Clinical performance of three automated screening assays for antibodies against nuclear antigens

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BACKGROUND
Connective tissue disease (CTD) is a synonym for a group of systemic autoimmune diseases with many similar clinical features. The analysis of patient samples for autoantibodies against nuclear antigens (ANA) and extractable nuclear antigens (ENA), a subset of ANA, represent an important aid in the diagnosis of CTD, e.g. Sjögren’s Syndrome (SS), Systemic Lupus Erythematosus (SLE), Systemic Sclerosis/Scleroderma (SSc), Polymyositis (PM) and Mixed Connective Tissue Disease (MCTD) [1].

Solid phase assays for screening patient serum samples for autoantibodies against ANA and ENA are commercially available under various names, e.g. Ro52 and Jo-1, to detect autoantibodies that have been reported to be frequently missed by immunoassays assays (IFA) [2]. Besides in their antigen composition, commercially available solid phase assays also differ in the source of the included antigens (native vs recombinant vs peptides).

The Thermo Scientific EliA® Symphony assay is a newly developed ENA screening assay that differs from other ANA/ENA screening assays by comprising only recombinant human proteins and a synthetic SmD2 peptide but no antigens from native sources [3, 4]. Previous studies reported that using recombinant proteins and the synthetic SmD2 peptide, improved the clinical performance of antibody assays by leading to an increased specificity [3, 10, 11].

AIMS
Using a defined serum panel of patients clinically diagnosed with various CTD as well as various disease controls, this study aimed to analyze the clinical performance of the EliA® Symphony assay [3, 4]. Additionally, its clinical performance was compared to two assays for the detection of ANA/ENA from different manufacturers that have a similar antigen composition (Table 1). The INOVA Diagnostics QUANTA Flash™ ENA assay is comprised of recombinant native and native antigens but excludes CENP-B in its analytic composition [5], while the A.Menarini Zenith RA™ ANA Screen assay has the same analytic composition as the EliA® Symphony assay plus dsDNA but their source (recombinant or native) were not indicated in the instructions for use [7].

METHODS
To analyze and compare the clinical performance, a serum panel comprising 404 samples from patients diagnosed with SLE, SjS, SSc, PM/DM and MCTD and 229 disease controls (Table 2) was analyzed with the EliA® Symphony assay and the two screening assays from the other manufacturers (Table 1). All samples were measured according to the manufacturers’ instructions. The reported results were analyzed using the commercial software Microsoft Excel and Analysys I. Graphpad Prism 4.

RESULTS I – CLINICAL PERFORMANCE

Table 1: Overview of the assays analyzed in this study. The included analytes and their source (recombinant, native or peptide) as well as key features are indicated as mentioned in the respective instructions for use [4-7].

Table 2: Overview of the serum panel analyzed in this study.

REFERENCE
5. INOVA Diagnostics Inc 518(s). - K:129023.
6. INOVA Diagnostics Inc. QUANTA Flash® ENA. - 70158. 2012:62155SSU.

TRADEMARKS
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