

## INTRODUCTION AND PURPOSE

Inflammatory Bowel Disease (IBD) denotes a group of disorders involving the gastro-intestinal tract as Crohn's Disease (CD) and Ulcerative Colitis (UC). There is a great interest in serological markers for IBD: ASCA are usually associated with CD and atypical perinuclear ANCA are mostly associated with UC. Currently there is not yet consensus on the clinical relevance of ASCA in IBD. The aim of this study was to evaluate the new Elia™ ASCA assay

on the PHADIA® 2500 (Thermo Scientific).

Different approaches were developed:

1. Analytical performances
2. Prevalence of ASCA IgG and/or IgA in IBD and non IBD populations
3. Correlation with ELISA ASCA assay performed on the Alegria® system (Orgentec).

## MATERIAL AND METHODS

### 1 Analytical performance

**Intra-assay precision:** coefficient of variation [CV] was calculated with the results of 28 determinations of an IgG and IgA positive serum in a single run

**Inter-assay precision:** coefficient of variation [CV] was calculated with the results of 26 determinations of the IgG or IgA positive control in 26 different runs.

### 2 Prevalence of IgG and/or IgA ASCA in IBD and non IBD populations

- 58 patients with IBD serological markers prescription (ASCA and ANCA) were selected from our routine :
  - 30 patients diagnosed CD with ASCA IgG and/or IgA positive

(Alegria® Orgentec) and negative ANCA (indirect immunofluorescence)

- 28 patients diagnosed UC with negative ASCA IgG and/or IgA (Alegria® Orgentec) and p-atypical positive ANCA (indirect immunofluorescence)
- 51 patients were selected for the non IBD control group: 29 with celiac disease, 12 with active hepatitis (B,C and E), and 10 with lupus or Sjogren disease.

### 3 Correlation with ELISA assay (Alegria® Orgentec)

A total of 133 sera were tested: 58 from the prevalence study with IBD serological markers prescription (ASCA and ANCA) and 48 more, not selected, from our routine.

## RESULTS AND DISCUSSION

### 1 Analytical performance

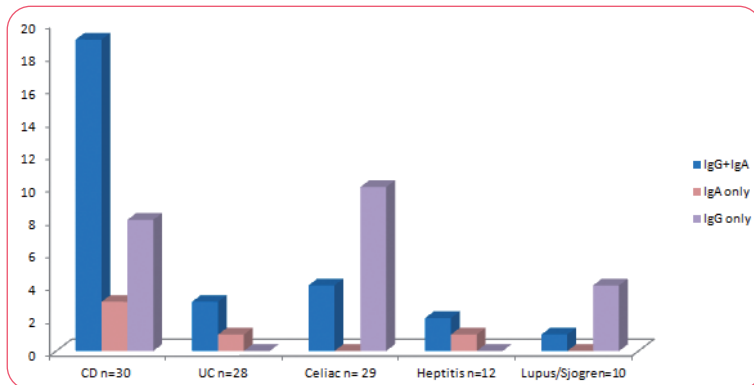
**Intra-assay precision CV** was 8% for IgG and 7% for IgA

**Inter-assay precision CV** was 5.5% for IgG and 5.6% for IgA

In light of the absence of recommendation by scientific societies for auto-immunity analysis and from our experience, these CV's are satisfactory and in complete accordance with the requirement of our laboratory.

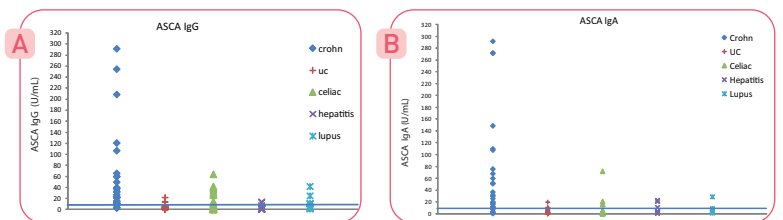
### 2 Prevalence of ASCA IgG and/or IgA in IBD and non IBD populations.

Fig. 1: Numbers of patient with positive ASCA in the different groups



A positive Elia ASCA IgA + IgG result ensures better sensitivity and specificity for CD especially for the differential diagnosis with UC. However we observed that almost 50% of the celiac population had ASCA IgG+ IgA or only IgG; almost all patients who were ASCA positive had also a high anti-transglutaminase IgA titre.

Fig. 2: Range of ASCA IgG (A) and IgA (B) values in the different groups



The figure 2 A and B show that ASCA IgG/IgA values for CD patients range from low to very high titres. However most of UC and non IBD groups showed low or moderate titres.

### 3 Correlation with ELISA assay (Alegria® Orgentec)

		PHADIA 2500		Total
ALEGRIA		+	-	
	+	51	10	61
	-	8	64	72
Total	59	74	133	

Table 1: ASCA IgG

Agreements observed on 86.5% of the observations. Kappa=0.727 [95% confidence interval: from 0.61 to 0.844]. The strength of agreement is considered to be good.

		PHADIA 2500		Total
ALEGRIA		+	-	
	+	25	2	27
	-	22	84	106
Total	47	86	133	

Table 2: ASCA IgA

Agreements observed on 82% of the observations. Kappa=0.563 [95% confidence interval: from 0.417 to 0.709]. The strength of agreement is considered to be moderate. We observed 22 discrepancies "phadia positive and alegria negative": 6/22 patients were suspected of CD, 2/22 had celiac disease. Unfortunately, we could not obtain clinical information on the other patients but we could also notice that ASCA IgA values were low (< 30 U/mL) and prescriptions were for IBD diagnosis (ASCA + ANCA).

## CONCLUSION

The new Elia™ ASCA assay represents a convenient and sensitive test for ASCA determination with good analytical performances and appears to be a helpful tool for IBD diagnosis. The specificity of the test is improved when IgG + IgA are positive, especially in the differential diagnosis with UC.

### BIBLIOGRAPHY

Desplat Jégo S, Johanet C, Escande A et al. Update on anti-saccharomyces cerevisiae antibodies, anti-nuclear associated anti-neutrophil antibodies and antibodies to exocrine pancreas detected by indirect immunofluorescence as biomarkers in chronic inflammatory bowel diseases: Result of a multicenter study. World J Gastroenterol 13 (2007):2312-18