

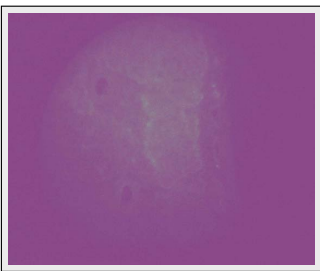
Available Serologic Testing

- Antigliadin IgG
- Antigliadin IgA
- Antiendomysial IgA
- Anti-tissue Transglutaminase IgA
- Total serum IgA level

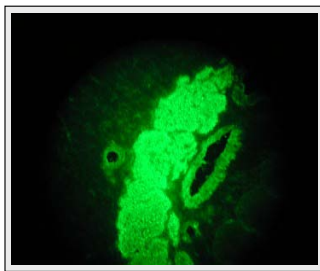
Antiendomysial IgA

- High sensitivity and specificity
- Less reliable in :
 - Children less than 3 years of age
 - IgA deficient patients
 - Labs with little experience running the test
 - Observer dependent
 - Requires primate tissue

Immunofluorescent Antiendomysial Antibody Test



Negative



Positive

Tissue Transglutaminase IgA

- tTG is the auto-antibody for the anti-endomysial antibody
- The human anti-tissue tTG has very high sensitivity and specificity
- ELISA test is not observer dependent
- Undetectable or falsely low in IgA deficient patients

Total Serum IgA Level

- Patients with IgA deficiency have a 31-fold increased risk of having celiac disease
- IgA deficient patients will have negative anti-gliadin IgA, antiendomysial IgA, and tTG IgA antibody tests
- IgA level should be checked along with the celiac disease antibodies
 - Normal values adjusted to age

Genetic Tests

- HLA alleles associated with CD
- DQ2 found in 95% of celiac patients
- DQ8 found in remaining patients
- Value of genetic testing
- High negative predictive value to rule out CD
 - Negativity for DQ2/DQ8 excludes the diagnosis of celiac disease with 99% confidence

PROMETHEUS LABORATORIES
 5739 Pacific Center Blvd.
 San Diego, CA 92121
 Toll Free: 888/423-5227
 www.prometheuslabs.com

Test Results
Celiac Disease Serology

Patient & Order Information		Report Recipient
Order ID: 000000	Patient: Test, Patient	Example Physician M.D.
DOB: 01/01/1900	SSN: -	Prometheus Laboratories Inc.
Institution ID: -	Sex: -	5739 Pacific Center Blvd
Ordered: 02/10/2003	Completed: 02/11/2003	Suite 123
Ordered By: Example Physician M.D.		San Diego, CA 92121
ICD9 Codes: V72.6		USA
Sample ID: SE00000000	Collection Date: 02/06/2003 2:00PM (Serum)	858/824-0895 Phone 858/824-0896 Fax
Test Ordered: Celiac Disease Serology		Institution Sample ID: -

Test Result:	Assay	Value	Reference Range
	Anti-Gliadin IgA ELISA	0.7 U/ml	<5.0 U/ml
	Anti-Gliadin IgG ELISA	0.8 U/ml	<10.0 U/ml
	Anti-Endomysial IgA IFA	Negative	Negative
	Anti-Human Tissue Transglutaminase IgA ELISA	2.8 U/ml	<4.0 U/ml
	Total Serum IgA by Nephelometry	154 mg/dl	See comments below

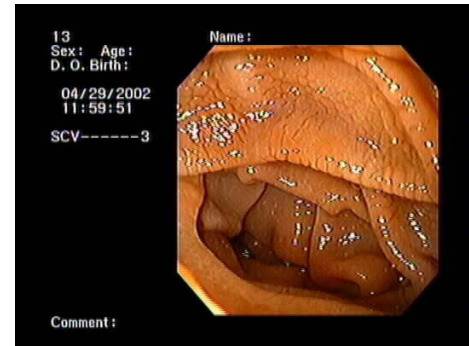
Total Serum IgA Reference Range:
 < 3 years: 8-220 mg/dl
 3-13 Years: 41-395 mg/dl
 > 13 years to adult: 44-441 mg/dl

Anti-endomysial IgA antibodies and tissue transglutaminase IgA antibodies are the serum markers most specific and sensitive for Celiac disease in patients on a normal diet and with normal levels of serum IgA. Using the new native human antigen anti-tissue transglutaminase IgA ELISA, we observed better correlation with anti-endomysial antibodies.

