26th CONGRESS OF THE ITALIAN SOCIETY FOR LABORATORY MEDICINE (SIMEL) 3 – 5 OCTOBER 2012

EVALUATION OF THE ANAYTICAL PERFORMANCEWS OF THE NEW CHORUS ANTI-CCP KIT: PRELIMINARY DATA

G. Morozzi[1], M.R.Bacarelli[1], G.Pucci[1], A.Simpatico[3], T.Bandini[2], L.Meli[2], G.Dal Maso[2], C. Scapellato[1]
[1] UOC Patologia Clinica, Azienda Ospedaliera Universitaria Senese, Siena -
[2] Diesse Diagnostica Senese S.p.A.-
[3] Università degli Studi, Siena Dip. Scienze Mediche, Chirurgiche e Neuroscienze – Reumatologia

Aim: To evaluate the analytical performances of the new CHORUS anti-CCP kit (second generation) in single test fomat.

Background: In recent years, the diagnostic approach to rheumatoid arthritis (RA) is significantly changed, thanks to the commercial availability of new biological drugs that can delay / block the progression of joint damage. Since patients should be subjected to aggressive treatment as soon as possible, it is crucial to make the diagnosis in the very early stages of the disease. The anti-citrullinated peptide antibodies are considered as the most important biomarkers of RA, as they appear early, persist during the course of the disease and are highly specific. For this reasons, new tests based on the several different citrullinated peptides are launched on the IVD market, although to date, the second generation anti-CCP test remains the "gold standard".

Materials and Methods: The disposable single test device contains all the reagents necessary for the execution of the test in the Chorus instrument; the antigen immobilized on the solid phase consists of highly purified synthetic peptides containing citrulline residues. For the calculation of specificity 213 sera were analyzed: 148 from subjects in apparent good health, 65 from subjects with different diseases (ANA +, thyroiditis, infections). For assessing sensitivity were examined: 26 sera from RA patients diagnosed according to the new ACR / EULAR and 148 sera sent to the laboratory with a request for anti-CCP, for a total of 174 sera. All samples were also analyzed with the test used by the laboratory (EliA CCP on ImmunoCAP 250 -Thermo Fisher Scientific-Phadia) and the extent of agreement between the two methods has been calculated by means of Coehen's kappa. For the calculation of reproducibility and repeateability 6 samples were analyzed in 9 replicates, for 8 sessions, and with 3 different batches of the kit and on 3 different instruments.

Results: the overall clinical specificity was found to be 97,6%.

Blood donors 88/90= 97.8% (IC 95%: 92.3-99.4%)
Subjects in apparent good health 57/58= 98.3% (IC 95%: 90.1-99.7%)
Autoimmune diseases 32/34=94.1%(IC 95%: 81.0-98.4%)
Infectious diseases 31/31= 100%(IC 95%: 89.0-100%)

As regards sensitivity, the test correctly identified 23 out of 26 Elia CCP positive samples

		EliA CCP Thermo Fisher		
		POS	NEG	Total
Anti-CCP Diesse	POS	74	4	78
	NEG	6	90	96
	Total	80	94	174

Concordance estimated by Coehn's kappa coefficient: 0.88

Sample	Within run		Between runs	
	average (AU/ml)	CV%	average (AU/ml)	CV%
1	70,3	2,1	66,6	6,3
2	32,6	3,5	28,2	14,5
3	30,1	2,6	28,4	13,5
4	24,5	3,4	17,2	21,7
5	23,8	4,5	16,5	16,1
6	8,7	3,1	7,5	13,8

Within run and between runs reproducibility

Sample	Between batches		Between intruments	
	average (AU/ml)	CV%	average (AU/ml)	CV%
1	65,7	5,3	63,3	5,9
2	27,1	12,7	25,2	12,4
3	27,6	12,0	25,5	12,6
4	17,1	16,4	15,7	13,3
5	16,6	14,2	15,8	12,0
6	7,3	11,2	7,2	10,4

Between batches and between instruments reproducibility

Conclusions: The analysis of the results obtained in this preliminary study shows that the diagnostic kit offers excellent performance; the evaluation of the kit on a larger number of samples clinically diagnosed as suffering from RA may be useful for a more objective assessment of the sensitivity