SimtomaX®

Study comparing Simtomax® to IgA/IgG tTG ELISA in a pediatric population considered at high risk for celiac disease

Study Characteristics

Study Site:	Immunology Laboratory, Lyon-Sud University Hospital, Pierre-Bénite, France
Principal Investigators:	Professor Jacques Bienvenu
Dates:	The study was performed from December 2010 to December 2011
Type of Study:	Retrospective
Patient Number:	250 children
Type of Samples:	Serum

Study Design

Population:	A retrospective cohort 250 children (125 females; mean age: 8.3years; median 8.2 years) presenting either clinical suspicions of celiac disease (CD) (gastrointestinal manifestations, growth failure, extraintestinal symptoms), high risk for CD (autoimmune disease) or were first degree relatives of patients with CD or other autoimmune disease.
Predicate:	IgA and IgG tissue Transglutaminase (tTG) ELISA (Celikey, Varelisa, Phadia, cut-off of 3 and 5 U/ml respectively); IgG tTG were used in case of total IgA deficiency (<0.06 g/l).

Results

		IgA/IgG tTG ELISA	
		+	-
Simtomax DGP	+	27	11
	-	2	210

Prevalence of CD in the tested cohort	11.60%
Sensitivity	93.10%
Specificity	95.02%
PPV	71.05%
NPV	99.06%

Publications / Oral Presentations/ Posters

Bienvenu F, Besson Duvanel C, Seignovert C, Rouzaire P, Lachauy A and Bienvenu J, Evaluation of a point of care test based on deamidated gliadin peptides for celiac disease screening in a large pediatric population, International Celiac Disease Symposium, Oslo, Norway, June 2011, poster

Bienvenu F, Besson Duvanel C, Seignovert C, Rouzaire P, Lachauy A and Bienvenu J, Evaluation of a point of care test based on deamidated gliadin peptides for celiac disease screening in a large pediatric population, 2012, European Journal of Gastroenterology & Hepatology, Dec;24(12):1418-23 http://www.ncbi.nlm.nih.gov/pubmed/23032795

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