuno-fluorescent assays (IFA)**
- **Results are reported in semi-quantitative units, eliminating subjective interpretation required with IFA**
- **Easy to use procedure can be automated allowing for a large number of specimens to be screened in a short period of time**

Catalogue #	Description	Pack size
10877	**REAADS anti-Mitochondria ELISA**	**96 wells**

Kit contains the following reagents:

96 purified recomb. Mitochondrial protein coated breakaway microwells in frame	12 strips x 8 wells
Sample Diluent (ready to use)	2 x 50 mL
Calibrator 1 (ready to use)	2 x 1.5 mL
Calibrator 2 (ready to use)	2 x 1.5 mL
Positive Control	1 x 0.2 mL
Negative Control	1 x 0.2 mL
HRP Conjugated goat anti-human immunoglobulins (ready to use)	1 x 15 mL
Substrate Solution (ready to use)	1 x 20 mL
Stop Solution (ready to use)	1 x 20 mL
Wash Concentrate (10x)	1 x 100 mL

Store at 2 - 8°C. Do Not Freeze. **For *in-vitro* diagnostic use** CE

Anti-LKM-1 Antibodies

The causes of the chronic liver disease include virus infection (HBV, HCV etc.), alcohol abuse, errors of the metabolic system and others. Autoimmunity plays a definite role in pathogenesis of a group of chronic active hepatitis known as auto-immune hepatitis (AIH). One of the main characteristics of AIH is the presence of the autoantibodies anti-nuclear antibody (ANA), anti-smooth muscle antibody, (ASMA) and others. Rizzetto et al in 1974 reported a new type of autoantibody in patients with chronic active hepatitis, which selectively reacts with proximal tubular epithelia of rat kidney sections with a different pattern from anti-mitochondrial antibodies (AMA) by indirect immunofluorescence (IIF). The autoantibody was studied in detail by Homberg et al and was named as anti-Liver / Kidney microsome (LKM) antibody.

Manns et al characterised a subgroup of AIH type II by the presence of this antibody and its clinical feature. Anti-LKM antibodies react with tissue sections of both liver and kidney by IIF, and were classified into 3 subtypes by staining patterns; anti-LKM-1 antibody in type II AIH, anti-LKM-2 in tienilic acid-induced hepatitis and anti-LKM-3 in chronic hepatitis D. Alvarez et al in 1985 reported that anti-LKM-1 antibodies in patients sera recognise a 50KD protein in rat liver microsomes and the protein has been identified as cytochrome P450IID6 in human liver by Manns and others.

The REAADS anti-LKM-1 kit is an enzyme linked immunosorbent assay (ELISA) test, which measures specifically and with high sensitivity anti-LKM-1 antibody present in the serum.

- **Recombinant LKM-1 protein is used as antigen therefore the test is highly specific**
- **The results are expressed as quantitative values (Unit/mL) and therefore changes of anti-LKM-1 values can be monitored in detail**
- **Many samples can be examined in a short period of time in an easy-to-use operation**
- **Convenient ELISA well strip or plate format**

Catalogue #	Description	Pack size
10882	**REAADS anti-LKM-1 ELISA**	**96 wells**

Kit contains the following reagents:

96 LKM-1 protein coated breakaway microwells in frame	12 strips x 8 wells
Sample Diluent (ready to use)	2 x 50 mL
Calibrator 1 (ready to use)	2 x 1.5 mL
Calibrator 2 (ready to use)	2 x 1.5 mL
Positive Control	1 x 0.2 mL
Negative Control	1 x 0.2 mL
HRP Conjugated goat anti-human immunoglobulins (ready to use)	1 x 15 mL
Substrate Solution (ready to use)	1 x 20 mL
Stop Solution (ready to use)	1 x 20 mL
Wash Concentrate (10x)	1 x 100 mL

Store at 2 - 8°C. Do Not Freeze. **For *in-vitro* diagnostic use** CE

Anti-MPO (p-ANCA) Antibodies

In 1982 Davis et al. described the presence of antineutrophil cytoplasmic antibodies (ANCA) in serum of patients with necrotising glomerulonephritis. The use of indirect immunofluorecence (IIF) identified two distinct pattern types described in 1988 by Falk et al, pANCA (perinuclear) and cANCA (cytoplasmic), in renal patients with systemic vasculitis. The major pANCA target antigen is myeloperoxidase and the major cANCA target antigen is proteinase III (PR-3). Several other antigens (lactoferrin, elastase, cathepsin G) are associated with ANCA reactivity to lesser degrees. Although the use of an ELISA can identify the presence of antibodies specific for MPO and PR-3, it is still recommended to use an IIF method for patient screening. Testing positive IIF samples by ELISA can provide useful additional information. ELISA assays that identify the presence of anti-MPO and anti-PR-3 antibodies can be used not only to confirm IIF positive patterns, but also distinguish specific systemic vasculitides. Anti-PR-3 antibodies are detected in the majority of active Wegener's granulomatosis patients and only occasionally positive for anti-MPO. Diseases such as microscopic poyarteritis and crescentic glomerulonephritis are more likely associated with the presence of anti-MPO antibodies.

The REAADS anti-MPO (p-ANCA) kit is an enzyme linked immunosorbent assay (ELISA) test, which measures specifically and with high sensitivity anti-MPO antibody present in the serum.

- **Detects anti-MPO antibodies in human serum using native purified proteins**
- **MPO and PR-3 are the major target antigen for anti-perinuclear and anti-cytoplasmic antineutrophil cytoplasmic antibodies (pANCA and cANCA) respectively**
- **Results are reported in semi-quantitative units (U/mL)**
- **Easy to use procedure can be automated allowing for a large number of specimens to be screened in a short period of time**

Catalogue #	Description	Pack size
10886	**REAADS anti-MPO (p-ANCA) ELISA**	**96 wells**

Kit contains the following reagents:

96 purified native MPO protein coated breakaway microwells in frame	12 strips x 8 wells
Sample Diluent (ready to use)	2 x 50 mL
Calibrator 1 (ready to use)	2 x 1.5 mL
Calibrator 2 (ready to use)	2 x 1.5 mL
Positive Control	1 x 0.2 mL
Negative Control	1 x 0.2 mL
HRP Conjugated goat anti-human immunoglobulins (ready to use)	1 x 15 mL
Substrate Solution (ready to use)	1 x 20 mL
Stop Solution (ready to use)	1 x 20 mL
Wash Concentrate (10x)	1 x 100 mL

Store at 2 - 8°C. Do Not Freeze. **For *in-vitro* diagnostic use** CE

Anti-PR3 (c-ANCA) Antibodies

In 1982 Davis et al. described the presence of antineutrophil cytoplasmic antibodies (ANCA) in serum of patients with necrotising glomerulonephritis. The use of indirect immunofluorecence (IIF) identified two distinct pattern types described in 1988 by Falk et al, pANCA (perinuclear) and cANCA (cytoplasmic), in renal patients with systemic vasculitis. The major pANCA target antigen is myeloperoxidase and the major cANCA target antigen is proteinase III (PR-3). Several other antigens (lactoferrin, elastase, cathepsin G) are associated with ANCA reactivity to lesser degrees. Although the use of an ELISA can identify the presence of antibodies specific for MPO and PR-3, it is still recommended to use an IIF method for patient screening. Testing positive IIF samples by ELISA can provide useful additional information. ELISA assays that identify the presence of anti-MPO and anti-PR-3 antibodies can be used not only to confirm IIF positive patterns, but also distinguish specific systemic vasculitides. Anti-PR-3 antibodies are detected in the majority of active Wegener's granulomatosis patients and only occasionally positive for anti-MPO. Diseases such as microscopic poyarteritis and crescentic glomerulonephritis are more likely associated with the presence of anti-MPO antibodies.

The REAADS anti-PR-3 (c-ANCA) kit is an enzyme linked immunosorbent assay (ELISA) test, which measures specifically and with high sensitivity anti-MPO antibody present in the serum.

- **Detects anti-PR-3 antibodies in human serum using native purified proteins**
- **MPO and PR-3 are the major target antigen for anti-perinuclear and anti-cytoplasmic antineutrophil cytoplasmic antibodies (pANCA and cANCA) respectively**
- **Results are reported in semi-quantitative units (U/mL)**
- **Easy to use procedure can be automated allowing for a large number of specimens to be screened in a short period of time**

Catalogue #	Description	Pack size
10881	**REAADS anti-PR-3 (c-ANCA) ELISA**	**96 wells**

Kit contains the following reagents:

96 purified native PR-3 protein coated breakaway microwells in frame	12 strips x 8 wells
Sample Diluent (ready to use)	2 x 50 mL
Calibrator 1 (ready to use)	2 x 1.5 mL
Calibrator 2 (ready to use)	2 x 1.5 mL
Positive Control	1 x 0.2 mL
Negative Control	1 x 0.2 mL
HRP Conjugated goat anti-human immunoglobulins (ready to use)	1 x 15 mL
Substrate Solution (ready to use)	1 x 20 mL
Stop Solution (ready to use)	1 x 20 mL
Wash Concentrate (10x)	1 x 100 mL

Store at 2 - 8°C. Do Not Freeze. **For *in-vitro* diagnostic use** CE

Anti-Thyroglobulin (Tg) Antibodies

Thyroglobulin (Tg), thyroid peroxidase (TPO) and the TSH receptor are considered the major autoantigens related to chronic autoimmune thyroiditis. The clinical diagnosis of chronic autoimmune thyroiditis is usually based on the presence of serum/plasma autoantibodies to Tg and TPO. In Graves disease the TSH receptor is the antigen most directly involved in the clinical manifestation of the disease. Thyroglobulin, a large water-soluble glycoprotein of 660kD is the precursor of thyroid hormones triiodothyronine (T3) and Thyroxine(T4).

Anti-Tg autoantibodies are predominantly of the IgG class and are detected often with TPO autoantibodies in the majority of Graves' disease cases (chronic primary hyperthyroidism), Hashimoto's thyroiditis and other variants of chronic primary hypothyroidism, such as myxoedema and asymtomatic thyroiditis. They have also been detected in cases of spontaneous post-partum painless thyroiditis, in associations of thyroid autoimmunity with rheumatoid arthritis and in non-thyroid autoimmune diseases such as Addison's disease and Type 1 diabetes mellitus.

The REAADS anti-Thyroglobulin (Tg) ELISA test kit enzyme linked immunosorbent assay (ELISA) test, which measures specifically with high sensitivity anti-Tg antibody present in the serum by ELISA.

