

Product Code	Description
A20001	AtheNA Multi-Lyte® ANA 96 Test Kit
A96001	AtheNA Multi-Lyte® ANCA Test Kit
A91001M	AtheNA Multi-Lyte® RF Test Kit
A51001	AtheNA Multi-Lyte® TPO/Tg Test Kit
A200S	AtheNA Multi-Lyte® Sheath Fluid (1 x 20L)
AX100	AtheNA Multi-Lyte® Calibrators/Controls (4 x 5ml)
AX9001	AtheNA Multi-Lyte® Daily Maintenance Reagents



Contact Wampole Laboratories for a complete list of AtheNA Multi-Lyte® assays, including infectious diseases and other tests under development.

# Autoimmune Testing on the AtheNA Multi-Lyte®



Marketed exclusively in the USA by:



2 Research Way  
Princeton, NJ 08540  
Phone: 800-257-9525  
Fax: 800-532-0295  
www.wampolelabs.com

Manufactured by:



**Zeus Scientific, Inc.**  
P.O. Box 38  
Raritan, NJ 08869  
908-526-3744  
Fax: 908-526-2058  
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For further information or to place an order, contact Wampole Laboratories.

- ANA Test System
- Rheumatoid Factor (RF) Test System
- TPO/Tg Test System
- ANCA Test System



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## The AtheNA Multi-Lyte® Test System. Becoming the new gold standard.

The AtheNA Multi-Lyte® test system uses multiplexing and microsphere-based immunoassay technology to offer a simple and streamlined alternative to subjective IFA and labor-intensive ELISA.

- Based on powerful xMAP® technology, which allows for simultaneous measurement of multiple analytes in a single assay.
- Provides both qualitative and quantitative detection.
- Intra-Well Calibration Technology<sup>†1</sup> provides patient-specific calibration ensuring accuracy and virtually eliminating drift.
- Reduces the number of steps required by 50% when compared to typical IFA and ELISA tests.
- Provides 50-times the confidence of IFA and ELISA<sup>†</sup>.
- Reduces hands-on labor costs by up to 95%<sup>\*</sup>.
- SAVE Diluent™ color-changing diluent assures sample verification and increases confidence that no well is missed.

The AtheNA Multi-Lyte® Test System has the capability to:

- Report individual analytes separately and/or simultaneously.
- Generate additional results long after the sample is discarded, by analyzing data stored within the system.

Wampole Laboratories offers the broadest FDA-cleared xMAP® technology testing menu on the market today – the Autoimmune tests currently available for the AtheNA Multi-Lyte® System, include a 10 test ANA panel, ANCA, RF, and TPO/Tg.

<sup>1</sup>Patent Pending  
<sup>†</sup>At least 50 discrete readings per result as opposed to 1 reading.  
<sup>\*</sup>Data on file.

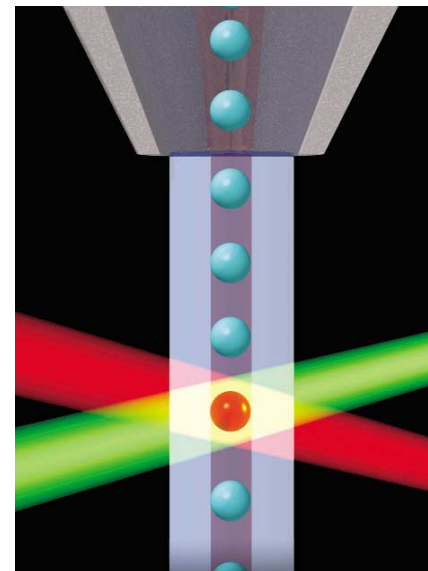
## ANA Test System

Using patented multiplexing xMAP® technology, the AtheNA Multi-Lyte® ANA Test System:

- Simultaneously performs ANA screening and reflex testing for 9 specific auto-antibodies:
  - DsDNA
  - SSA
  - SSB
  - Sm
  - RNP
  - Scl-70
  - Jo-1
  - Centromere-B
  - Histones
- All from one sample. All in one well.

The system provides significant savings in cost and improvements in productivity:

- No need to split samples.
- No need to purchase or inventory 10 different immunoassay kits.
- Test all 10 significant ANA markers with one system, one kit, in one hour.
- Reflex results are more accurate because you perform testing on the same sample at the same time as the ANA screen.
- Report additional auto-antibodies without having to re-test the sample, because you're able to archive all test results.



## Relative Agreement using Routine ANA Requested Specimens\*

Assay Method	Total Samples	Number Positive	Number Negative	Percent Concordance
AtheNA SSA	471	62	409	88%
SSA ELISA	471	56	415	
AtheNA SSB	481	47	434	93%
SSB ELISA	481	15	466	
AtheNA Sm	486	11	475	98%
Sm ELISA	486	4	482	
AtheNA RNP	465	61	404	87%
Sm/RNP ELISA	465	18	447	
AtheNA Scl-70	474	39	435	92%
Scl-70 ELISA	474	2	472	
AtheNA Jo-1	482	27	455	95%
Jo-1 ELISA	482	3	479	
AtheNA dsDNA	462	64	398	86%
dsDNA ELISA	462	43	419	
AtheNA Histone	123	2	121	98%
Histone ELISA	123	0	123	
AtheNA Cent-B	479	45	434	93%
Cent by IFA	479	9	470	
AtheNA Qualitative ANA	470	125	345	80%
ANA by HEp-2	470	78	392	

\*Data derived from 510(k) submission to FDA



## TPO/Tg Test System

- The AtheNA Multi-Lyte® TPO/Tg Test System is used to detect IgG class antibody to Thyroid Peroxidase (TPO) and Thyroglobulin (Tg) in human serum simultaneously in a single well.
- The AtheNA Multi-Lyte® TPO/Tg Test System has been calibrated to standards provided by the World Health Organization (WHO). TPO has been calibrated to WHO 66/387 and Tg has been calibrated to WHO 65/93.

## Rheumatoid Factor (RF) Test System

- The AtheNA Multi-Lyte® Rheumatoid Factor Test System is used to detect Rheumatoid Factor IgM in human serum.
- The AtheNA Multi-Lyte® Rheumatoid Factor Test System has been calibrated to a standard provided by the World Health Organization (WHO). It has been calibrated to WHO 64/2.

## ANCA Test System

- The AtheNA Multi-Lyte® ANCA Test System, is used for the qualitative and semi-quantitative detection of 2 separate IgG class anti-neutrophil cytoplasmic antibodies (ANCA) – Myeloperoxidase (MPO) and Proteinase 3 (PR3) – in human serum simultaneously in a single well.
- The test system may be used as an aid in the diagnosis of various autoimmune vasculitic disorders, such as Wegener's Granulomatosis, ICGN, MPA and PRS.

