DiYaLab ZJG

Rapid Autoantibody Screening Solution

Accessible For Anywhere

Affordable For Anyone

Seeking Medical Truth
and Safeguarding Human Health

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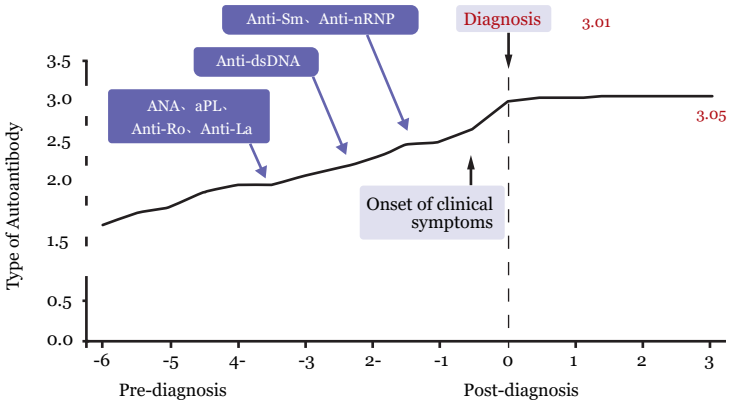
01 The Growing Burden of Autoimmune Diseases

Autoimmune diseases (AIDs) have become a significant and escalating global public health challenge, characterized by immune-mediated inflammation and tissue damage. According to a 2023 study published in The Lancet, nearly **10.2%** of the global population is affected[1]. The World Health Organization (WHO) has identified AIDs as the third leading "killer" threatening human health. The diagnostic journey for AIDs is often prolonged due to non-specific clinical presentations and limitations of conventional screening methods, resulting in delayed interventions and poorer patient outcomes , and cause a heavy socioeconomic burden. Therefore, identifying efficient and practical early screening approaches is a pressing need to break the deadlock in current clinical practice.

02 Autoantibody Screening —The Irreplaceability From Early Warning to Intervention

Autoantibodies are core biomarkers of AIDs and can often be detected years before clinical symptoms appear, provides a critical window for early disease warning[5]. Substantial research confirms that the appearance of many critical autoantibodies precedes clinical onset by years, for instance

- **9.4 years** before patients exhibit clinical symptoms. SLE-associated autoantibodies can test positive[2].
  - ANA, aPLs, anti-Ro, and anti-SSA/SSB appear earliest, average 3.4 years before diagnosis.
  - Anti-Sm and anti-nRNP emerge latest, average 1.2 years before diagnosis.
- **4.5 years** prior to symptom onset in RA patients, Anti-CCP antibodies are detectable.
- **10 years** before any clinical signs or abnormal laboratory findings in PBC patients, AMA-M2 can test positive.



Therefore, screening for autoantibodies in high-risk populations or in patients with non-specific symptoms, represents a crucial intervention during a "golden window of opportunity." Early diagnosis allows for timely monitoring and preventive treatment, which can significantly slow disease progression, reduce the risk of irreversible organ damage, improve long-term outcomes, and ultimately alleviate the burden on both individuals and society.

03 Challenges of Current Screening Technologies

The current adopted detection methods for autoantibodies,such as Indirect Immunofluorescence (IIF) and Immunoblotting, present significant barriers to widespread screening

- **High technical barriers:** Requiring specialized laboratories and trained personnel.
- **Long turnaround times:** Hours to days.
- **Significant subjective interpretation:** Difficult to standardize.
- **High costs and limited accessibility:** Especially in resource-limited settings.

These constraints severely hinder the expansion of screening programs, with the majority of at-risk individuals remaining undiagnosed prior to the onset of irreversible organ damage.

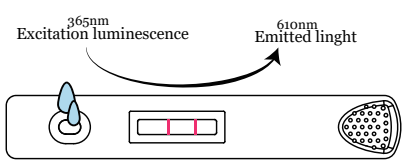
04 The 15-Minute Rapid Autoantibody Test —Break Down Barriers of Traditional Screening

Addressing these challenges, DiaYaLab innovatively developed and launched 15-minute Autoantibody Rapid Test, and It represents a paradigm shift in diagnostic accessibility for AID, this innovative technology offers:

- **Efficiency:** Results are available within 15 minutes, meeting the need for rapid clinical decision-making.
- **Operational Simplicity:** Typically requires only a small sample of fingerstick blood or serum, with straightforward steps and no additional consumables.
- **High Accessibility:** Low technical barriers and minimal cost enable universal implementation across the healthcare system, from large hospitals to small clinics.