- **Tg protein is used as the antigen therefore the test is highly specific**
- **The results are expressed as quantitative values (Unit/mL) and therefore changes of anti-Tg values can be monitored in detail**
- **Many samples can be examined in a short period of time in an easy-to-use operation**
- **Convenient ELISA well strip or plate format**

Catalogue #	Description	Pack size
10879	**REAADS anti-Thyroglobulin (Tg) ELISA**	**96 wells**

Kit contains the following reagents:

96 antigen Tg coated breakaway microwells in frame	12 strips x 8 wells
Sample Diluent (ready to use)	2 x 50 mL
Calibrator-1 (ready to use)	2 x 1.5 mL
Calibrator-2 (ready to use)	2 x 1.5 mL
Positive Control	1 x 0.2 mL
Negative Control	1 x 0.2 mL
Conjugated Reagent (ready to use)	1 x 15 mL
Substrate Solution (ready to use)	1 x 20 mL
Stop Solution (ready to use)	1 x 20 mL
Wash Concentrate (10x)	1 x 100 mL

Store at 2 - 8°C. Do Not Freeze. **For *in-vitro* diagnostic use** CE

Anti-Thyroid Peroxidase (TPO) Antibodies

In patients with advanced thyroiditis antibodies directed at a thyroid antigen distinct from Thyroglobulin (Tg) have been found. This antigen was termed thyroid microsomal antigen (TMA), and since then, considerable evidence has accumulated to indicate that TMA and thyroid peroxidase (TPO), a membrane-bound glycoprotein enzyme with an approximate mass of 101kD, whose in vivo function is the iodination of tyrosine in the synthesis of the thyroid hormones T3 and T4 are antigenically related and that they may be identical moities. Autoantibodies to the thyroid microsomal/peroxidase antigen may play a pathogenic role in destructive autoimmune thyroid disease by their ability to fix complement and thus induce cytolysis.

Anti-TPO antibodies are found often in conjunction with Tg autoantibodies, in the majority of patients with Hashimoto's Thyroiditis, Graves' disease and in cases of Primary Myxoedema. Anti-TPO antibodies are found in other non-thyroid conditions, e.g. pernicious anemia, diabetes mellitus, rheumatoid arthritis, Addison's disease and Sjögren's Syndrome. In addition, anti-TPO antibodies are detectable at low levels in 2-8% of apparently healthy individuals, particularly in the elderly and more often in women than in men, although their clinical significance is unclear.

The REAADS anti-Thyroid peroxidae (TPO) ELISA test kit is an enzyme linked immunosorbent assay (ELISA) test, which measures specifically with high sensitivity anti-TPO antibody present in the serum by ELISA.

- **TPO protein is used as the antigen therefore the test is highly specific**
- **The results are expressed as quantitative values (Unit/mL) and therefore changes of anti-Tg values can be monitored in detail**
- **Many samples can be examined in a short period of time in an easy-to-use operation**
- **Convenient ELISA well strip or plate format**

Catalogue #	Description	Pack size
10880	**REAADS anti-Thyroid Peroxidase (TPO) ELISA**	**96 wells**

Kit contains the following reagents:

96 antigen TPO coated breakaway microwells in frame	12 strips x 8 wells
Sample Diluent (ready to use)	2 x 50 mL
Calibrator-1 (ready to use)	2 x 1.5 mL
Calibrator-2 (ready to use)	2 x 1.5 mL
Positive Control	1 x 0.2 mL
Negative Control	1 x 0.2 mL
Conjugated Reagent (ready to use)	1 x 15 mL
Substrate Solution (ready to use)	1 x 20 mL
Stop Solution (ready to use)	1 x 20 mL
Wash Concentrate (10x)	1 x 100 mL

Store at 2 - 8°C. Do Not Freeze. **For *in-vitro* diagnostic use** CE

Anti-ENA (6) Antibodies

The serological characterization of autoantibodies reacting with human cellular and nuclear components is of major importance in the diagnosis of systemic rheumatic diseases. Systemic rheumatic diseases are autoimmune disorders which include systemic lupus erythematosus (SLE) and lupus variants, scleroderma, mixed connective tissue diseases, Sjögrens Syndrome, CREST, polymyositis and rheumatoid arthritis.[1-5] The extractable nuclear antigens (ENAs) play an important role in the differential diagnosis of the above disorders.

Sm is a non-histone glycoprotein and antibodies directed against this extractable nuclear antigen are specific serological markers of SLE. Antibodies to the U1-RNP (ribonucleoprotein) are found in a number of connective tissue diseases, but principally in SLE (30-40%) and mixed connective tissue disease (MCTD) >95%. MCTD presents as a combination of clinical features which may also be seen in SLE, polymyositis and scleroderma and although antibodies to dsDNA, Sm and Ro are infrequently found in MCTD, high titers of anti-RNP antibodies are usually considered diagnostic of the disease. The Ro(SS-A) and La(SS-B) antigens are RNA protein complexes and antibodies against these complexes are found in Sjögrens syndrome (60% and 40% respectively), SLE (30% and 15%), scleroderma and neonatal lupus erythematosus. Presence of these antibodies in patient sera has been connected with particular clinical manifestations and also linked with congenital heart block. Antibodies to the Scl-70 autoantigen, also recognized as the enzyme Topoisomerase 1, are found in approximately 20% of scleroderma patients, and are highly diagnostic of this disease. In the diffuse form of the disease the frequency may be as high as 70%. Antibodies to the Jo-1 autoantigen, also recognized as the enzyme histidyl-t RNA synthetase, are found in approximately 25% of patients with polymyositis. It has also been shown that a high proportion of patients with interstitial lung disease, associated with polymyositis, are positive for the antibody.

The REAADS ENA 6 Screen kit is a qualitative indirect enzyme immunoassay for the detection of antibodies specific for the Sm, RNP, Ro(SS-A), La(SS-B), Scl-70 and Jo-1 antigens in human serum or plasma.

- **Simultaneous detection, of IgG class autoantibodies specific for Sm, RNP, Ro(SS-A), La(SS-B), Scl-70 and Jo-1 in human serum or plasma**
- **Result expressed as an easy-to-interpret positive or negative ratio**
- **Many samples can be easily screened for the presence of ENAs in an easy-to-use operation**
- **Convenient ELISA well strip or plate format**

Catalogue #	Description	Pack size
10387	**REAADS ENA 6 Screen ELISA**	**96 wells**

Kit contains the following reagents:

96 ENA 6 coated breakaway microwells in frame	12 strips x 8 wells
Sample Diluent Concentrate (5x) (red solution)	1 x 25 mL
ENA 6 Screen Reference (ready to use)	2 x 1.5 mL
ENA 6 Screen Positive Control	1 x 0.1 mL
Negative Control	1 x 0.1 mL
IgG anti-human (murine) HRP Conjugate (blue solution, ready to use)	1 x 15 mL
Substrate Solution (ready to use)	1 x 15 mL
Stop Solution (ready to use)	1 x 15 mL
Wash Concentrate (16x)	2 x 25 mL

Store at 2 - 8°C. Do Not Freeze. **For *in-vitro* diagnostic use** CE

Anti-Histone Antibodies

Histones are proteins which are attached to DNA in all eukaryotic cells, and together they comprise the basic structural sub-unit – the nucleosome – of chromatin. Research indicates that histones may play a significant administrative role in the cell regulation of gene activation. Antibodies to histone were first observed in the serum of a patient with systemic lupus erythematosus (SLE) in 1960, and since then reports suggest a prevalence of 21%-81% in SLE, particularly during active phases of the disease. Anti-histone antibody (AHA) is the most significant autoantibody detected in drug-induced SLE, and as such, it may be used to verify the diagnosis. AHAs have also been detected in the sera of patients with other connective tissue disorders such as rheumatoid arthritis (RA), juvenille chronic arthritis, leprosy, monoclonal gammopathy, and primary biliary cirrhosis.

The REAADS Anti-Histone test is a qualitative or quantitative indirect enzyme immunoassay for the detection of IgG and IgM autoantibodies specific for histone antigen in human serum or plasma.

- **Combined detection of IgG and IgM antibodies**
- **Result expressed as an easy-to-interpret positive or negative ratio**
- **Alternative qualitative or quantitative assay format**
- **Convenient ELISA well strip or plate format**

Catalogue #	Description	Pack size
10075	**REAADS anti-Histone ELISA**	**96 wells**

Kit contains the following reagents:

96 Histone coated breakaway microwells in frame	12 strips x 8 wells
Sample Diluent Concentrate (5x) (red solution)	1 x 25 mL
Anti-Histone Reference (ready to use)	1 x 1.5 mL
Anti-histone Standards (0, 2, 8, 30, 100 U/mL)	5 x 1.0 mL
Anti-Histone Positive Control	1 x 0.1 mL
Negative Control	1 x 0.1 mL
IgG/IgM anti-human (murine) HRP Conjugate (blue solution, ready to use)	1 x 15 mL
Substrate Solution (ready to use)	1 x 15 mL
Stop Solution (ready to use)	1 x 15 mL
Wash Concentrate (16x)	2 x 25 mL

Store at 2 - 8°C. Do Not Freeze. **For *in-vitro* diagnostic use** CE

Anti-Gliadin Antibodies

Celiac disease (CD) is characterised by the presence of villous atrophy in a jejunal biopsy specimen. The disease is caused by hypersensitivity to gluten, and withdrawal of gluten from the diet cures the patient. Although the mechanisms are still unknown, recent studies strongly suggest an immunological pathogenesis (intraepithelial lymphocytes γ/δ- and α/β- T- cells, cell mediated immunity, cytokines). Genetic factors, e.g. HLA-B8 or DR3 / DR7, are known to be associated with susceptibility to celiac disease. High prevalence (2.3 - 4.1%) of celiac disease has been reported in juvenile (type I) diabetes mellitus. The overall lifetime incidence of celiac disease has been estimated 1:100 - 1:300. Once diagnosed, celiac patients are advised to follow gluten-free diet. Strict dietary compliance is recommended to avoid long-term risks associated with celiac disease - poor general health and growth, malabsorption and the risk of developing intestinal lymphoma. Although celiac disease can present and consequently be diagnosed at almost any stage in life, many patients are diagnosed in childhood. In children under 2 years of age celiac disease may still present with classical symptoms, i.e. severe gastrointestinal symptoms with faecal fat excretion, anaemia, folate deficiency and malnutrition, but in older children and adults typical symptoms are rarely seen. Therefore, reliable methods for screening of celiac disease have been searched from the beginning of 1970's.

The REAADS Anti-Gliadin IgA and IgG tests are enzyme linked immunosorbent assays (ELISA) using an Alk. Phos. Conjugate and intended for the determination of human anti-Gliadin IgG and IgM antibodies in serum.

