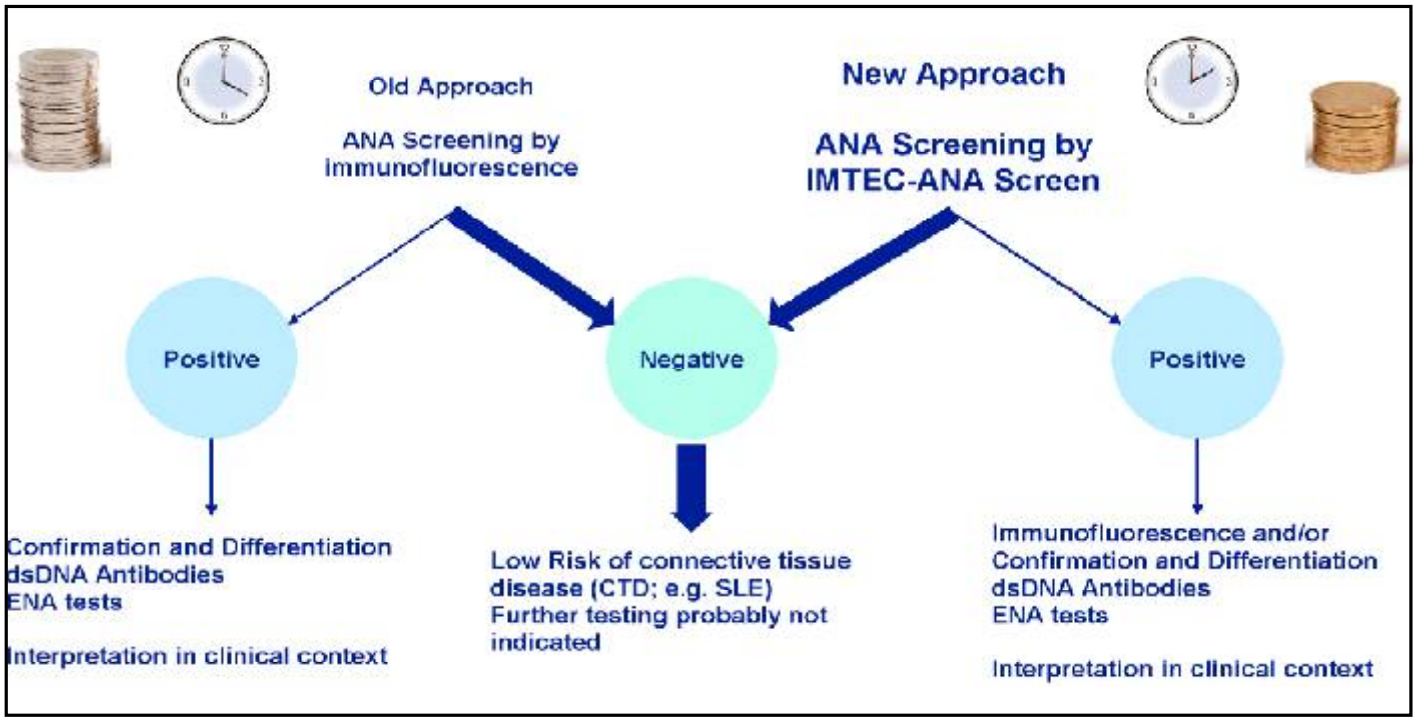
The New Benchmark for ANA Screening

The growing volume of antinuclear antibody (ANA) tests in routine laboratories requires cost- and time-efficient techniques whilst maintaining a high sensitivity and specificity. The IMTEC-ANA-Screen is an automatable alternative to traditionally used immunofluorescence and shows performance superior to other ANA Screen ELISA tests in the market.

The determination of ANA forms the mainstay of laboratory diagnosis of systemic rheumatic diseases such as: Systemic Lupus Erythematosus (SLE), Mixed Connective Tissue Disease (MCTD), Dermato- and Polymyositis, Scleroderma and CREST Syndrome. Conventionally, the test is carried out on human epithelial cells (HEp2) using the indirect immunofluorescence technique (IFT).

With the increasing awareness of autoimmune diseases among physicians, ANA tests are considered to be a screening test in current clinical practice. This has a major impact on laboratory work with the growing volume of analyses that need to be performed rapidly whilst maintaining good sensitivity and specificity.

Detection of ANAs by IFT is a sensitive but subjective and labor-intensive technique, in which expertise in interpretation is of great importance. ELISA tests for the qualitative detection of antinuclear antibodies in up to 90 patient samples on one microplate allow an objective, standardized and automated high-throughput analysis. ANA screening with ELISA thereby reduces costs and turn-around time, enabling skilled staff to concentrate on positive and specific cases.

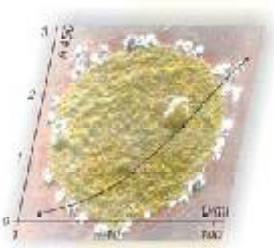


Several commercially available ELISA tests have been reported to have limitations in epitope repertoire, sensitivity, and specificity. Principally, three different approaches can be differentiated that differ significantly in their diagnostic performance:

> Best Performer: IMTEC-ANA Screen

Intact cell nuclei supplemented with cytoplasmic antigens

This approach is based on a highly efficient presentation of all relevant antigens imitating a natural matrix and composition. This guarantees a superior diagnostic performance to the following approaches.



→ *To be continued on page 9*

Sequel to page 8

> Good performer: e.g. Diasorin, INOVA

Total cell extracts of HEp-2 or HeLa cells

The high antigen load leads to a high, unspecific background signal and therefore false negative and false positive results are frequently observed.

> Medium Performer: e.g. Phadia, Euroimmun, Biorad

Mixture of purified antigens

The limited number of antigens ensures a good specificity, but conscious exclusion of unknown or rare nuclear antigens will lead to false negative results.

The IMTEC-ANA Screen assay is uniquely based on the covalent binding of entire human cell nuclei and additional cytoplasmic antigens (e.g. Jo-1, mitochondria) to the microplate. This innovative approach has proven to be superior to other commercially available assays in the market in terms of sensitivity and specificity.

With its IMTEC product line, HUMAN GmbH offers a broad range of quantitative and qualitative tests for the determination of antinuclear autoantibodies for the diagnosis of systemic rheumatic diseases. Become acquainted with our values.

IMTEC-ANA Screen	ITC60001/ITC70001
IMTEC-dsDNA-Antibodies	ITC59001
IMTEC-ENA Screen	ITC60002/ITC70002
IMTEC-ENA Profile	ITC60033
IMTEC-ANA-LIA	ITC92000
IMTEC-ANA/dsDNA-LIA	ITC92001