This innovation makes large-scale, systematic autoantibody screening feasible across wider demographics, which is especially critical for the early detection of individuals at high risk for autoimmune disorders.

TRFIA Testing Procedure



Sample ID:***
Sample type: whole blood
Test:ANA
Test result: 56.6 U/mL
Reference range:≤20U/mL

Sample collecting | Incubation 15 min | Result reading , 10s | Printing & uploading

05

ANA Rapid Testing —The Key to Unlock Effective High-risk Screening For Immune Disorders

As a cornerstone of screening, Antinuclear Antibody (ANA) testing offers unparalleled universality. It is detectable in nearly all systemic autoimmune diseases, such as systemic lupus erythematosus (SLE), Sjögren's syndrome, and systemic sclerosis. International guidelines, including those from the American College of Rheumatology, recommend ANA as a first-line screening tool for patients suspected of having autoimmune disorders. By identifying ANA-positive individuals early and conducting targeted follow-up and further investigations, the time to diagnosis can be significantly shortened. This allows treatment to begin before irreversible organ damage occurs, markedly improving long-term patient outcomes and fundamentally reducing both disease-related disability and societal care costs.

In 2020, An American study revealed that from 1988 to 2012, the ANA positivity rates in the U.S. general population were as follows: 11.0% (1988–1991), 11.5% (1999–2004), and 15.9% (2011–2012), demonstrating an upward trend over the years. Additionally, ANA positivity was associated with gender and age: overall, females had a higher ANA positivity rate than males, and the rate gradually increased with age[3].