- **Both IgA and IgG isotypes can be determined**
- **Total incubation time: 90 minutes at room temperature**
- **All Celiac diagnostic kits use the same common reagents, use an Alk. Phos. Conjugate and must be read at 405nm**
- **Easily automated**
- **Convenient ELISA well strip or plate format**

Catalogue #	Description	Pack size
11365	**REAADS anti-Gliadin IgA ELISA**	**96 wells**

Kit contains the following reagents:

96 Gliadin-coated breakaway microwells in frame	12 strips x 8 wells
Sample Diluent (ready to use)	2 x 50 mL
Anti-IgA Gliadin Standards 0, 25, 50, 100 AU (ready to use)	4 x 1.5 mL
Negative Control (ready to use)	1 x 1.5 mL
IgA Positive Control (ready to use)	1 x 1.5 mL
Anti-human IgA (goat) Alk. Phos. Conjugate (red solution, ready to use)	1 x 12 mL
pNPP Substrate Solution (ready to use)	1 x 12 mL
Stop Solution (ready to use)	1 x 15 mL
Wash Concentrate (25x)	1 x 40 mL

11366	**REAADS anti-Gliadin IgG ELISA**	**96 wells**

Kit contains the following reagents:

96 Gliadin-coated breakaway microwells in frame	12 strips x 8 wells
Sample Diluent (ready to use)	2 x 50 mL
Anti-IgG Gliadin Standards 0, 25, 50, 100 AU (ready to use)	4 x 1.5 mL
Negative Control (ready to use)	1 x 1.5 mL
IgG Positive Control (ready to use)	1 x 1.5 mL
Anti-human IgG (goat) Alk. Phos. Conjugate (red solution, ready to use)	1 x 12 mL
pNPP Substrate Solution (ready to use)	1 x 12 mL
Stop Solution (ready to use)	1 x 15 mL
Wash Concentrate (25x)	1 x 40 mL

Store at 2 - 8°C. Do Not Freeze. **For *in-vitro* diagnostic use** CE

Anti-tissue Transglutaminase Antibodies

Celiac disease (CD) is characterised by the presence of villous atrophy in a jejunal biopsy specimen. The disease is caused by hypersensitivity to gluten, and withdrawal of gluten from the diet cures the patient. Although the mechanisms are still unknown, recent studies strongly suggest an immunological pathogenesis (intraepithelial lymphocytes γ/δ- and α/β- T- cells, cell mediated immunity, cytokines). Genetic factors, e.g. HLA-B8 or DR3 / DR7, are known to be associated with susceptibility to celiac disease. High prevalence (2.3 - 4.1%) of celiac disease has been reported in juvenile (type I) diabetes mellitus. The overall lifetime incidence of celiac disease has been estimated 1:100 - 1:300. Once diagnosed, celiac patients are advised to follow a gluten-free diet. Strict dietary compliance is recommended to avoid long-term risks associated with celiac disease - poor general health and growth, mal-absorption and the risk of developing intestinal lymphoma. Although celiac disease can present and consequently be diagnosed at almost any stage in life, many patients are diagnosed in childhood. In children below 2 years of age celiac disease may still present with classical symptoms, i.e. severe gastrointestinal symptoms with faecal fat excretion, anaemia, folate deficiency and malnutrition, but in older children and adults typical symptoms are rarely seen. Therefore, reliable methods for screening of celiac disease have been searched from the beginning of 1970's.

The REAADS Anti-tTG IgA and IgG tests are enzyme linked immunosorbent assays (ELISA) using an Alk. Phos. Conjugate and are intended for the determination of human anti-tTG IgG and IgM in serum.

- **Both IgA and IgG isotypes can be determined**
- **Total incubation time: 90 minutes at room temperature**
- **Celiac diagnostic kits use the same common reagents, use an Alk. Phos. Conjugate and must be read at 405nm**
- **Easily automated**
- **Convenient ELISA well strip or plate format**

Catalogue #	Description	Pack size
11367	**REAADS anti-tTG IgA ELISA**	**96 wells**

Kit contains the following reagents:

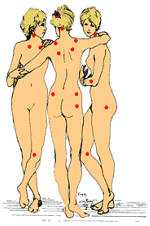
96 Human Recombinant tTG coated breakaway microwells with frame	12 strips x 8 wells
Sample Diluent (ready to use)	2 x 50 mL
Anti-IgA Transglutaminase Standards (0, 12.5, 25, 50, 100 AU) (ready to use)	5 x 1.5 mL
Negative Control (ready to use)	1 x 1.5 mL
IgA Positive Control (ready to use)	1 x 1.5 mL
IgA anti-human (goat) Alk. Phos. Conjugate (red solution, ready to use)	1 x 12 mL
pNPP Substrate Solution (ready to use)	1 x 12 mL
Stop Solution (ready to use)	1 x 15 mL
Wash Concentrate (25x)	1 x 40 mL

11368	**REAADS anti-tTG IgG ELISA**	**96 wells**

Kit contains the following reagents:

96 Human Recombinant tTG coated breakaway microwells with frame	12 strips x 8 wells
Sample Diluent (ready to use)	2 x 50 mL
Anti-IgG Transglutaminase Standard (ready to use)	1 x 1.5 mL
Negative Control (ready to use)	1 x 1.5 mL
IgG Positive Control (ready to use)	1 x 1.5 mL
IgG anti-human (goat) Alk. Phos. Conjugate (red solution, ready to use)	1 x 12 mL
pNPP Substrate Solution (ready to use)	1 x 12 mL
Stop Solution (ready to use)	1 x 15 mL
Wash Concentrate (25x)	1 x 40 mL

Store at 2 - 8°C. Do Not Freeze. **For *in-vitro* diagnostic use** CE



Autoimmune Assays

Anti-Polymer Antibodies

The Fibromyalgia Syndrome (FMS) is a common chronic disorder of widespread pain that afflicts millions of individuals. Associated signs and symptoms include tender points, fatigue, morning stiffness, sleep disorder, headache and cognitive problems. Not all of the signs and symptoms are present in every patient, and each individual patient may have different signs and symptoms at different times. The American College of Rheumatology (ACR) criteria require that a patient manifest localized tenderness in at least 11 of 18 specific sites on the body (known as tender points) and have a history of chronic wide-spread pain of greater than 3 months' duration in order to receive a diagnosis of FMS.

The APA assay detects antibodies in human serum which bind to partially polymerized polyacrylamide. These antibodies have been detected in the majority of fibromyalgia patients tested, and antibody titers correlated with the severity of symptoms in these patients. Studies have also shown that the presence of the antibodies can be used to help differentiate fibromyalgia from other autoimmune diseases.

The Anti-Polymer Antibodies Test is an enzyme-linked immunosorbant assay (ELISA) for the detection of IgG anti-polymer antibodies in human serum.

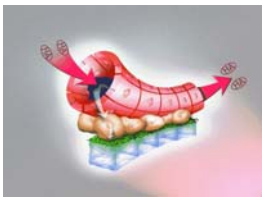
- **The APA ELISA detects IgG anti-polymer antibodies (APA) in human serum**
- **The presence of the antibodies distinguishes fibromyalgia patients from other autoimmune disease patients**
- **The O.D. correlates closely with various clinical measures of fibromyalgia symptom severity**
- **Results are reported in semi-quantitative units**
- **The easy-to-use test can readily be automated**

Catalogue #	Description	Pack size
11440	**Anti-Polymer Antibodies (APA) ELISA**	**96 wells**

Kit contains the following reagents:

96 APA antigen coated breakaway microwells with frame	12 strips x 8 wells
Sample Diluent (green solution)	1 x 60 mL
Calibrator Serum (human)	1 x 0.25 mL
Positive Control (human)	1 x 0.25 mL
Normal Control (human)	1 x 0.25 mL
Anti-human IgG (goat) HRP-Conjugate (blue solution, ready to use)	1 x 15 mL
Substrate Solution (ready to use)	1 x 15 mL
Stop Solution (ready to use)	1 x 15 mL
Wash Concentrate (33x)	2 x 30 mL

Store at 2 - 8°C. Do Not Freeze. **For *in-vitro* diagnostic use** CE



Gastroenterology Assay

Hyaluronic Acid

Hyaluronic Acid (HA), also called hyaluronate or hyaluronan, is a muco-polysaccharide widely distributed throughout the body. HA is produced mainly by fibroblasts and other specialised connective tissue cells. As a free molecule, HA can be found in the plasma and synovial fluid. HA is quickly removed from circulation by specific receptors present in sinusoidal cells (SEC) of the liver; the estimated half-life in plasma is 5-6 minutes. Increased plasma HA levels may result from decreased removal of HA from plasma as a result of liver damage or increased production of HA by synovial cells and release into circulation.

Until now, the diagnosis of liver fibrosis and cirrhosis has been confirmed mainly by histological examination of tissue specimens obtained by liver biopsy, and conventional liver function tests (LFTs). However, liver biopsy is an invasive procedure that may cause serious complications including bleeding and infection. Plasma HA levels have been correlated with the degree of fibrosis and cirrhosis in advanced liver disease and may be a non-invasive, less costly method to monitor these patients. In addition, unlike conventional LFTs, HA levels reflect the function of sinusoidal endothelial cells (SEC) and may be useful as an early marker of liver damage. Therefore the quantitative measurement of HA levels in the blood is a useful tool for the assessment of the degree of liver fibrosis and cirrhosis in various liver diseases.

- **HA is a highly specific marker for fibrosis in chronic Hepatitis C patients with moderate to severe disease**
- **Regular and excessive alcoholic intake can damage the liver. Early detection of alcoholic liver cirrhosis may be established by routinely testing for HA in blood**
- **HA may also be used in the early detection of liver allograft rejection by monitoring transplant patients on a daily basis**
- **Easy to use, 96 well microplate format, reagent complete kit**
- **Total incubation of 2 hours at room temperature**

Catalogue #	Description	Pack size
029-001	**Hyaluronic Acid (HA) ELISA**	**96 wells**

Kit contains the following reagents:

96 stabilised HABP-coated breakaway microwells with frame	12 strips x 8 wells
Reaction Buffer (blue solution) (ready to use)	1 x 57 mL
HA Reference Solutions (50,100, 200, 500, 800 ng/mL)	5 x 0.5 mL
HA High Control	1 x 0.5 mL
HA Low Control	1 x 0.5 mL
HRP-conjugated HABP Solution (red solution, ready to use)	1 x 13 mL
Substrate Solution (ready to use)	1 x 13 mL
Stopping Solution (ready to use)	1 x 15 mL
Wash Concentrate (33x)	1 x 30 mL

Store at 2 - 8°C. Do Not Freeze. **For *in-vitro* diagnostic use** CE

PIFA® Heparin / Platelet Factor 4 Rapid Assay

The risk of heparin induced thrombocytopenia (HIT) is greatly increased in patients with recent exposure to heparin. HIT is often caused by platelet-activating antibodies that recognize complexes of Heparin/PF4. As a result, antibody detection is rapidly becoming a standard of care in haematology and cardiology. Currently available laboratory tests for HIT are classified by CLIA as high complexity, take many hours to perform, and often provide confirmation of HIT or HIT and thrombosis (HITT) after the symptoms are seen in a patient. As a result, there is a need for an easily performed, rapid test that help s clinicians identify and treat patients at risk for HIT or thrombosis.
HIT is caused by heparin-dependent antibodies formed to the heparin/platelet factor 4 complex, and 1-5% of adults exposed to heparin develop these antibodies. These antibodies are initially formed when a patient has been on heparin therapy for five or more days. An immune response to a heparin dose may be observed sooner if the patient has had previous exposure to heparin. The hallmark symptoms of HIT are a drastic fall in platelet count and thrombosis. Other symptoms may include coetaneous reactions, from a simple allergic reaction to lesions to necrosis.
Studies have determined that the antibodies associated with Type II HIT recognize sites on a platelet protein designated “platelet factor 4” (PF4) that are created when PF4 is complexed with heparin or another linear polyanionic compound.
Currently, there are three laboratory testing methods that are most commonly used to identify HIT antibodies: C-14 Serotonin Release Assay, Platelet Aggregation Studies, and Enzyme-Linked Immunoassay. However, these tests are used primarily as a confirmation of HIT after the symptoms are seen in a patient and take many hours to perform.

