Publication of the Month

December 12/11: anti-dsDNA determination differs among available methods

Key messages:

- *The evaluated methods show comparable performance, but none is gold standard qualified.*
- *Clinicians should be aware of suboptimal test accuracy when interpreting anti-dsDNA test results.*

Ghirardello A, Villalta D, Morozzi G, et al., Forum Interdisciplinare per la Ricerca sulle Malattie Autoimmuni (FIRMA)
Diagnostic accuracy of currently available anti-double-stranded DNA antibody assays. An Italian multicentre study
Clin Exp Rheumatol 2011;29:50-6

Background: Antibodies against dsDNA are specific markers for systemic lupus erythematosus (SLE) and related to disease activity. The determination of anti-dsDNA antibodies differs between the available methods due to the heterogeneity of the antibodies but also due to the different assays principles and analytical variables of the methods.

Summary: Different anti-dsDNA determining methods (Farrzyme, EliA dsDNA, CLIFT and Farr RIA) were evaluated testing samples from SLE patients at first evaluation and in follow-up, from healthy subjects and patients with rheumatic, infectious or neoplastic diseases.

Sensitivity in % in SLE patients	**Farrzyme**	**Farr**	**EliA**	**CLIFT**
at first visit (n=59)	66	95	81	83
during follow-up (n=164)	50	89	66	83

EliA has the clearest difference between patients at first visit and during follow-up. Obviously, EliA dsDNA mirrors the decrease in activity with the treatment.

Specificity in %	**Farrzyme**	**Farr**	**EliA**	**CLIFT**
Overall controls (n=216)	91	89	92	91
Disease controls (n=161)	~ 92	~ 95	~ 97	~ 97
CTD patients, non-SLE (n=64)	92	75	83	81
anti-TNFα-treated RA (n=45)	87	87	93	80

While overall specificity was comparable in all assays, differences occurred in the respective control groups.
Antibody levels detected by EliA, Farrzyme and CLIFT were significantly higher in patients with active disease and correlated with the ECLAM score.

Conclusions: Since a gold standard method does not exist at present, in interpreting anti-dsDNA antibody test results clinicians should be aware of suboptimal accuracy of currently available assays.

Comment: In this study, CLIFT has a very unusual high sensitivity and a very low specificity. In most other comparative studies, the specificity of CLIFT goes up to 100% while the sensitivity is usually below 50%. However, these differences just support again that anti-dsDNA tests are not comparable from one lab to the other or from one country to the other and that clinicians have to be always aware of the method and the cut-off used to detect anti-dsDNA antibodies.