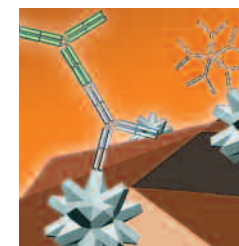




BioPlex™ 2200 ANA Screen with MDSS

The first and only fully-automated,
multiplexed ANA Screen





Like no other

The BioPlex™ 2200 ANA Screen with MDSS detects antibodies of clinical significance — the results that matter.

By detecting only clinically significant autoantibodies, the BioPlex™ 2200 ANA Screen provides the laboratory with more relevant information. These results will help the clinician to better diagnose systemic autoimmune diseases such as Systemic Lupus Erythematosus (SLE), Mixed Connective Tissue Disease (MCTD), Sjögren's Syndrome (SS), Scleroderma (Systemic Sclerosis), Dermatomyositis, Polymyositis and CREST Syndrome.

The BioPlex™ 2200 System uses multiplex technology that permits simultaneous detection and identification of many antibodies in a single tube.

The BioPlex™ 2200 ANA Screen with MDSS reports results for the following:

- ANA Screen*
- dsDNA (quant)
- Chromatin
- Ribosomal Protein
- SS-A (52 and 60)**
- SS-B
- Sm
- Sm/RNP
- RNP (A and 68)**
- Scl-70
- Jo-1
- Centromere B

* ANA Screen is a composite roll up of all individual results.
 ** Individual results available outside US only.

Confidence

Internal Quality Control

For every sample processed, three internal quality control beads dramatically improve confidence in results:

- Serum Verification Bead (SVB) confirms presence of serum/plasma in sample
- Internal Standard Bead (ISB) standardizes detector performance

- Reagent Blank Bead (RBB) identifies sample problems associated with non-specific binding

Full Automation

The fully automated BioPlex™ 2200 enhances quality by minimizing human error.

Efficiency

Novel Multiplex Chemistry

Magnetic bead technology enables thorough washing for improved signal to noise ratios and better overall performance compared to homogeneous methods

Ready-to-Use Multiplexed Calibrators and Controls

Multiplexing reduces hands-on time and significantly reduces the cost per patient result.

High Throughput Capability

Up to 1200 (1400 outside US) results per hour for reduced hands-on time and labor costs.

eFlex™ Software

The BioPlex™ 2200 features a powerful package of software tools that provides optimum flexibility.

KEY BENEFITS INCLUDE:

- “Add-on” of new test orders from previously run patient samples
- Creation of custom ANA panels
- MDSS efficiently and consistently processes numerous antibody results
- Bi-directional LIS connectivity

Quality

Antibodies of Clinical Significance

By targeting only antibodies associated with autoimmune disease, the BioPlex™ 2200 ANA Screen improves clinical specificity, thus reducing the number of false positive results.

Enhanced Performance for SLE Disease

The BioPlex™ 2200 ANA Screen features both anti-Chromatin and anti-Ribosomal P tests for improved detection of SLE and a quantitative anti-dsDNA test for better monitoring of SLE patients.

Medical Decision Support Software (MDSS) for the ANA Screening

The ANA Screen with MDSS is the first and only FDA cleared autoimmune product with an interpretive software algorithm that associates patient antibody results with specific autoimmune diseases. The optional MDSS:

- Combines the power of rapid multiplex testing with consistent analysis of ANA profiles
- Provides valuable information on correlation of patient antibody results with specific autoimmune diseases
- Uses an interpretive algorithm trained with over 15,000 test results from a diverse cohort of over 1400 clinically characterized patients