The PIFA® Heparin/Platelet Factor 4 Rapid Assay is a qualitative *in-vitro* diagnostic device designed for the detection of antibodies to the Platelet Factor 4 (PF4) sensitized micro spheres.

- **Compact cassette format, no special instrumentation**
- **Easy-to-interpret results and control windows**
- **Facilitates near-patient testing of an individual**
- **Fresh serum specimen**
- **Simple test procedure takes 5 steps**
- **Assay takes approximately 10 minutes**

Catalogue #	Description	Pack size
4036025	**PIFA® Heparin/PF4 Rapid Assay**	**6 units**

Store at 2 - 8°C. Do Not Freeze. **For *in-vitro* diagnostic use** CE

Protein C

Protein C plays a key role in the naturally occurring anticoagulant pathway that regulates haemostasis. Through complex interactions with other components of the coagulation cascade, Protein C contributes to the maintenance of normal haemostasis by limiting clot formation and by promoting fibrinolysis. Deficiency of Protein C, either congenital or acquired, may lead to serious thrombotic events, such as thrombophlebitis, deep vein thrombosis, or pulmonary embolism. In congenital deficiency, decreased Protein C activity may result from low concentrations and/or abnormal function. Acquired deficiency, resulting from decreased levels of Protein C, may be seen in neonates, liver disease, and during oral anticoagulant therapy.

Protein C Antigen

The REAADS Protein C Antigen ELISA test kit is a double antibody capture assay for measuring Protein C levels in human plasma, expressed in relative percent (%) of normal. The assay uses a six-point curve to determine levels of Protein C. The assay is intended to be used as an aid in the diagnosis of Protein C deficiency in patients with thrombotic disorders. The REAADS Protein C Antigen Test Kit will accurately detect antigen levels as low as 5% of normal.

- **Convenient ELISA well strip or plate format**
- **Objective, accurate and reproducible**
- **Reagent complete kit**
- **60 minutes total incubation time**

Catalogue #	Description	Pack size
035-001	**REAADS Protein C Antigen ELISA**	**96 wells**

Kit contains the following reagents:

96 anti-human Protein C antibody coated breakaway microwells with frame	12 strips x 8 wells
Sample Diluent (blue-green solution) (ready to use)	1 x 60 mL
Lyophilised Reference Plasma	3 x 0.5 mL
HRP Conjugated anti-Human Protein C Antibody (blue solution, ready to use)	1 x 12 mL
One Component Substrate (ready to use)	1 x 13 mL
Stopping Solution (ready to use)	1 x 15 mL
Wash Concentrate (33x)	1 x 30 mL

Store at 2 - 8°C. Do Not Freeze. **For *in-vitro* diagnostic use** CE

Protein S

Protein S is a vitamin K dependent plasma protein synthesised in the liver, vascular endothelium and megakaryocytes, which plays an important role along with Protein C in the regulation of haemostasis. Protein S serves as a cofactor for the anticoagulant and fibrinolytic effects of activated Protein C. Approximately 40% of the Protein S circulates in the functionally active free form, while 60% is complexed to C4b-binding protein and is inactive. Protein S deficiency, either congenital or acquired, may lead to serious thrombotic events, such a thrombophlebitis, deep vein thrombosis, or pulmonary embolism. While susceptibility to thrombosis has been related to changes in the level of free Protein S, the measurement of both total and free Protein S is useful in classifying patients with congenital Protein S deficiency.

Protein S Antigen

The REAADS Protein S Antigen ELISA test kit is a double antibody capture assay for measuring total and free Protein S levels in human plasma, expressed in relative percent (%) of normal. The assay is intended to be used as an aid in the diagnosis of Protein S deficiency in patients with thrombotic disorders. The REAADS Protein S Antigen Test Kit will accurately detect antigen levels as low as 5% of normal

- **Total and Free Protein S**
- **Convenient ELISA well strip or plate format**
- **Reagent complete kit**
- **Assayed controls available**
- **Six point reference curve**
- **60 minutes total incubation time**

Catalogue #	Description	Pack size
036-001	**REAADS Protein S Antigen ELISA**	**96 wells**
Kit contains the following reagents:		
96 anti-human Protein S antibody coated breakaway microwells in frame		12 strips x 8 wells
Sample Diluent (blue-green solution) (ready to use)		1 x 60 mL
Lyophilised Reference Plasma		3 x 0.5 mL
HRP Conjugated anti-Human Protein S Antibody (red solution, ready to use)		1 x 12 mL
Substrate (ready to use)		1 x 13 mL
Stopping Solution (ready to use)		1 x 15 mL
Wash Concentrate (33x)		1 x 30 mL
Free Protein S Reagent (PEG) (ready to use)		1 x 2 mL

Store at 2 - 8°C. Do Not Freeze. **For *in-vitro* diagnostic use** CE

Monoclonal Free Protein S Antigen

The REAADS Monoclonal Free Protein S enzyme linked immunosorbent assay (ELISA) uses a monoclonal antibody specific for free Protein S to measure free Protein S levels in citrated human plasma. No pre-treatment of samples with polyethylene glycol (PEG) is required. Results are reported in percent (%) of normal, relative to the reference plasma that has been standardised against the Secondary Standard for Coagulation/International Society on Thrombosis and Haemostasis (SSC/ISTH) preparation, which is calibrated to World Health Organization (WHO) standards.

- **Utilises a monoclonal antibody specific for Free Protein S**
- **Convenient ELISA well strip or plate format**
- **Reagent complete kit**
- **Assayed controls available**
- **Six point reference curve**
- **60 minutes total incubation time**

Catalogue #	Description	Pack size
051-001	**REAADS Monoclonal Free Protein S ELISA**	**96 wells**

Kit contains the following reagents:

96 monoclonal human free Protein S ab coated breakaway microwells in frame	12 strips x 8 wells
Sample Diluent (blue-green solution) (ready to use)	1 x 60 mL
Lyophilised Reference Plasma	3 x 0.5 mL
HRP Conjugated anti-Human Protein S Antibody (red solution, ready to use)	1 x 12 mL
Substrate (ready to use)	1 x 13 mL
Stopping Solution (ready to use)	1 x 15 mL
Wash Concentrate (33x)	1 x 30 mL

Coagulation Controls

Normal control plasma (Level 1) and abnormal control plasma (Level 2) which may be used in Corgenix (REAADS) von Willebrand Factor Antigen, Protein C Antigen, Protein S Antigen, and Monoclonal Free Protein S Antigen ELISA. Corgenix coagulation controls are assayed as follows:

Protein C	*ELISA, EID, chromogenic*	*Prothrombin Time*	*clotting*
Total Protein S	*ELISA, EID*	*Act Partial Thromboplastin Time*	*clotting*
Free Protein S	*PEG ELISA, EID, monclonal ELISA*	*Fibrinogen*	*clotting*
Von Willebrand	*ELISA, EID*	*Extrinsic Factors (II,V,VII,X)*	*clotting*
Ristocetin Cofactor	*Platelet Agglutination*	*Intrisic Factors (VIII,IX,XI,XII)*	*clotting*
Plasminogen	*EID, chromogenic*	*Factors VIII,X*	*chromogenic*
Antithrombin III	*EID, chromogenic*	*Alpha2-antiplasmin*	*chromogenic*

Catalogue #	Description	Pack size
701-001	**Lyophilised Coagulation Control 1 (Normal)**	**10 x 1mL**
702-001	**Lyophilised Coagulation Control 2 (Abnormal)**	**10 x 1mL**

Store at 2 - 8°C. Do Not Freeze. **For *in-vitro* diagnostic use** CE

Von Willebrand Factor

Von Willebrand Factor (vWF) is an important pro-coagulant blood clotting protein which mediates platelet adhesion to sites of vascular injury and stabilises Clotting Factor VIII from proteolytic cleavage in circulation. Von Willebrand Disease (vWD) is caused by either partial quantitative deficiency i.e. a shortage of vWF (Type I) or a qualitative i.e. functional (Type II) deficiency. VWD Type III is rare and characterised by virtually complete deficiency of vWF. Deficiencies in vWF may result in abnormal bleeding due to impaired platelet function and clotting factor inhibition. vWD is the most common inherited bleeding disorder, and is clinically characterised by easy bruising or prolonged bleeding from mucosal surfaces. While approximately 80% of vWD patients have Type I deficiency, both quantitative (antigenic) and qualitative (functional) assays may be required for a laboratory diagnosis of vWD. Higher molecular weight multimers of von Willebrand factor (vWF) serve to bind activated platelets through specific membrane glycoprotein's to connective tissue fibers exposed at wound sites and thus promote blood clotting and wound healing.

Von Willebrand Factor Antigen

The REAADS von Willebrand Factor Antigen (vWF:Ag) ELISA test kit is an enzyme linked immunosorbent assay (ELISA) test for determining von Willebrand Factor levels in human plasma, expressed in relative percent (%) of normal. The assay is intended to be used as an aid in the diagnosis of von Willebrand Disease in patients with bleeding disorders, and to help distinguish between vWD and classic Hemophilia A. The REAADS vWF:Ag Test Kit accurately detects antigen levels as low as 5% of normal.