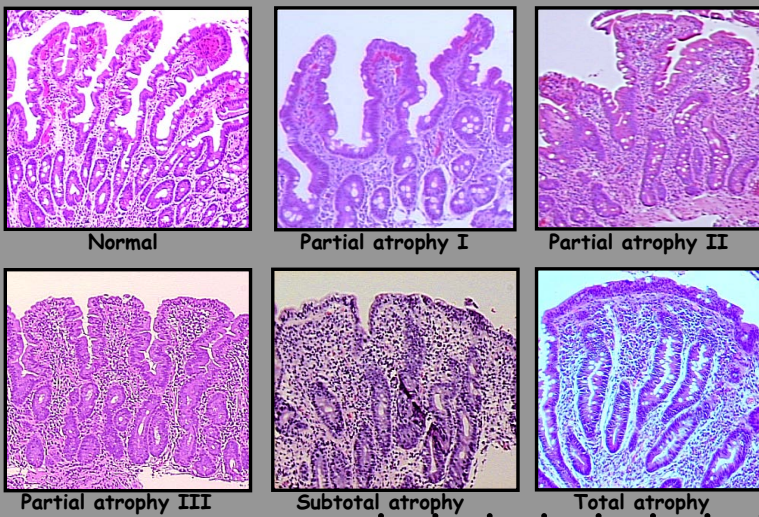
Anti-gliadin IgA antibodies are also very sensitive and specific for Celiac disease and are often used to monitor dietary compliance.

Celiac patients have an increased incidence of IgA deficiency. Therefore, negative IgA antibody assay results do not necessarily rule out Celiac disease. Anti-gliadin IgG antibodies are very sensitive for Celiac disease, but have lower specificity (higher false positive rate) than the IgA antibody assays.

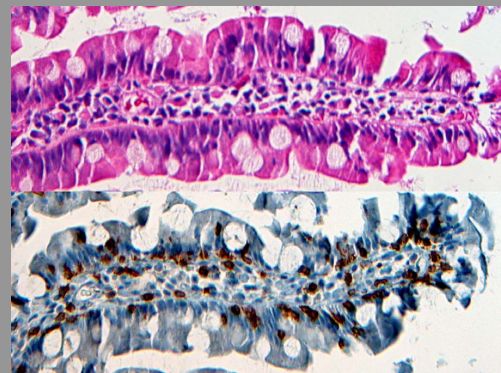
Scalloping in Celiac Disease



Gold Standard: Biopsy



Duodenal Biopsy in a 9 Year-old with Type I Diabetes: Indeterminate Case with CD3 Staining for Lymphocytes



After the diagnosis

- Appropriate follow up
- Additional testing
 - Bone density
 - B 12
 - RBC folate
 - Thyroid testing

Monitoring the GFD

- 1st month -Symptoms
- 3-6 months -Correction of deficiencies
- 6 months-Serology tests
- 1 year- Biopsy occasionally needed

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Follow up

- Individualize
- Importance of follow up visits
- Initial follow up 4-6 weeks
- Every 3-4 months



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Unexpected Sources

- Medications (starch)
- Glues and pastes
- Play putty
- Communion
- Airborne flour
- Contamination



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Oats Controversy

- Finnish Oats study(adults)
 - 5 year follow up
 - Specially grown and tested oats
 - 50 Grams per day
 - Controlled by biopsy and serology
- Irish study and Danish studies similar results



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Continued symptoms

- Accidental gluten ingestion
- Accidental gluten ingestion
- Accidental gluten ingestion



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Contamination Possibilities

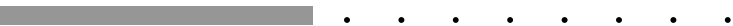
- Processing or milling
- Packaging
- In the store (flour bins)
- Kitchen contamination



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Oats? Not Yet

- 11% of oats samples have wheat/barley contamination
- Shared sequences of glutamine repeats
- Studies excluded severe patients
- Adults only



Continued symptoms

- Bacterial Overgrowth
 - Extremely common
 - Usually not suspected
 - No diagnostic testing necessary
 - Easy to treat
 - Probiotics – Lactobacillus GG
 - Yogurt with live cultures

Microorganisms

- Lactobacillus GG
 - Culturelle
- Lactobacillus reuteri
 - Probiotica
 - Stonyfield Yogurt



Microorganisms

- Lactobacillus acidophilus
 - Milk, yogurt
- Lactobacillus bulgaricus
 - Lactinex
 - Yogurt
- Lactobacillus casei
 - Actimel
 - Yogurt



Continued symptoms

- Lactose Intolerance
 - Deficiency of the enzyme lactase
 - Lactose is present in many foods, spreads and medications
 - No diagnostic testing necessary
 - Treatment with the enzyme lactase (Lactaid Caplets)
- Fructose Intolerance