EliA SymphonyS – the first fully automated random access assay using only recombinant human antigens and a synthetic SmD peptide to screen for autoantibodies against extractable nuclear antigens (ENA)

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BACKGROUND

Connective tissue diseases (CTDs) are a group of closely related multisystem conditions with many similar clinical features. The diverse and overlapping symptoms, particularly early in the course of the disease, make diagnosis challenging [1, 2]. The screening of patients for autoantibodies against the so-called extractable nuclear antigens (ENA), a subset of antinuclear autoantibodies (ANA), are an important aid in the diagnosis of CTDs, e.g. Sjogren’s Syndrome (SS), Systemic Lupus Erythematosus (SLE), Systemic Sclerosis/Scleroderma (SSc), Polymyositis/DERMATOMYOSITIS (PM/DM) and Mixed Connective Tissue Disease (MCTD) [1].

OBJECTIVE

Using a defined serum panel of patients clinically diagnosed with CTD as well as various disease controls, we aimed to analyze the clinical performance of EliA SymphonyS® and to compare it with the QUANTA Flash® ENA7 assay (INOVA Diagnostics), which is comprised of recombinant and native antigens, but excludes CENP-B in its analytic composition [5].

METHODS

A serum panel comprising 404 samples from patients diagnosed with SLE, SS, SSc, PM/DM and MCTD and 229 disease controls was analyzed with both EliA SymphonyS® and the screening assay from the other manufacturer to analyze and compare clinical performance.

RESULTS – CLINICAL PERFORMANCE

Table 1: Overview of antigens used in the tests analyzed in this study [4-6].

<table>
<thead>
<tr>
<th>Antigen</th>
<th>EliA Symphony®</th>
<th>INOVA QUANTA Flash ENA®</th>
</tr>
</thead>
<tbody>
<tr>
<td>SS-A/RO52</td>
<td>Human recombinant</td>
<td>Recombinant*</td>
</tr>
<tr>
<td>SS-A/RO60</td>
<td>Human recombinant</td>
<td>Recombinant*</td>
</tr>
<tr>
<td>SS-B/La</td>
<td>Human recombinant</td>
<td>Recombinant*</td>
</tr>
<tr>
<td>Scl-70</td>
<td>Human recombinant</td>
<td>Recombinant*</td>
</tr>
<tr>
<td>Jo-1</td>
<td>Human recombinant</td>
<td>Recombinant*</td>
</tr>
<tr>
<td>CENP-B</td>
<td>Human recombinant</td>
<td>Not applicable -</td>
</tr>
<tr>
<td>RNP</td>
<td>Human recombinant</td>
<td>Call thymus</td>
</tr>
<tr>
<td>Sm</td>
<td>SmD3 peptide</td>
<td>Call thymus</td>
</tr>
</tbody>
</table>

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

Table 3: Clinical performance of EliA SymphonyS® and INOVA Quanta Flash ENA7 analyzing the sample cohort from table 2.

RESULTS II – CLINICAL PERFORMANCE IN SYSTEMIC SCLEROSIS PATIENTS

Table 4: EliA SymphonyS® and QUANTA Flash ENA7 are anti-ENA antibody screening assays, however an international standard for antigen composition and tier does not exist. Therefore, only the agreement and not the correlation between the two tests was determined. The upper limit of the measuring range from the respective test manuals were applied [4, 6].

CONCLUSIONS

- An excellent clinical performance of the EliA SymphonyS® assay supports the diagnosis of CTDs.
- The EliA SymphonyS® test produces fewer false positive results due to its performance characteristics, thereby supporting an evidence-based diagnosis, and likely a lower cost of care*
- Employing only recombinant antigens and synthetic peptides offers the benefits of recombinant protein technology, e.g. high lot-to-lot consistency without the negatives of native antigen sources, e.g. quality variances of native material and inadvertent co-purification of other (unknown) proteins.
- The inclusion of CENP-B in the EliA SymphonyS® antigen composition, provides the laboratory with the capability to screen patient samples, e.g. from SSc patients, where the predominant autoantibodies is CENP.

REFERENCES

4. Pradis AB. EliA Symphony® - DIRECTIONS FOR USE. 2017;250
5. INOVA Diagnostics Inc. 510(k) - K120283.
6. INOVA Diagnostics Inc. QUANTA Flash® ENA7 - 701258. 2012;621255DEU

TRADEMARKS

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