- **Convenient ELISA Procedure**
- **Objective, accurate and reproducible**
- **Reagent complete kit**
- **Total incubation time: 40 minutes**

Catalogue #	Description	Pack size
034-001	**REAADS von Willebrand Factor Antigen ELISA**	**96 wells**

Kit contains the following reagents:

96 anti-human vWF antibody coated breakaway microwells with frame	12 strips x 8 wells
Sample Diluent (blue-green solution, ready to use)	1 x 60 mL
Lyophilised Reference Plasma	3 x 0.5 mL
HRP Conjugated anti-Human vWF Antibody Solution (red solution, ready to use)	1 x 12 mL
Substrate (ready to use)	1 x 13 mL
Stopping Solution (ready to use)	1 x 15 mL
Wash Concentrate (33x)	1 x 30 mL

Store at 2 - 8°C. Do Not Freeze. **For *in-vitro* diagnostic use** CE

Von Willebrand Factor Activity (functionality)

The von Willebrand Factor Activity (vWF:Act) ELISA test kit is an enzyme linked immunosorbent assay (ELISA) test for the quantitative detection of vWF activity in citrated human plasma. The assay utilises a purified murine anti-vWF IgG monoclonal antibody which recognises a functional epitope on the vWF molecule to assess vWF activity levels. Results can be reported in IU/mL or percent (%) of normal, relative to a calibrator that has been standardised against the third International Standard for Factor VIII and von Willebrand Factor in plasma (91/666).

- **Utilizes a monoclonal antibody which recognises a functional epitope on vWF molecule**
- **Reagent complete kit includes Calibrator and Controls**
- **Sensitive and precise**
- **Easy to use**

Catalogue #	Description	Pack size
10826	**REAADS von Willebrand Factor Activity ELISA**	**96 well kit**

Kit contains the following reagents:

96 stabilised monoclonal vWF antibody coated breakaway microwells with frame	12 strips x 8 wells
Sample Diluent (blue-green solution, ready to use)	1 x 60 mL
Lyophilised Reference Plasma	3 x 0.5 mL
HRP-conjugated anti-Human vWF Antibody Solution (blue solution, ready to use)	1 x 12 mL
Substrate (ready to use)	1 x 13 mL
Stopping Solution (ready to use)	1 x 15 mL
Wash Concentrate (33x)	1 x 30 mL

Collagen Binding Assay

The worldwide incidence of vWD is estimated at 1% to 3% but may be more common since mild cases may remain undetected. The Collagen Binding Assay (CBA) enzyme linked immunosorbent assay (ELISA) is a test procedure that quantitates the binding of vWF to collagen type III coated on to microtiter wells. Collagen binding of vWF is associated with the higher molecular weight (HMW) forms of vWF, believed to be functionally more important in haemostasis than lower molecular weight (LMW) forms. Therefore CBA may correlate more closely with vWF function and bleeding problems than other ELISA for vWF which measure total (LMW + HMW) vWF.

- **Reagent complete kit, convenient procedure**
- **96-well microplate format**
- **2.5 hour total incubation at room temperature**
- **May be used in conjunction with vWF:Ag assays to differentiate between vWD Types I and II**

Catalogue #	Description	Pack size
11160	**REAADS Collagen Binding Assay ELISA**	**96 wells**

Kit contains the following reagents:

96 Collagen coated breakaway microwells with frame	6 strips x 16 wells
Lyophilised vWF Antigen Standard	2 x 2 mL
Lyophilised vWF Antigen Controls	4 x 2 mL
HRP-conjugated vWF Antibody Solution (ready to use)	1 x 11 mL
TMB Substrate (ready to use)	1 x 11 mL
Stopping Solution (ready to use)	1 x 11 mL
Wash Concentrate (33x)	2 x 11 mL

Ristocetin

Ristocetin is a glycopeptide antibiotic isolated from Nocardia lurida that initiates binding of von Willebrand Factor (vWF) to platelet glycoprotein Ib, resulting in platelet aggregation or agglutination. Ristocetin is widely used as an agonist for *in vitro* testing of platelet function.

In the presence of von Willebrand factor, ristocetin induces the aggregation of platelets in platelet-rich plasma or standardised fixed platelet suspensions. Platelet aggregation utilises a modified spectrophotometer to quantitate light transmission through a turbid suspension of platelet-rich plasma. As platelets begin to clump, the plasma clears, increasing the amount of light transmitted through the solution. Alternatively, a luminometer can be used to measure platelet aggregation in whole blood where aggregation in response to ristocetin is measured by change in electrical impedance between two electrodes, and ATP release is detected with fluorescence. Platelets from von Willebrand patients have an impaired aggregation response when exposed to ristocetin. Defective ristocetin-induced platelet aggregation has also been found in conjunction with other disease states, including Bernard-Soulier Syndrome, as well as aspirin ingestion.

Ristocetin associated assays

Two assays have been developed to assess platelet function in the presence of ristocetin. **Ristocetin-induced platelet aggregation (RIPA)** assays measure the aggregation of the patient platelets in the presence of ristocetin. Many vWD patients have reduced RIPA at concentrations between 1.0 and 1.5 mg/mL. However, in type IIB vWD, a molecular mutation causes enhanced responsiveness to ristocetin so that low levels (0.2 to 0.6 mg/mL) will aggregate their platelets but not those of normal individuals.

A more definitive test, the **Ristocetin Cofactor Assay (vWFR:Co)** measures the ability of patient plasma to agglutinate formalin-fixed platelets in the presence of ristocetin, reflecting the quantity of functional vWF. This assay is more sensitive to mild reductions in vWF than RIPA, and is often used to monitor therapy in vWD patients.

Catalogue #	Description	Pack size
706-001	**Ristocetin**	**6 x 100 mg vials**

Product Description:

Ristocetin is provided in vials containing 100 mg of lyophilised material, and must be reconstituted with 0.85% saline before use. An appropriate amount of the lyophilised material can be weighed out and diluted in a glass vial if the entire 100 mg of ristocetin in the vial is not used at one time.

Storage Conditions:

Lyophilised vials of ristocetin can be stored at room temperature until the expiration date printed on the vial. Once reconstituted, ristocetin is stable for 7 days when stored at 2 - 8ºC, or for 4 weeks if frozen and stored at -20ºC.

For *in-vitro* diagnostic use CE

Ristocetin Cofactor

The Ristocetin Cofactor Assay (vWFR:Co) measures the ability of patient plasma to agglutinate lyophilised formalin-fixed platelets in the presence of ristocetin, reflecting the quantity of functional vWF. This assay is often used to monitor therapy in vWD patients.

Following reconstitution, the lyophilized platelets are incubated with Ristocetin and dilutions of a normal standardized human plasma introduced with known amounts of Ristocetin Cofactor activity and a standard curve prepared. A patient plasma is then introduced as a source of Ristocetin Cofactor activity in the presence of Ristocetin and reconstituted platelets from which an aggregation pattern (slope) is determined. The Ristocetin Cofactor activity is interpolated from the standard curve.

Catalogue #	Description	Pack size
HB5516FG	**Ristocetin Cofactor Assay Kit**	**40/80 tests**
Kit contains the following reagents:		
Lyophilised Platelets		4 x 5 ml
Calibrator		2 x 1 mL
Ristocetin		2 x 1 mL
Abnormal Control Plasma		2 x 1 mL
Tris – Buffered Saline		2 x 10mL
HB-5507-FG	**Ristocetin 10 mg/ml**	**1 x 1 ml**
HB-5518-FG	**Control Plasma (kit)**	**10 x 0.5 ml**
HB-5519-FG	**Reference Standard Plasma (kit)**	**10 x 0.5 ml**
HB-5520-FG	**Lyophilised Platelets (kit – 5 ml)**	**5 x 5 ml**
HB-5521-FG	**Lyophilised Platelets (kit – 10 ml)**	**1 x 10 ml**
HB-5534-FG	**Tris-Buffered Saline**	**1 x 100ml**

Store at 2 - 8°C. Do Not Freeze. **For *in-vitro* diagnostic use** CE

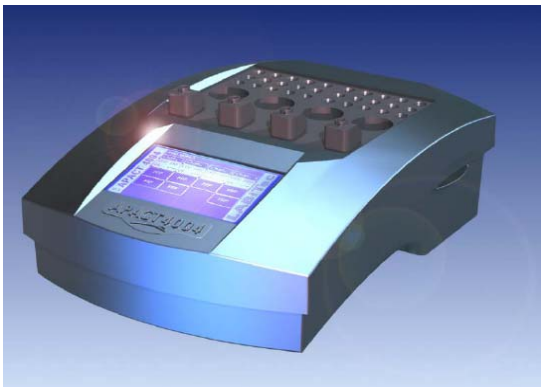
Blood Collection and Sample Handling Devices

HB-1107-FG	**Haemolance Lancets High Flow (150) (YELLOW)**
HB-1108-FG	**Haemolance Lancets High Flow (150) (YELLOW)**
HB-1109-FG	**Qpette 25ul fixed volume**
HB-1110-FG	**Qpette 125ul fixed volume**
HB-1111-FG	**Pipette 5-50ul variable volume**
HB-1112-FG	**Pipette 20-200ul variable volume**
HB-1113-FG	**Single Channel Pipette, 25ul fixed volume**
HB-1114-FG	**Pipette 100-1000ul, single channel variable volume**
HB-1115-FG	**Yellow Pipette Tips (200ul) Tray of 96**
HB-1116-FG	**Yellow Pipette Tips (200ul) Bag of 1000**
HB-1117-FG	**Blue Pipette Tips (1000ul) Tray of 60**
HB-1118-FG	**Blue Pipette Tips (1000ul) Pack of 1000**

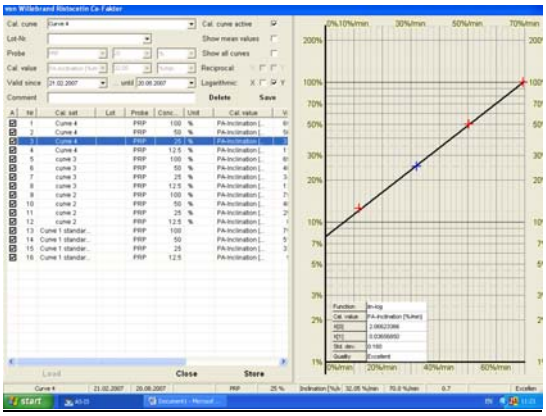
APACT 4004 Aggregometer

4 channel microprocessor controlled unit

- **Touch Screen with real time display**
- **Calculated % max. Aggregation, Slope %/min**
- **Measuring sensitivity to 30,000 Platelets/ul**
- **Data Storage via multimedia card**
- **PC software with on-screen graphics**



Specifications:
32 Bit Microprocessor, 8Mbit SRAM, 4Mbit Flash
Power supply input 90-264 V @ 47-63 Hz
Reference curves can be stored separately for each method
1-9 curve points
Units; %, s, mOD, ug/l, mg/l, ng/l
Touch-Screen monochrome LCD-display; 240 x 128 pixel
Long-life white LED background lighting
Integrated Touch Panel with 10 x 5 buttons
Graphical display of up to 4 measuring curves
High resolution photometer (740nm) up to 3 OD
Thermo block with precise temperature control at 37.4 deg C
30 cuvette incubating positions
4 independent photometric measuring channels
4 independently controlled mixers (250 – 1200 U/min)
1 reagent stirring position (250 – 1200 U/min)
Multimedia card interface (for data storage)
2 serial RS232 (for printer and external PC)
100-240V, 47/63Hz
Dimensions: W 23 x D 30 x H 14 cm
Weight: 6 kg
Optional Printer
Thermal serial dot print method (8 x 320 dots / line)
90 mm print width
AC power adaptor 120 – 230 V
Dimensions: W 16 x D 17 x H 7 cm



Catalogue #	Description
HB-5543-FG	**APACT 4004 Platelet Aggregometer**
HB-5538-FG	**Micro- Cuvettes in Dispo System (5 x 500)**
HB-5540-FG	**Thermal printer for APACT 4004**
HB-5542-FG	**APACT LPC Software with Cable**

For *in-vitro* diagnostic use CE

Haemostasis Assays

Platelet Aggregation

Platelet aggregation testing is most often indicated when there is a bleeding tendency which is qualitatively similar to bleeding caused by a low platelet count but the platelet count is normal.

