IDS-ISYS MULTI-DISCIPLINE AUTOMATED SYSTEM IS A SIMPLE AND RELIABLE TOOL FOR CELIAC DISEASE DIAGNOSIS

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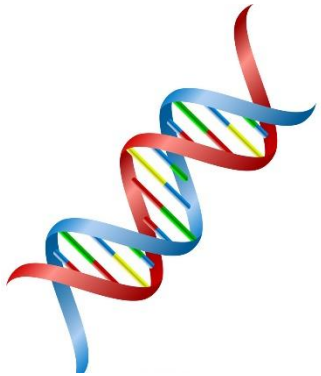
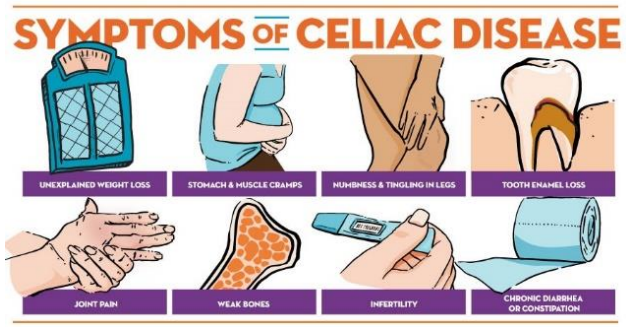


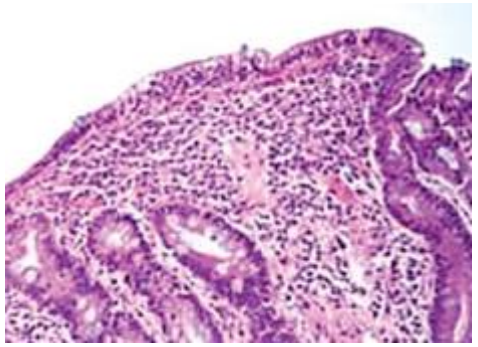
Celiac disease

Symptoms



Blood testing

Gut histology



Serum IgA anti-tissue transglutaminase (IgA anti-tTG)

- THE blood test for CD screening
- Highly specific and sensitive for CD
- Useful for follow-up of CD patients
- Sensitive to total IgA deficiency
- Quantative results with ELISA methods

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Sample area

- Up to 120 samples
- Continuous loading and unloading
- All types of tubes supported

Efficiency

- Full walk-away automation
- Compact, benchtop design
- True Random Access
- MTBF (mean time between failures) > 200 days

Chemiluminescence assay (CLIA) and unitary tests

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Evaluation of IgA anti-tTG (and total IgA) quantification by CLIA in a retrospective cohort of patients blood-tested for CD

- To evaluate analytical performance
- To compare results with routine ELISA / IFI

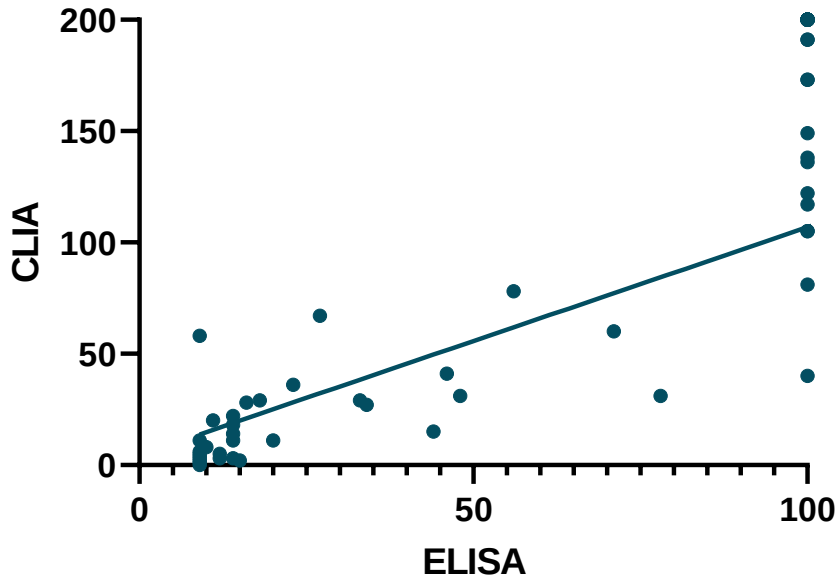
Cohort of patients routinely tested for IgA anti-tTG (ELISA from Eurospital, Italy) and IgA EMA (Monkey oesophagus from Medica, USA) (n=175, including 59 CD)

Antibody pattern	Number of samples	Age of patients (y/o)	Sex ratio M/F
IgA anti-tTG - / IgA EMA +	0	-	0/0
IgA anti-tTG + / IgA EMA -	3	60.3	2/1
IgA anti-tTG - / IgA EMA -	106	45.9	55/51
IgA anti-tTG + / IgA EMA +	58	23.1	15/43
Total IgA deficiency	8	36.9	6/2
Total	175	41.6 [1-93]	78/97

IgA EMA: IgA anti-endomysial antibodies

	WITHIN-RUN VARIATION			BETWEEN-RUN VARIATION		
	Low level	Medium level	High level	Low level	Medium level	High level
Eurospital ELISA value (UA/ml) (N>9)	16	23	>100	16	48	>100
Number of runs	30			17		
ISYS Mean value (UA/ml)(N<10) [ET]	13 [0.5]	31 [1.5]	107 [3.6]	25 [9.6]	56 [2.7]	68 [14.4]
CV (%)	4.09	4.93	3.40	38.2 But all values >10	4.75	21.2

A good correlation between CLIA and ELISA for IgA anti-tTG titers



Pearson r	
r	0.8127
95% confidence interval	0.7554 to 0.8576
R squared	0.6604
P value	
P (two-tailed)	<0.0001
P value summary	****
Significant? (alpha = 0.05)	Yes
Number of XY Pairs	175

Degree of agreement

	IgA anti-tTG +	IgA anti-tTG -	
IgA anti-tTG +	59	4	63
IgA anti-tTG -	0	112	114
	59	114	175

Value of κ	Strength of Agreement
< 0.20	Poor
$0.21 - 0.40$	Fair
$0.41 - 0.60$	Moderate
$0.61 - 0.80$	Good
> 0.80	Very Good

Number of observed agreements: 171 (97.71% of the observations)
Number of agreements expected by chance: 95.5 (54.59% of the observations)

Kappa= 0.950

SE of kappa = 0.025 ; 95% confidence interval: From 0.901 to 0.998 (GraphPad)

There was a discrepancy in the two methods for 4 samples out of 175.

All total IgA deficiency have been detected by ids isys

	IgA anti-tTG (UA/ml) (ELISA N<9 ; CLIA N <10)	IgA EMA (end-point titer; N <10)	Total serum IgA (g/l)	Clinical data
Patient # 1	12 vs 4.2	40	3.3	Woman, 78 y/o, CD since 2013, poorly followed GFD
Patient # 2	14 vs 3.0	<10	6.04	Man, 53 y/o, Diabetes, no CD diagnosis
Patient # 3	12 vs 6.1	40	1.34	Woman, 29 y/o, blood sample at time of CD diagnosis
Patient # 4	15 vs 1.5	<10	1.19	Woman, 72 y/o, ALS, no CD diagnosis

2/4 clinical chart analyses are in favor of CLIA

but ELISA values are closed to the threshold of positivity

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Detection of IgA anti-tTG by CLIA

- ✓ presents very good analytical performance
- ✓ detects IgA deficiency in the same time
- ✓ is a reliable tool for IgA anti-tTG detection

Thank you for your attention and take care of you !

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