ASSESSMENT OF THE POSSIBLE ROLE OF MICRO-ARRAY TESTING IN THE DIAGNOSTIC FLOW-CHART OF A SPECIALIST REFERRAL LABORATORY FOR AUTOIMMUNE DISEASES

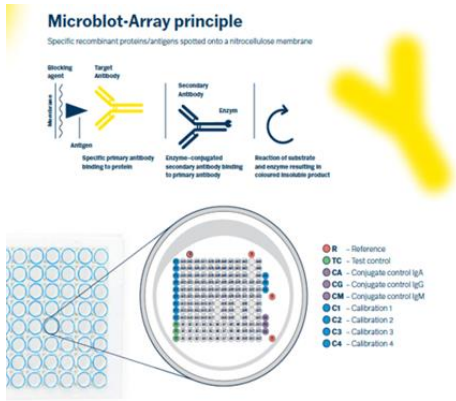
Giulia Maria Picone, Barbara Donati Marello, Paola Merlach, Giulio Mengozzi, Tilde Manetta
Clinical Biochemistry Laboratory, Città della Salute e della Scienza University Hospital of Turin, Italy

Background and Aims

Antinuclear antibodies (ANA) are tested by indirect immunofluorescence (IIF) combined with solid-phase immunoassay; based on these first-level tests, second level investigations, such as immunoblots, should be performed to identify different antigens. The aim of this study was to compare our routine diagnostic workup with a new micro-array approach.

Methods

Our routine flow-chart includes IIF and EliA 16 antigen CTD screening on Phadia™ 2500 platform (ThermoFisher Scientific) eventually followed by one or more immunoblots (ANA DFS70, SSc, myositis, autoimmune hepatitis; Euroimmun). Microblot-Array ANA kit (TestLine Clinical Diagnostic s.r.o., Brno, Czech Republic, distributed by Pantec) adopts iCHIP® technology to detect 44 antigens.



Results

First, we assessed 63 selected sera from our routine. The overall agreement between Microblot-Array and either the combined (IIF + CTD) or the triple approach including second-level blots was 54.0% and 52.4%, respectively. As compared to our screening test 24 samples resulted negative with Microblot-Array and 5 samples were positive only with the array system. Among discrepant results, Mi-2, YARS, P0, OJ and RNPs specificities appeared the most frequently involved. We then tested 92 daily routine samples. The agreement between Microblot-Array and the combined approach (IIF + CTD) increased to 64.1%, half of results being negative with both testing protocol and 13 positive only with Microblot-Array.

IFI ANA + CTD			
ARRAY TESTLINE		POSITIVO	NEGATIVO
	POSITIVO	32	5
	NEGATIVO	24	2

ANA IFI + CTD + IMMUNOBLOT			
ARRAY TESTLINE		POSITIVO	NEGATIVO
	POSITIVO	33	3
	NEGATIVO	27	0

ANA IFI + CTD			
ARRAY TESTLINE		POSITIVO	NEGATIVO
	POSITIVO	13	13
	NEGATIVO	20	46

Conclusions

Although preliminary, these results suggest that new Microblot-Assay may be considered as either a complementary or confirmatory tool rather than a screening test. Taking advantage of the multiple antigen mix, at least in part avoiding the need of different blots, its role should be prospectively validated in an unselected clinically characterized population.

The microblot-array can be considered in prospective studies:

- As screening tests we are not yet sure, we need further studies.
- As confirmation test there very doubts.
- As IFI o CTD support tool seems to be perfect.

Radin M, Sciascia S, Cecchi I, Mengozzi G, Roccatello D. The potential role of SLE-key test in identifying patients with Systemic Lupus Erythematosus: Results from a prospective, real-word experience. Eur J Intern Med. 2019 Oct;68:e12-e14. doi: 10.1016/j.ejim.2019.07.026. Epub 2019 Aug 2.

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AZIENDA OSPEDALIERO - UNIVERSITARIA Città della Salute e della Scienza di Torino