Platelet aggregation testing helps to diagnose diseases of platelet dysfunction and distinguish between inherited bleeding problems such as haemophilia or von Willebrand disease, and acquired bleeding problems due to medication or other disease states.

The most commonly used method for platelet aggregation is the Born method. Platelet Rich Plasma (PRP) is stirred and incubated at 37°C. Platelet aggregation is initiated by the addition of one of the reagents listed overleaf and the change in light transmittance monitored over a 5 minute period.

Von Willebrand Syndrome:
Normal response to ADP, Collagen, Epinephrine and Arachidonic Acid. Reduced response to Ristocetin (increased response to low concentration Ristocetin in Type IIb).

Bernard Soulier Syndrome:
Normal response to ADP, Collagen, Epinephrine and Arachidonic Acid. Reduced response to Ristocetin.

Glanzmann Thrombasthenia:
No response to ADP, Collagen, Epinephrine and Arachidonic Acid.

Aspirin-like Disorder or Aspirin Ingestion:
Reduced or absent second wave ADP response. Reduced response to Epinephrine, and low concentration Collagen. No response with Arachidonic Acid.

Storage Pool Disease:
Normal, or reduced first wave, and reduced second wave with ADP. Normal response to collagen and Arachidonic Acid. Reduced response to Epinephrine.

Catalogue #	Description	Pack size
HB-5501-FG	**ADP (0.2mM)**	**1 x 1 mL**
HB-5502-FG	**ADP (0.2mM)**	**2 x 1 mL**
HB-5503-FG	**Collagen (100 µg/mL)**	**1 x 1 mL**
HB-5504-FG	**Collagen (100 µg/mL)**	**2 x 1 mL**
HB-5510-FG	**Epinephrine (100 µM)**	**1 x 1 mL**
HB-5511-FG	**Epinephrine (100 µM)**	**2 x 1 mL**
HB-5513-FG	**Aggregation kit (2 x 1 mL ADP, 2 x 1mL Collagen, 2 x 1 mLEpinephrine)**	
HB-5505-FG	**Arachidonic Acid (5 mg/mL)**	**1 x 1 mL**
HB-5506-FG	**Arachidonic Acid (5 mg/mL)**	**2 x 1 mL**
HB-5507-FG	**Ristocetin (10 mg/mL)**	**1 x 1 mL**
HB-5508-FG	**Ristocetin (10 mg/mL)**	**2 x 1 mL**
HB-5509-FG	**Ristocetin (15 mg/mL)**	**1 x 1 mL**
HB-5512-FG	**TRAP 6 (1mM)**	**1 x 1 mL**
HB-5533-FG	**TRAP 6 (1mM)**	**2 x 1 mL**
HB-5514-FG	**Aspirin (30mg/mL)**	**1 x 1 mL**
HB-5535-FG	**Aspirin (30mg/mL)**	**2 x 1 mL**
HB-5515-FG	**Prostaglandin E1 (300nM)**	**1 X 1 mL**
HB-5544-FG	**Prostaglandin E1 (300nM)**	**2 X 1 mL**
HB-5537-FG	**Aggrastat®**	**1 x 1 mL**
HB-5545-FG	**Aggrastat®**	**2 x 1 mL**

Store at 2 - 8°C. Do Not Freeze. **For *in-vitro* diagnostic use** CE

Factor Deficient Plasmas

Plasma coagulation factors are proteins which circulate inside the vascular system as part of the blood plasma. During the coagulation process, the coagulation factors are activated by proteolytic processes. Coagulation can be initiated by the Intrinsic or Extrinsic pathways. The activation of the plasma factors proceeds through the 'cascade' theory, resulting in the conversion of Prothrombin to Thrombin, and Fibrinogen to Fibrin. Deficiencies in the levels of any of the plasma factors can lead to clinical manifestations such as bleeding. The nature of the deficiency can be either genetically inherited, or acquired in conditions such as liver disease or cancer.

An important test in the laboratory is to investigate the reasons for any unexplained bleeding tendency, which often requires the measurement of coagulation factor levels. The most commonly used methods for measuring factor levels are based upon the prothrombin time (factors II, V, VII and X) and activated partial thromboplastin time (factors VIII, IX, XI and XII). In these assays, the ability of the patient's plasma to normalise the prolonged coagulation time of the specific factor deficient plasma is determined. The clotting time of the patient + factor deficient plasma is compared to a standard curve produced by serial dilution of reference plasma with known levels of the coagulation factors.

- **Less than 1% residual factor of interest**
- **Human plasma source**
- **Negative for hepatitis B, hepatitis C and HIV**
- **Long stability**
- **Convenient pack size**

Catalogue #	Description	Pack size
HB-3301-FG	**Factor II Deficient**	**5 x 1mL**
HB-3302-FG	**Factor V Deficient**	**5 x 1mL**
HB-3303-FG	**Factor VII Deficient**	**5 x 1mL**
HB-3304-FG	**Factor VIII Deficient with 'depleted von Willebrand factor'**	**5 x 1mL**
HB-3305-FG	**Factor VIII Deficient with 'normal von Willebrand factor'**	**5 x 1mL**
HB-3306-FG	**Factor IX Deficient**	**5 x 1mL**
HB-3307-FG	**Factor X Deficient**	**5 x 1mL**
HB-3308-FG	**Factor XI Deficient**	**5 x 1mL**
HB-3309-FG	**Factor XII Deficient**	**5 x 1mL**

Store at 2 - 8°C. Do Not Freeze. **For *in-vitro* diagnostic use** CE

Control and Standard Plasmas

Precision Control Plasmas
Economic, lyophilised human plasma control, ecommended for daily precision testing of routine coagulation testing (PT, APTT, Fibrinogen and Thrombin Time). The normal control provides results in the normal range, and the abnormal control provides extended clot times for PT and APTT and Thrombin Time, and reduced fibrinogen levels. Nominal values are provided for mechanical and photo-optical measurement systems.

Reference Plasma and Controls
Lyophilised human plasma assayed using international reference preparations where available, recommended for use when test results are compared against a standard curve, such as factor assays, fibrinogen and antithrombin III. The Reference Plasma should be used to establish the standard curve and the normal and abnormal controls can be used to ensure accurate quantitation of the analyte of interest.

Heparin Control Plasmas
Lyophilised, human plasma, containing sodium heparin, at levels covering the therapeutic targets for heparin therapy. These plasmas are suitable for use with clot-based assays, such as the APTT, as well as chromogenic heparin assays.

D-Dimer Control Plasmas
Plasma-based D-dimer preparations which contain purified human D-dimer. Controls are designed to provide low and high levels of D-dimer. As there is no single reference preparation available for D-dimer, the values obtained need to be determined with individual assay protocols.

Lupus Anticoagulant Control Plasmas
Sourced from donors positive for Lupus anticoagulants, these control plasmas provide low and high level results for antiphospholipid syndrome.

- **Prepared from human source plasma**
- **Negative for hepatitis B, hepatitis C and HIV**
- **Long stability**
- **Convenient pack size**

Catalogue #	Description	Pack size
HB-4401-FG	**Normal Control Plasma**	**10 x 1mL**
HB-4402-FG	**Normal Control Plasma**	**50 x 1mL**
HB-4403-FG	**Abnormal Control Plasma**	**10 x 1mL**
HB-4404-FG	**Abnormal Control Plasma**	**50 x 1mL**
HB-4407-FG	**Normal Standard Plasma**	**10 x 1mL**
HB-4408-FG	**Normal Assay Plasma**	**10 x 1mL**
HB-4409-FG	**Abnormal Assay Plasma**	**10 x 1mL**
HB-4405-FG	**Heparin Control Plasma – level 1**	**10 x 1mL**
HB-4406-FG	**Heparin Control Plasma – level 2**	**10 x 1mL**
HB-4425-FG	**D-Dimer Control Plasma – level 1**	**10 x 0.5mL**
HB-4426-FG	**D-Dimer Control Plasma – level 2**	**10 x 0.5mL**
HB-4427-FG	**Lupus Anticoagulant Control Plasma – level 1**	**10 x 0.5mL**
HB-4428-FG	**Lupus Anticoagulant Control Plasma – level 2**	**10 x 0.5mL**

Store at 2 - 8°C. Do Not Freeze. **For *in-vitro* diagnostic use** CE

PT Point of Care (POC)

The Manchester Capillary Prothrombin Time reagent is a combined thromboplastin reagent for use in the *in vitro* control of patient anticoagulant therapy by finger prick or venous blood prothrombin times. The reagent is a combination of rabbit brain thromboplastin and processed ovine plasma. The processed ovine plasma acts as a source of factor V and fibrinogen. The reagent is supplied lyophilised and is recalcified before use by the addition of a diluent containing calcium chloride. The method is responsive to depletion of the vitamin K dependent clotting factors II, VII and X. Mixing blood or plasma with the reagent results ultimately in the formation of a clot. The time taken for the clot to form is measured and used to determine the anticoagulant status of the patient.