Comparison with EIA Specific Methods

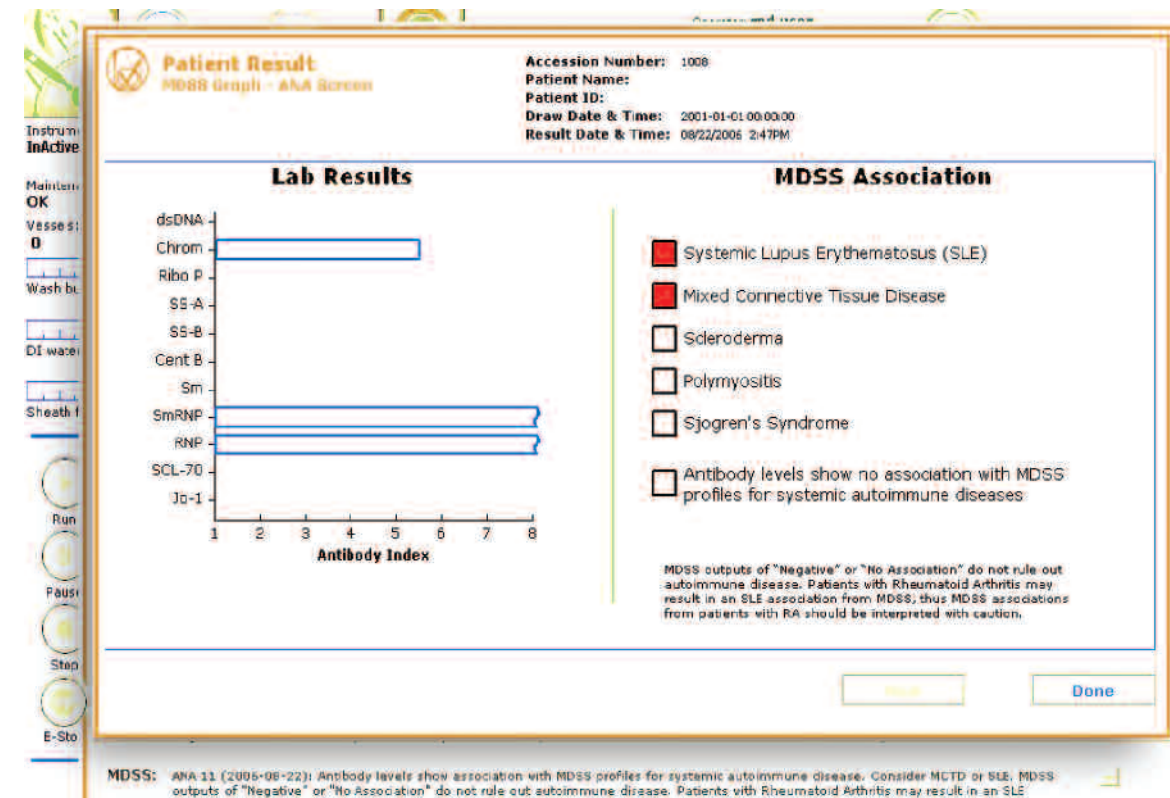
BioPlex™ 2200 ANA Screen vs. Manual EIA

Antibody N=908	Positive Samples	Negative Samples	% Overall Agreement
ANA Screen	351	369	79.3%
dsDNA*	108	724	94%
Chromatin	158	750	86%
Ribosomal Protein	21	887	98%
SS-A	170	738	97%
SS-B	69	839	97%
Sm	40	868	97%
SmRNP	113	795	96%
RNP*	95	784	95%
Scl-70	17	891	98%
Jo-1	11	897	99%
Centromere B	32	876	99%

* dsDNA N = 832 samples with RNP N = 879 samples

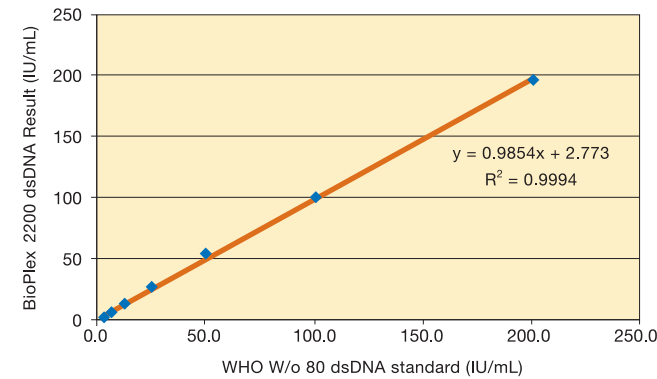
Prospective patient samples were tested for specific autoantibodies with both

BioPlex™ 2200 Medical Decision



Comparison of dsDNA External Standard

WHO W/o 80 Standard



Testing was conducted to assess the quantitation claims of the BioPlex™ 2200 ANA Screen dsDNA assay results. This was carried out using the WHO W/o 80 external standard. Dilution linearity was confirmed with a correlation coefficient of greater than 99.9%.

Reproducibility

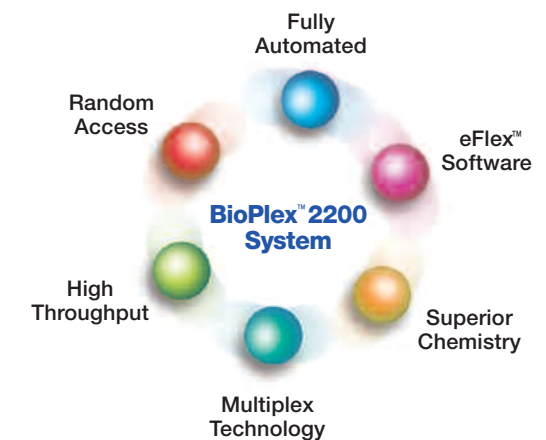
BioPlex™ 2200 ANA Screen

	dsDNA (IU/ml)	Chromatin (AI)	Ribo-P (AI)	SSA-52 (AI)	SSA-60 (AI)	SSB (AI)	Sm (AI)	SmRNP (AI)	RNP A (AI)	RNP 68 (AI)	Scl-70 (AI)	Jo-1 (AI)	Centromere B (AI)
N=40, Site 2													
Mean	24.7	2.3	2.7	2.8	2.8	3.8	3.0	2.7	2.9	3.4	2.4	3.6	2.4
Intra-Assay %CV	2.9	4.1	2.5	4.7	3.5	3.1	3.0	2.5	3.8	4.2	3.2	3.8	3.7
Inter-Assay %CV	7.0	8.3	7.1	8.6	7.3	8.4	7.8	6.8	8.4	8.6	7.3	8.2	8.6