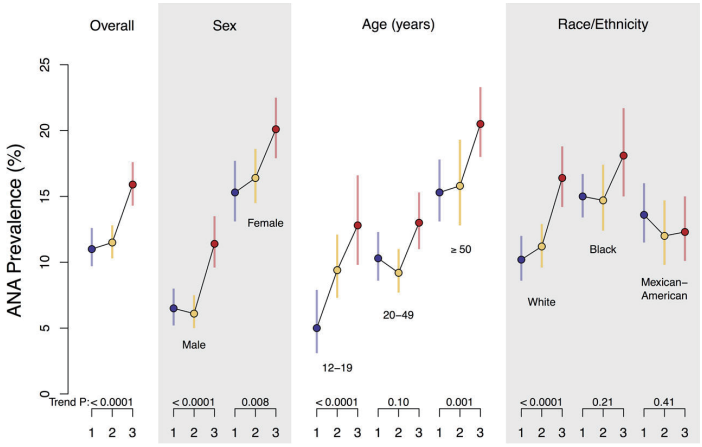


Figure 2: Prevalence of antinuclear antibodies (ANA) in the U.S. population

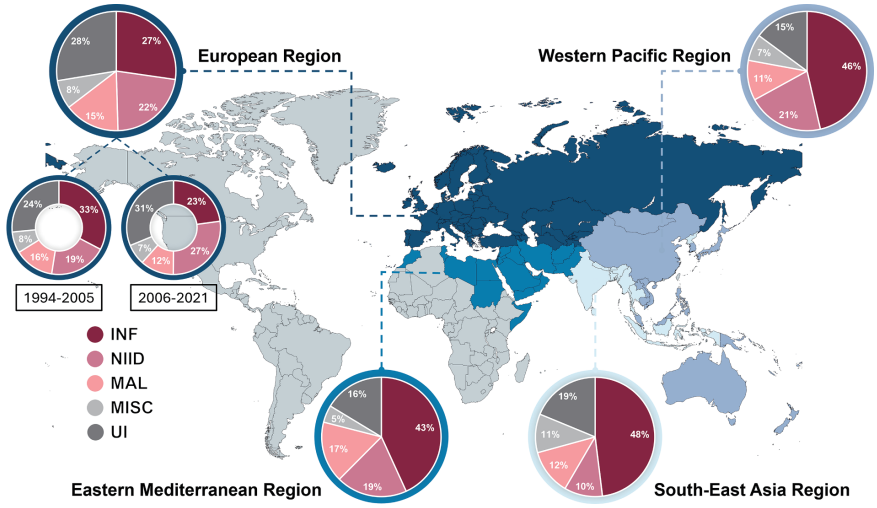
06

Fever of Unknown Origin (FUO) —A Critical Clinical Entry Point for ANA Screening

Epidemiology and Etiology of FUO

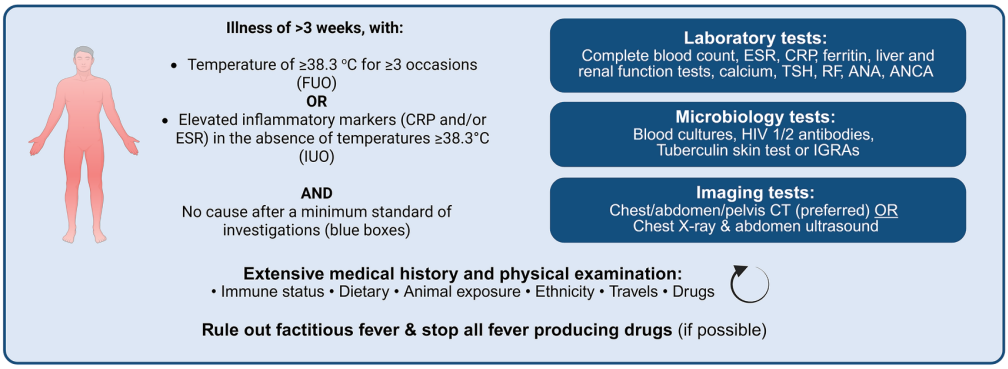
- In clinical practice, "Fever Of Unknown Origin" is one of the most common entry points for initiating ANA screening. FUO defined as fever >38.3°C lasting over three weeks without an initial diagnosis.

- Recent studies show that FUO accounts for up to 3 % of hospital admissions. The causes of FUO are often common diseases presenting with atypical symptoms. The classical five category system used to stratify the etiology of FUO includes: infectious diseases (INF), on-infectious inflammatory diseases (NIID), malignancies (MAL), miscellaneous diseases (MISC) and undiagnosed illnesses (UI). And also studies results indicate a significant increase in the proportion of fever cases attributable to NIID and UI in recent years., which counts for 15-30% of FUO cases making them a leading differential after infections[4].



Classical Diagnostic Approach for FUO

- Based on the latest Delphi consensus, the systematic inclusion of **C-reactive protein (CRP), serum ferritin (Fer), and antinuclear antibody (ANA)** testing in the standardized initial laboratory workup for FUO, has been established as a core strategy to significantly enhance diagnostic efficiency. This combination enables parallel screening of the three major etiological categories—infection, autoimmune disease, and malignancy—facilitating early risk stratification and streamlining the diagnostic pathway[4].



- **Combined CRP-Fer-ANA Testing Optimizes Early Differentiation and Diagnostic Efficiency in FUO**
  - **Rapidly narrow down the differential diagnosis**
    - **Infection/Acute Inflammation:** Elevated **CRP**, especially when interpreted alongside PCT, prioritizes the search for bacterial infections or acute inflammatory states.
    - **Autoimmune Diseases:** Positive ANA (moderate-to-high titer) raises suspicion for connective tissue diseases (e.g., SLE), even without classic symptoms.
    - **Malignancies and Inflammatory Syndromes:** Extremely high ferritin (>1000 μg/L, notably >5000 μg/L) strongly suggests Adult-Onset Still ‘s Disease or hemophagocytic syndromes, often linked to lymphoma.
  - **Optimize the Efficiency of Clinical Diagnosis and Treatment.**
    - **Shorter Diagnosis Time:** The triad moves beyond sequential exclusion, offering early categorical clues that streamline advanced testing (imaging, biopsies, etc.), avoiding unnecessary steps.
    - **Cost-Effectiveness:** Low-cost tests guide targeted use of higher-cost or invasive procedures, optimizing resources and reducing patient burden.

07

Performance of DiYaLab TRIFA ANA Rapid Detection Assay

Sensitivity of the TRFIA ANA assay against clinically confirmed diagnosis samples (confirmed with multiple diagnostic methods).(N=491 with clinical diagnosis)

- Not all samples underwent IFA testing, so the sensitivity was not calculated here.
- Methods used for confirmation included: Immune Blot, ELISA, RIA and flow cytometry multiplex fluorescence.
- TRFIA ANA Rapid Assay shows high sensitivity in these sample with diagnosis confirmed through a multi-method approach.