Freshly collected whole blood or plasma is mixed with pre-warmed Manchester Capillary Reagent. The time taken for clot formation can be measured by mechanical, photo-optical or manual (visual) methods. The clot time is converted to the INR using the mean normal PT time (MNPT) and ISI. The patient anticoagulation status can then be assessed against therapeutic targets. Accurate values for the MNPT and local system ISI should be determined prior to patient testing by use of the Hart Biologicals INR Correction Kit

- **Responsive to the depletion of the vitamin K dependant clotting factors**
- **Low ISI, typically 1.00-1.10**
- **Short clot times allow rapid test throughput**
- **Calibrated using current International Reference thromboplastins**
- **Suitable for use by manual tilt-tube or on mechanical and photo-optical instruments**

INR Correction Kit

A set of 13 lyophilised plasmas with INR values assigned using reference thromboplastins. Used to calibrate the 'local system ISI and MNPT' to ensure accurate INR reporting.

- **Determine instrument and reagent specific ISI**
- **Obtain local Mean Normal PT Time from calibration curve**
- **Utilises plasma from donors on long term oral anticoagulant therapy**
- **Certified using current International Reference thromboplastins**
- **Suitable for use by manual tilt-tube or on mechanical and photo-optical instruments**

Capillary PT Test Control Plasmas

Lyophilised human plasma controls designed for use with the Manchester Capillary PT Test. Three levels of control are provided; INR 1.0-1.1, INR 2.0-2.5 and INR 4.0-4.5 to ensure complete control of the therapeutic range for anticoagulant therapy.

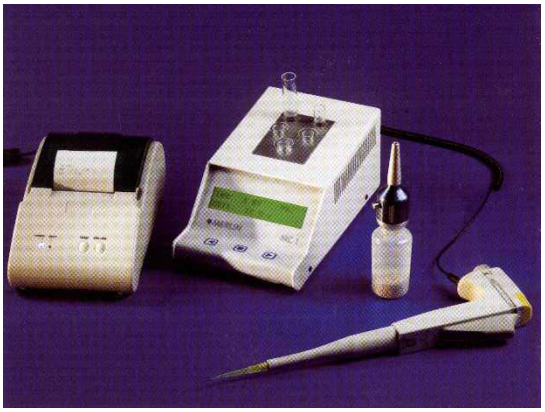
Catalogue #	Description	Pack size
HB-1101-FG	**Manchester Combined Capillary Prohrombin Test kit** 5 x 6 mL lyophilised plasma reagent, 5 x 6 mL reconstitution reagent	**120/240 tests**
HB-1133-FG	**Manchester Combined Capillary Prohrombin Test kit** 5 x 1.5 mL lyophilised plasma reagent, 5 x 1.5 mL reconstitution reagent	**30/60 tests**
HB-4410-FG	**INR Verify Set**	
HB-4411-FG	**Capillary Precision control – normal**	**10 x 0.5 mL**
HB-4412-FG	**Capillary Precision control – level l**	**10 x 0.5 mL**
HB-4413-FG	**Capillary Precision control – level 2**	**10 x 0.5 mL**
HB-4414-FG	**CPC Control Plasma (Coumarin)**	**10 x 0.5 ml**
HB-4415-FG	**INR Correction Kit** (12 x 0.5 mL lyophilised calibration plasmas)	

Store at 2 - 8°C. Do Not Freeze. **For *in-vitro* diagnostic use** CE

Thrombi-Stat MC1WB

Single channel mechanical coagulometer

- **Uses finger prick whole blood sample**
- **Automatic INR results**
- **Fully interfaceable**
- **Small and lightweight for clinic use**



Specifications:
Mechanical endpoint measurement principle
Ball method with one measuring channel
Automatic INR calculation
Storage of 100 results capacity
Micro-cuvette option for running half test volumes
LCD two row high-definition graphic display
Membrane keypad
Pulse operation for detection of low fibrinogen samples
Two sample pre-incubation stations
Two reagent pre-warm stations
Ball dispenser
Auto-start via electronic pipette
Data output to HiruMed™ RAID anticoagulant management software, thermal printer or on-screen display

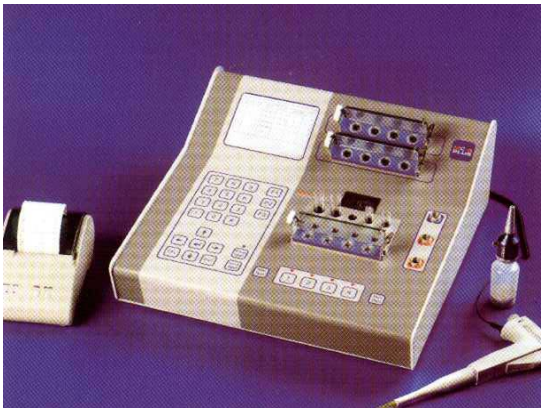
Dimensions: 21.8 x 12.5 x 9.3 (L x W x H)
Weight: 1.2 kg

Optional Extras:
Printer - eg Seiko or Epson
Haemolancets (150 and 4000 unit pack sizes)
Tips for electronic pipette
Reagents and controls

Thrombi-Stat MC4WB

4 channel mechanical coagulometer

- **Uses finger prick whole blood sample**
- **Automatic INR results**
- **Fully interfaceable**
- **Optional optical channel (406/650nm)**



Specifications:
Mechanical endpoint measurement principle
Ball method with four measuring channels
One channel for optical detection at 405 / 650 nm (optional)
Automatic INR calculation
Open system for all clotting tests
Suitable for batch or patient orientated testing
Micro-cuvette option for running half test volumes
High-definition graphic display (320 x 240 pixels)
Membrane keypad
Pulse operation for detection of low fibrinogen samples
Ball dispenser
Auto-start via electronic pipette
Data output to HiruMed™ RAID anticoagulant management software, thermal printer or on-screen display

Dimensions: 43.0 x 42.0 x17.0 (L x W x H)
Weight:11.0 kg

Optional Extras:
Printer - eg Seiko or Epson
Haemolancets (150 and 4000 unit pack sizes)
Tips for electronic pipette
Reagents and controls

Catalogue #	Description
HB-1119-FG	**Thrombi-stat™ MC1 single channel whole blood coagulometer (macro)**
HB-1120-FG	**Thrombi-stat™ MC1 single channel whole blood coagulometer (micro)**
HB-1121-FG	**Thrombi-stat™ MC4 four channel whole blood coagulometer (macro)**
HB-1122-FG	**Thrombi-stat™ MC4 channel whole blood coagulometer (micro)**
HB-1122-FG	**Thrombi-stat™ MC4 coagulometer with photometer**
HB-1123-FG	**Cuvettes & Balls (macro) (1000)**
HB-1124-FG	**Cuvettes & Balls (micro) (1000)**
HB-1125-FG	**Printer for MC1 and MC4**

For *in-vitro* diagnostic use CE

Instrumentation

Corgenix offers a full range of BioTek® Microplate Instrumentation, plate readers to measure absorbance, microplate washers for 96-well applications and data reduction software that expands every application from research to the clinical market. All Corgenix assays are fully programmed on the BioTek® instruments.

ELx800 Universal Microplate Reader

As a stand-alone microplate reader, the ELx800 is designed for applications within the clinical, biotechnology research and pharmaceutical areas. The on-board data reduction surpasses many PC software packages with its extensive curve-fitting, cut-off calculation, data transformation and validation capabilities. When purchased through Corgenix, the Elx800 is pre-programmed for Corgenix assays.

- **Extensive on-board data analysis, including curve-fitting, transformations, and control validation**
- **Stores up to 55 assay definitions in memory**
- **Panel assay capability**
- **Reads 24-, 48-, or 96 well microplates**
- **Stores test results and standard curves**
- **On-board diagnostic testing of optical and performance specifications**
- **Optional UV 340 nm capability**
- **Optional 72- and 96-well Terasaki and 384-well plate reading**
- **Optional language versions English, French, German, Italian, Spanish, Portuguese**

On-board Data Analysis

Extensive curve fitting (linear, cubic, quadratic, 4-P, log-Logit, Cubic-spline, Point to Point), stores 25 standard curves, auto plate layout for blanks, controls, standards and samples, control and assay validation, transformation formulas, cut-off and call criteria, up to 8 microplate test results saved in reader's memory

On-board Diagnostic Testing

The ELx800's on-board diagnostic include the Reader's System Test, which checks the entire optical path, and the Universal Test Plate Software, which tests for accuracy, linearity and repeatability when used with the optional universal test plate

Software Interfacing

The Elx800 interfaces with the following software packages, KC4 for Windows™, KC-Jr (DOS), Delta-Soft 3 (Mac), IBM Datalogging, Capture Data™ for Excel™

For *in-vitro* diagnostic use CE

Specifications

Microplates:	6-, 12-, 24-, 48- and 96-well microplates. Optional 72- and 96-well Terasaki and 384-well capability
Speed:	30 seconds for 96 wells
Wavelength range:	400-750 nm. UV option 340-750 nm
Filters:	5-cavity wheel. Supplied: 405, 450, 490, 630 nm. 340 nm with UV option
Absorbance range:	0.000 to 3.000 Abs
Resolution:	0.001 Abs
Accuracy:	+/- 1% +/- 0.010 Abs from 0 to 2.000 Abs @ 405 nm
Linearity:	+/- 1% from 0 to 2.000 Abs, +/- 3% from 2.000 to 3.000 Abs @ 405 nm
Repeatability:	+/- 0.5% +/- 0.005 Abs from 0 to 2.000 Abs @ 405 nm
Dimensions:	41.9 cm (D) x 38.1 cm (W) x 17.8 cm (H)
Weight:	8.4 kg
External Outputs:	RS232 serial interface, parallel printer interface
Display:	2 x 24 LCD display
Power:	External, 24v power supply for 100-240 VAC input @ 50-60 Hz

ELx50 96-/384-Well Auto Strip Washer

As a self contained and programmable instrument, the ELx50 allows for full control of precise fluidic delivery from the gentle dripping of a simple squeeze bottle to the full force of pressure delivery systems. The ELx50 is a fast and versatile automated strip washer, which comes equipped with a patented Dual-Action™ 16-channel manifold. This breakthrough design allows for independent control of the dispensing and aspiration manifolds for overfill washing and overflow protection in 96-well formats. Additionally, for a 96-well format, the Dual-Action manifold provides incomparable wash performance with two sets of dispensing and aspiration tubes per well. This exclusive method of two-fold aspiration guarantees low residuals. When purchased through Corgenix, the Elx50 is pre-programmed for Corgenix assays.

- **Wash single strips or full plates**
- **Suitable for EIA, RIA Fluorescence, Chemiluminescence, DNA Probe and Cellular assays**
- **Syringe drive fluid delivery system for precise control over all fluid flow rates**
- **75 stored protocols**
- **AutoPrime feature**
- **Bottom Washing and Crosswise Aspiration protocols**
- **Optional Automatic Buffer Switching**
- **Optional language versions English, French, German, Italian, Spanish, Portuguese**

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Programming Flexibility

With the combination of new flash memory chips and the intuitive keypad, assay protocols are easily programmed for the following functions; wash, prime, dispense, aspirate, rinse, maintenance routines. Each program contains, among other parameters; user defined program name, 75 protocols, 1-10 wash cycles, 8 or 12 channel manifold type, shaking time and intensity, 1-600 second soak time, flow rate in volume/well/second.

