

INVESTIGATION OF ANA SCREENING METHODS IN THE DIAGNOSIS OF AUTOIMMUNE DISEASES

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Background

Antinuclear antibodies (ANA) detection is important in the diagnosis of several autoimmune diseases and indirect immunofluorescence (IIF) on HEp-2 cells is the most commonly used method, which is however affected by several pitfalls. Automated ANA readers have been recently proposed, but some limitations still endure and new ANA solid phase assays (SPA) on automated closed platforms are evolving. The aim of this multi-center study was to evaluate ANA screening in patients with a diagnosis of systemic autoimmune diseases and regular follow-up by a novel SPA compared to IIF.

Methods

270 well defined autoimmune patients were recruited. Control groups included 34 non-autoimmune pathological controls and 62 healthy donors. ANA screening was performed using QUANTA Flash CTD Screen Plus (BIO-FLASH instrument, Inova Diagnostics, San Diego, USA) which includes the most relevant nuclear/cytoplasmic antigens. ANA were also detected by HEp-2 IIF with both visual and automated interpretation (NOVA View, Inova Diagnostics).

Results

The comparison between SPA and IIF showed a good overall (83.1%) and negative agreement (88.8%) with a slightly lower positive concordance (81.0%). The agreement markedly improved after RA patients were excluded, as the SPA does not include RA specific antigens. Looking at diagnosis, the SPA displayed comparable specificity and lower sensitivity vs IIF (Table 1).

Agreement	SPA vs. IIF	SPA vs. IIF (excluding RA)
% Positive Agreement (95% CI)	81.0% (73.4–83.0%)	87.1% (82.9–91.4%)
% Negative Agreement (95% CI)	88.8% (82.5–95.0%)	89.1% (82.8–95.5%)
% Overall Agreement (95% CI)	83.1% (76.6–84.9%)	87.7% (84.2–91.2%)
Cohen's <i>kappa</i>	0.62	0.71

Conclusions

The QUANTA Flash CTD Screen Plus shows good agreement with IIF especially when RA patients are not considered. Further studies are needed, preferably on diagnostic samples, to define the potential position of the new SPA in ANA testing algorithms.