Disease Name	Sample No.	IFA	Confirmed with multiple methods	Sensitivity%	DiYaLab TRFIA ANA	
		Positive No.	Sample No. Confirmed Positive		Positive No.	Sensitivity%
SLE	62	59	62	100.00%	60	96.77%
SS	38	28	34	89.47%	34	89.47%
MCTD	24	8	23	95.83%	24	100.00%
SSC	56	45	52	92.86%	50	89.29%
RA	43	22	13	30.23%	21	48.84%
MDA5+KL-6	188	25	87	46.28%	92	48.94%
ASS	80	39	63	78.75%	72	90.00%

Performance of TRFIA Rapid ANA Assay Compared to Immune Blot for Outpatient Radom Samples (N=510)

- 2 samples tested positive by immune Blot, but DiYaLab ANA negative, also show negative result conformed by IFA ANA. It means Immune Blot results for these 2 sampls are false positive
- 10 samples tested negative by Immune Blot, but DiYaLab ANA positive.
  - 1 sample has confirmed diagnosis (SS), Immune Blot test result shows false negative.
  - 5 samples show positive restult tested by with multiple methods. Immune Blot result show false negative. The rest 4 samples should be DiYaLab false Positive.

		Immune Blot (15 assays)				DiYalab ANA (Cutoff＜20U/ml)	Immune Blot	Confirmed with multiple methods
		Positive	Greyzone	Negetive	Total			
DiYaLab ANA	Positive	46		10	56	23.34	Negative	Positive
	Greyzone	1	5	1	17	23.97	Negative	Clinical Positive
	Negetive	2		435	437	22.59	Negative	
	Total	49	5	456	510	20.71	Negative	Positive
	Neg accordance%		97.75%			20.19	Negative	
	Pos accordance%		95.83%			21.53	Negative	
						20.77	Negative	

Column1	Immune Blot	DiYaLab ANA
Specitivity	88.68%	100.00%
Specitivity	99.56%	99.12%

23.38	Negative	Positive
102.09	Negative	Positive
22.32	Negative	Positive

Performance of TRFIA Rapid ANA Assay Compared to IFA for Physical Examination Samples (N=584)

- 18.73% Positive rate tested by IFA ANA testing in 584 physical examination samples.
- 3.2% Positive , and 2.9% grey-zone rate tested by DiYaLab ANA in 584 physical examination , So DiYaLab Rapid ANA Assay is better suited for screening in general health examinations.

Column1	IFA	7 ENA Assay	DiYaLab ANA
Negetive	324	584	548
GreyZone	90		17
Positive	107		19

IFA Positive%	IFA		DiYaLab ANA	
			Neg	Pos
	Total	584	548	36
	Neg	387	375	12
33.73%	1:40	90	80	10
18.32%	1:80	61	54	7
7.88%	1:160	23	21	2
3.94%	1:320	7	7	0
2.74%	1:640	5	4	1
1.88%	1:1280	9	6	3
0.34%	1:2560	2	1	1

Reference

[1] Conrad N, et al. Incidence, prevalence, and co-occurrence of autoimmune disorders over time and by age, sex, and socioeconomic status: a population-based cohort study of 22 million individuals in the UK. Lancet. 2023.

[2] Arbuckle MR, McClain MT, Rubertone MV, Scofield RH, Dennis GJ, James JA, Harley JB. Development of autoantibodies before the clinical onset of systemic lupus erythematosus. N Engl J Med. 2003 Oct 16;349(16):1526-33. doi: 10.1056/NEJMoa021933. PMID: 14561795.

[3] Dinse GE, Parks CG, Weinberg CR, Co CA, Wilkerson J, Zeldin DC, Chan EKL, Miller FW. Increasing Prevalence of Antinuclear Antibodies in the United States. Arthritis Rheumatol. 2020 Jun;72(6):1026-1035. doi: 10.1002/art.41214. Epub 2020 Apr 30. PMID: 32266792; PMCID: PMC7255943.

[4] Antoniadou C, Gavriilidis E, Chatzopoulos P, Gkouliavera M, Skendros P. Fever and inflammation of unknown origin in the 21st century. Eur J Intern Med. 2025 Dec;142:106443. doi: 10.1016/j.ejim.2025.106443. Epub 2025 Aug 20. PMID: 40841245

[5] Catharina Eriksson, Heidi Kokkonen, et al. Autoantibodies predate the onset of systemic lupus erythematosus in northern Sweden. Arthritis Research & Therapy 2011, 13:R30.

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