Efficient Washing

Lower background absorbance and smaller residual volumes is cut with Bottom Washing and Crosswise Aspiration routines. Bottom washing provides vigorous fluid dispensing at the well surface with high volumes of wash buffer for rapid dilution of reagent. Crosswise application removes residual fluid by aspirating in two programmable well positions. Programmable aspiration rates reduce carryover and provide high washing efficiency.

Maintenance and Safety

At the press of a button, pre-programmed maintenance protocols can be initiated which automatically rinses the fluidics system, flushes the manifold, soaks the manifold in the wetted condition and primes the system automatically. Using the optional automatic buffer switching facility, the appropriate buffer/rinse can be switched to and the fluidic system rinsed through. The Elx50 incorporates a built-in aerosol cover, built-in decontamination routine with the electronics isolated from the fluidics

Microplates:	Accomodates all 96-well microplates and strips.
Well shape:	Flat, round or 'V' bottom
Residual volume:	<5% / well, dependent on plate type and aspiration protocol
Fluid flow rates:	150 – 1000 ul / well / second
Soak time:	1 – 600 seconds
Dispense volumes:	50 – 3000 ul / well
Display:	2 x 24 LCD display
Keypad:	Membrane type with 25 alpha numeric keys
Dimensions:	40.0 cm (D) x 35.0 cm (W) x 16.25 cm (H)
Weight:	8.9 kg
External Outputs:	RS232 serial interface
Power:	External, 24v power supply for 100-240 VAC input @ 50-60 Hz

Catalogue #	Description
ELx800	**Standard Microplate Reader (un-programmed)**
ELx800C	**Standard Microplate Reader (pre-programmed with Corgenix protocols)**
ELx800U	**Standard Microplate Reader with UV (340nm) capability**
Elx50/8	**Standard Microplate Washer (unprogrammed) for 96 well plates and 1 x 8 strips**
Elx50/8C	**Standard Microplate Washer (programmed) for 96 well plates and 1 x 8 strips**
Elx50/8V	**Standard Microplate Washer with automatic buffer switching facility**

Fully Automated ELISA Instrumentation

Corgenix can provide instrumentation protocols for all its assays on a range of automated instrumentation. Please contact us as tech@corgenix.co.uk for information on protocols available and further assistance

For *in-vitro* diagnostic use CE

Other Products and Services

Educational aids

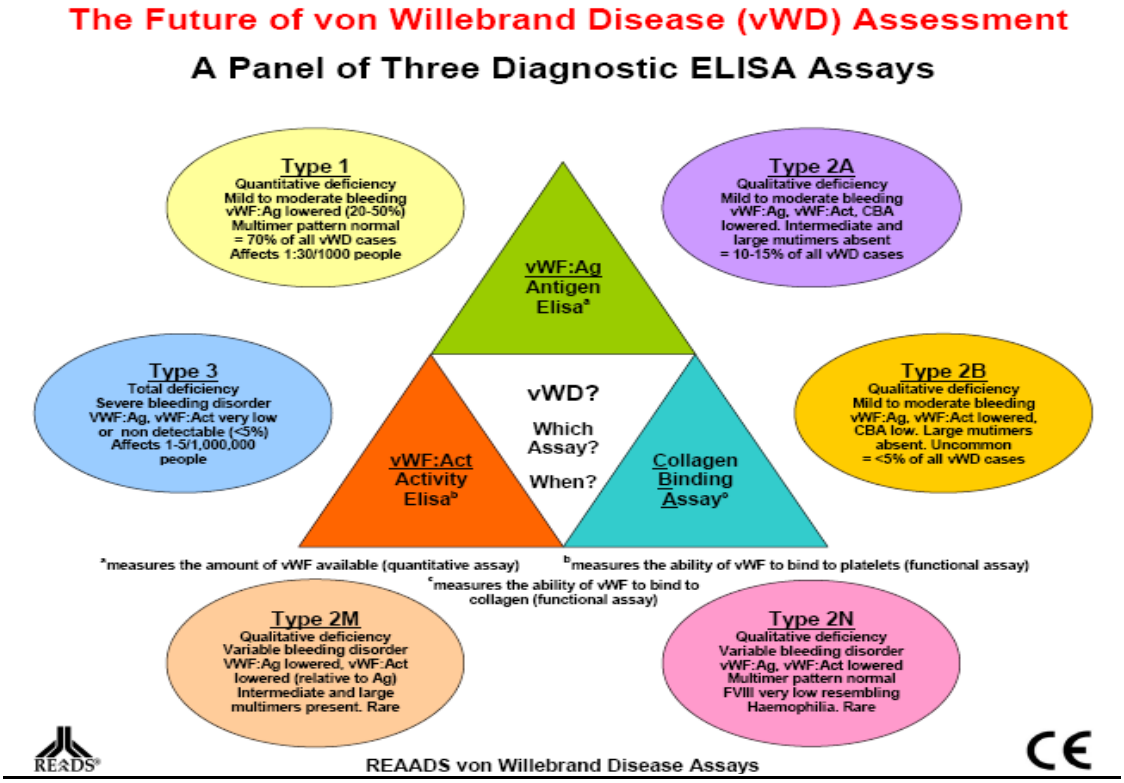
Corgenix offers a range of educational information to support the use of its products. These are supplied free of charge on request. Please contact your local Corgenix representative or Corgenix Customer Services at info@corgenix.co.uk for your personal copy.

Antiphospholipid Antibody Screening Procedure – Cat# CI 010

This chart presents an overview of an investigative procedure to adopt when screening for Antiphospholipid Syndrome

Von Willebrand Disease – Cat# CI 021

This chart presents an overview of the various forms of this hereditary bleeding disorder



Autoimmune Disease – Cat# CI 030

This chart presents an overview of the procedure to adopt when investigating Autoimmune Disease

Hyaluronic Acid – Cat# CI 040

This chart presents the role of Hyaluronic Acid as a predictive marker for Liver Disease, Fibrosis and Cirrhosis

Corgenix Products and Services Worldwide

Corgenix Products and Services are available worldwide. Corgenix has trained Distributors and Representatives in the following countries who can provide the expert assistance you may need.

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For the contact details of the Corgenix distributor in your country please contact sales@corgenix.co.uk

Other Information

General Terms and Conditions of Sale

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Orders are accepted directly by telephone, facsimilie, mail, e-mail, online and in person or via your local Corgenix representative or distributor who are located worldwide. Please state on the order product code, description, quantity, delivery and invoice address (if different) and supply a valid Order Number supported by a VAT Exemption Certificate if appropriate. To order direct please contact:

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Corgenix UK Ltd.
40 Commerce Road
Lynch Wood
Peterborough PE2 6LR
UK

Telephone: +(44) 1733 238400
Facsimilie: +(44) 1733 238412
E-mail: sales@corgenix.co.uk
Web site: www.corgenix.co.uk
VAT Registration Number: GB 657 6399 79

North America (USA, Canada and Mexico)

Corgenix, Inc
11575 Main Street, Suite 400
Broomfield 80020, CO
USA

Telephone: +(1) 800.729.5661 or +(1) 303.457. 4345
Facsimilie: +(1) 303.457.4519
E-mail: info@corgenixonline.com
Web site: www.corgenixonline.com
ISO 13485 : 2003 Certificate number: FM 511119

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All prices quoted in the UK are exclusive of Value Added Tax (VAT) which will be added to all invoices relating to the delivery of goods within the UK. VAT will not be added to invoices for goods where a valid VAT exemption certificate has been supplied. VAT will not be charged on goods purchased in the UK but being exported providing satisfactory evidence of destination is presented. Payment of any import duty and/or local taxes is the responsibility of the purchaser of the goods.

Payment Terms

Terms of sale are net 30 days from the date of invoice, in the currency stated unless otherwise agreed. All remittances should be made direct to our bank and without charges.

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No goods should be returned without first obtaining authorisation from Corgenix. Please notify Customer Services of the need to return product and the reason for return i.e. defective product or product ordered / shipped in error. A Material Returns Authority (MRA) number will be issued by Corgenix authorising the return together with shipping instructions / costs.

Invoicing

All queries relating to invoices should be made within 14 days of receipt of invoice. Corgenix reserve the right to refuse any credit for goods wrongly ordered.

Specification and Warranty

Corgenix reserves the right to modify, change or discontinue any item in this catalogue without notice and at any time. All information presented in this publication is believed to be correct at the time of press. Corgenix warrants the performance of its products when used as described by the Package Inserts included. Corgenix will not be held responsible for any loss incurred caused by the misuse, improper storage and handling of its products.

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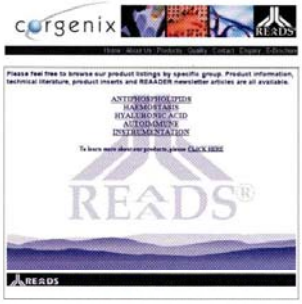

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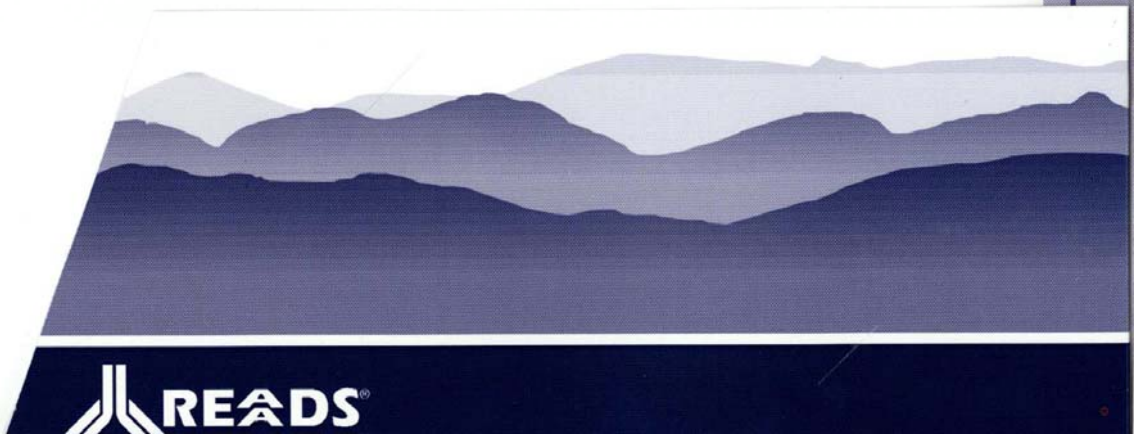
A downloadable copy of our Product E-Brochure is available.



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