Following CLSI EP5-A guidelines, the BioPlex™ 2200 ANA Screen positive control was run for 10 days for a total of 40 replicates at one clinical site. Overall performance showed intra-assay (within-run) precision between 2.5 – 4.7% CV and inter-assay (between-run) precision between 6.8 – 8.6% CV. This shows excellent reproducibility compared to other multiplex assays, whose inter-assay %CVs range from 5.5 - 42.8%. The low CVs on the BioPlex™ 2200 ANA Screen can be attributed to **a)** full automation, **b)** magnetic bead, heterogeneous format of the assay and **c)** 200 measurements per analyte (up to four times other multiplex methods).

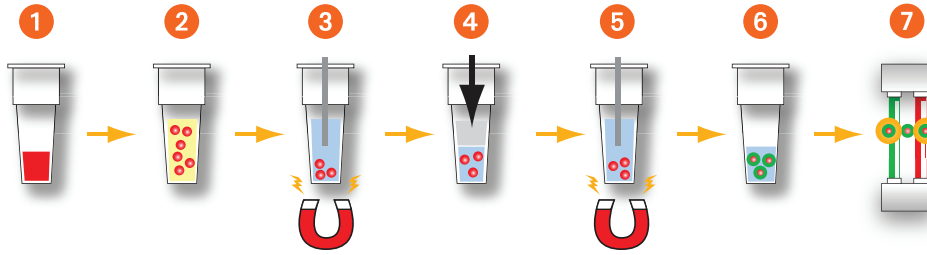
The Medical Decision Support Software (MDSS) uses an interpretive algorithm trained with over 15,000 test results from a diverse cohort of over 1400 clinically characterized patients. When used in conjunction with the ANA Screen, it is an optional laboratory tool that associates patient antibody results with predefined MDSS profiles that have been correlated with the following systemic autoimmune diseases:

- Systemic Lupus Erythematosus (SLE)
- Mixed Connective Tissue Disease (MCTD)
- Sjögren's Syndrome (SS)
- Scleroderma (Systemic Sclerosis)
- Polymyositis.



ANA Screen Assay Procedure

Indirect Assay Format is used for the BioPlex 2200 ANA Screen



1. Patient sample (5 µL) automatically added to reaction vessel
2. Sample diluent & beads (dilution 1:60) added and incubated at 37°C
3. Wash step
4. Conjugate added and incubated at 37°C
5. Wash step
6. Bead resuspended in wash buffer
7. Flow-based, dual laser detection



ANA Screen Reagent Pack

Contains all the necessary reagents (sample diluent, beads and conjugate) to process 100 patients and up to 12 results (14 outside of the U.S.) per patient.



ANA Screen Calibrator Set

Calibrators are ready-to-use and multiplexed. For dsDNA, a six point 4 PL fitted curve is used to calculate quantitative results. For the other analytes, a point-to-point curve fit, using four calibrators, is used to calculate semi-quantitative results.



ANA Screen Control Set

Quality Controls are ready-to-use and multiplexed. The set includes a negative control as well as a multi-analyte positive control containing antibodies present for analytes within the ANA Screen Reagent Pack.

Ordering Information

Catalog No. **Description**

BioPlex 2200 ANA Screen

665-1150	ANA Screen Reagent Pack	1 pack
665-1160A	BioPlex 2200 ANA Screen with MDSS Instructions For Use	1 pkg
663-1100	ANA Screen Calibrator Set	1 set
663-1120	ANA Screen Calibrator Set CD	1 CD
663-1130	ANA Screen Control Set	1 set
663-1140	ANA Screen Control Set CD	1 CD

BioPlex 2200 System and Bulk Reagents

660-0000	BioPlex™ 2200	1 instrument
660-0800	Sample Racks (30 per box)	1 box
660-0801	Sample Tray	1 tray
660-0817	Instrument Sheath Fluid (2 per box)	1 box
660-0818	Instrument Wash Buffer	1 box
660-2003	Reaction Vessels (1000 per bag)	1 bag
666-0001	Instrument Detector Calibration Pack ...	1 pack
666-0002	Instrument Detector Clean Pack	1 pack
666-0003	Instrument Probe Cleaning Solution (4 per box)	1 box



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*Clinical
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