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Distributed Products

In the United States, several significant products are distributed by Inverness Medical Professional Diagnostics through agreements with other companies. You can find out more at www.invernessmedicalpd.com

Distributed products include:

AtheNA Multi-Lyte® Test Systems

The AtheNA Multi-Lyte® test system is a breakthrough in diagnostic testing and represents a high-performance step-saving alternative to indirect fluorescent (IFA) and enzyme-linked immunosorbent (ELISA) assays.

The test system may be used as an aid in the diagnosis of patients with various infectious and autoimmune diseases and connective tissue disorders such as systemic lupus erythematosus (SLE), mixed connective tissue disease (MCTD), Sjögren's syndrome, CREST syndrome and myositis. Additional results can be obtained long after the sample is discarded by analyzing data stored within the system.

AtheNA Multi-Lyte systems are multiplexed, fluorescent, bead-based systems designed to perform simultaneous multiple assays from a single sample in one well. They offer a simple and streamlined alternative to IFA and ELISA testing, providing improved clinical sensitivity and comparable clinical specificity in a labor-saving, automation-friendly format. Customized software has been designed for easy data reduction, concise specimen reports and user-friendly data management applications.

In autoimmune diseases, AtheNA Multi-Lyte systems include the AtheNA Multi-Lyte® ANA Test System which simultaneously performs ANA screening and reflex testing for nine specific auto-antibodies (SSA, SSB, Sm, RNP, Scl-70, Jo-1, dsDNA, Centromere B and Histone) in a single well, the AtheNA Multi-Lyte® ANCA Test System, the AtheNA Multi-Lyte® Rheumatoid Factor Test System, and the AtheNA Multi-Lyte® TPO/Tg Test System.

Currently available in infectious disease diagnostics are AtheNA Multi-Lyte systems for two microparticle-based Epstein-Barr virus immunoassays, one for the qualitative detection of IgM class antibody and the other for IgG antibody. The test systems are intended to aid laboratory diagnosis of EBV-associated infectious mononucleosis and to provide epidemiological information on the diseases caused by EBV.

AtheNA Multi-Lyte® is a registered trademark of Zeus Scientific, Inc. All AtheNA Multi-Lyte® serological assays are developed and manufactured by Zeus Scientific, Inc., and distributed by [Inverness Medical Professional Diagnostics](#) in the United States.

DIASTAT™ Anti-CCP

A highly sensitive and specific second-generation peptide-based test, DIASTAT™ Anti-CCP is an ELISA based on the detection of autoantibodies against the cyclic citrullinated peptide (CCP) containing modified arginine residues in human serum or plasma. Enabling early and accurate diagnosis of rheumatoid arthritis (RA), the Anti-CCP assay provides an additional tool in the diagnosis and management of patients with RA.

DIASTAT™ is a registered trademark of Axis-Shield Diagnostics Limited (UK). DIASTAT™ Anti-CCP is manufactured by Axis-Shield, and distributed by Inverness Medical Professional Diagnostics in the United States.

ELISA cardiac risk assessment tests

Homocysteine and Macra™ Lp(a) are ELISA kits that quantitatively measure two important cardiac risk markers: homocysteine and lipoprotein (a). An elevated serum or plasma homocysteine level is increasingly viewed as a strong and independent risk factor for cardiovascular disease. Numerous studies since the early 1970s have associated elevated levels of Lp(a) with increased risk of coronary artery disease. The Lp(a) assay is cleared under 510(k) for monitoring levels of Lp(a) and for predictive coronary risk assessment.

Homocysteine and Macra™ Lp(a) are manufactured by AxisShield and Trinity Biotech Plc (Ireland), respectively, and distributed by Inverness Medical Professional Diagnostics in the United States.

TechLab®

The portfolio of TechLab® products includes rapid non-invasive intestinal diagnostics tests in the areas of intestinal inflammation, antibiotic-associated diarrhea and parasitology.

One cornerstone of TechLab® developments is in vitro diagnostic testing for *C. difficile*. These tests, which range from tissue culture assay reagents to ELISAs and most recently, rapid membrane tests, detect *C. difficile* antigen (glutamate dehydrogenase) and toxins A and B directly in fecal specimens.

C. Diff Tox A/B II™ is a 96well ELISA that can be performed in one hour in the regular format or 30 minutes in the rapid format. *C. Diff Tox B* and the *C. difficile* Toxin/antitoxin kit are also available, and can be used to detect toxin in fecal specimens.

Infectious inflammatory diarrheas are typically caused by *Shigella*, *Salmonella*, *Campylobacter*, and *C. difficile*. Non-infectious inflammatory diarrheas are due to ulcerative colitis and Crohn's disease. The LEUKO-TEST is an in vitro diagnostic aid for the diagnosis of these types of disease.

Tests for the antibody detection of the protozoan parasites *Giardia* spp, *Cryptosporidium* spp, and *Entamoeba histolytica* are also available.

In May 2006 Inverness Medical acquired 49% of the capital stock of TechLab Inc. and Inverness Medical has exclusive global distribution rights to the TechLab product range.

The product portfolio includes:

ELISAs

[*C. Diff Tox A/B II™*](#)

[Giardia II](#)

[E. Histolytica II](#)

[Cryptosporidium II](#)

[Giardia/Cryptosporidium Chek®](#)

[C. Diff Chek 260](#)

[C. Perfringens Enterotoxin](#)

[IBD Chek®](#)

[IBD Scan®](#)

Rapids & Miscellaneous

[C. Diff goat antitoxin](#)

[C. Diff culture filtrate](#)

[C. Diff Toxin/antitoxin](#)

[C. Difficile Tox B](#)

[Faecal Quik prep](#)

[Leuko Test](#)

[IBD-EZ VUE®](#)

[C. Diff Quik Check®](#)

[C. Diff Tox A/B Quik Chek®](#)

[C. Diff Quik Chek Complete™ \(Not currently available in U.S\)](#)