



PRONOSTICS
Knowledge for Health

UltraPlex™ ANA

Multiplexing just went digital...

Pronostics present the first fully
barcoded immunoassay for
simultaneous testing of multiple
autoimmune disease biomarkers.

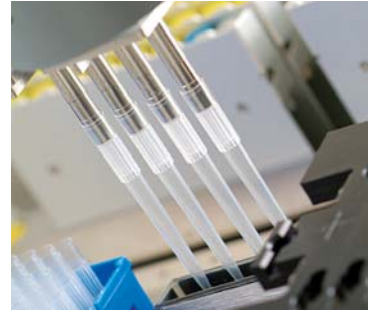
Pronostics Ltd. is an ISO 13485:2003 certified company

www.pro-nostics.com

www.ultraplex.com

UltraPlex™ ANA

Autoantibodies, including those against ANA (Anti Nuclear Antigens) occur with high frequency in the serum of patients with connective tissue disorders and rheumatic diseases. Results of serologic tests for detection of these autoantibodies, including antibodies to specific nuclear antigens such as double-stranded DNA (dsDNA), play an important role in the diagnosis of systemic rheumatic diseases.



Most laboratories use indirect immunofluorescence (IIF) for ANA testing. Reading IIF patterns is time consuming, subjective, prone to misinterpretation and can be difficult even for the most experienced technologist. The difficulty in pattern interpretation highlights the need for autoantigen-specific immunoassays for diagnosis.

UltraPlex™ ANA simultaneously tests for 10 key autoantibodies using walk-away digital multiplexing technology, eliminating subjective errors and freeing up the time of skilled staff.

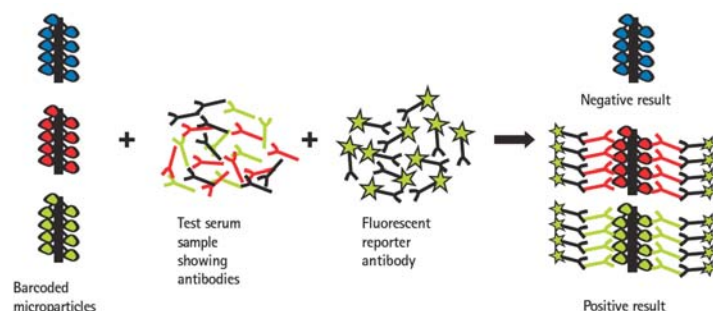
The UltraPlex™ ANA digital multiplex immunoassay identifies autoantibodies against the following 10 antigens in patient samples: Centromere, SS-A (60 kDa), SS-A (52 kDa), SS-B, Scl-70, Jo-1, Sm, SmRNP, RNP-70 and dsDNA.

The ten ANA antigens are each individually tagged with uniquely coded microparticles - UltraCodes. An uncoated microparticle (Qmax zero) is also included and used as an internal reference control in the multiplexed test. This greatly reduces false positive results, particularly those seen in patients suffering from SLE and other similar indications. The combination of physically barcoded UltraCodes and UltraPlex™ SmartDecode software provide error-free tracking of each microparticle and therefore allow mixing of all ANA antigens and Qmax zero. For ease of use and long-term stability, these reagents are supplied lyophilised as a single SmartBead in each well of a microtitre plate.

The assay procedure, including patient sample dilution, addition of reagents and determination of results is fully automated. The combination of the UltraPlex™ SmartStation liquid handling robot and UltraPlex™ SmartReader barcode scanner eliminate sample handling and processing time and provides a total walk-away solution.

Figure 1

UltraPlex™ components and assay results.



Product Presentation

UltraPlex™ SmartReader.



UltraPlex™ ANA is supplied in a 96-well plate format and includes all the necessary reagents and controls for processing 80 patient samples. The barcoded antigens and Qmax zero internal reference standard are supplied ready-to-use in a lyophilised SmartBead.

The UltraPlex™ system includes the UltraPlex™ SmartStation liquid handling robot and UltraPlex™ SmartReader, the combination of which provides a fully automated assay procedure and data acquisition process. The UltraPlex™ SmartReader employs Pronostics' user-friendly SmartDecode software to accurately measure and report test results in a range of user-selected formats, which can be directly fed into the user's LIMS system.

UltraPlex™ ANA

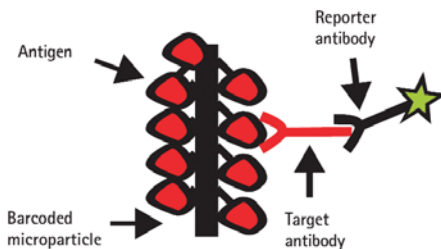
- No specialist training or experience required
- Consistent results, both within an assay and between users
- Assay and hardware not affected by temperatures from 15 to 32°C
- Generates full 10-antigen profile for 160 patients per 8 hour day
- Test employs recombinant and highly purified antigens
- No need for confirmation of results through ELISA (sensitivity >90%)
- Internal reference standard Qmax zero reduces false positive results (specificity >95%)

UltraPlex™ dsDNA

- 6-point standard curve with each 96-well kit
- Calibrated against WHO Wo/80 reference standard
- Results show excellent agreement with Crithidia anti-dsDNA assay
- Positive and negative controls included in the kit
- Working range from 10 to 500 IU/ml, sensitivity 10 IU/ml
- Linear across working range (observed over expected 108%, range 87% to 125%)

Figure 2

Positive antigen - antibody interaction



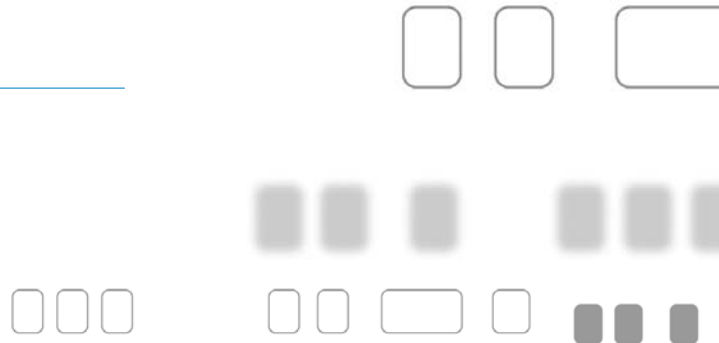
Fast facts and benefits

- Multiplexed assay increases productivity and provides compelling economic benefits
- Miniaturisation reduces reagent and sample volumes
- Simultaneous assays performed under uniform conditions
- 96-well microtitre plate format with standardised protocols
- Multiplexed reagents ready for use in each well
- Lyophilised SmartBeads provide stability and reproducibility
- Internal reference standard Qmax zero greatly reduces false positives
- Minimal “hands-on” time facilitated by the UltraPlex™ SmartStation
- UltraPlex™ SmartReader provides automated generation of results
- Validated against CDC human reference sera panel and multiple panels of clinical samples
- dsDNA standardised against WHO Wo/80 reference material
- Digital multiplexing provides error-free decoding
- UltraPlex™ ANA assay system is temperature independent from 15 to 32°C



Follow-on UltraPlex™ assays

- | | |
|-------------------------|-------------------|
| • UltraPlex™ Thyroid | Available now! |
| • UltraPlex™ Coeliac | Available now! |
| • UltraPlex™ Rheumatoid | Under development |
| • UltraPlex™ Liver | Under development |
| • UltraPlex™ Vasculitis | Under development |
| • UltraPlex™ APS | Under development |



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