














BioCLIA[®] Autoimmune Control Set

human tTG IgA

tTG IgA Assay Controls

Key to Symbols Used

	Catalog Number		Expiration Date
	For <i>In Vitro</i> Diagnostic Use		Lot Number
	Store between +2°C and +8°C		Consult Instruction for Use
	Manufacturer		Authorized Representative in European Union
	Control 1		Contains Sufficient for < n > Tests
	Control 2		Chemical Risk Warning
			Biological Risk Warning

BioCLIA® Autoimmune Control Set,

human tTG IgA

Intended Use

The BioCLIA Autoimmune Control Set, human tTG IgA is intended for the quality control purposes of the BioCLIA human tTG IgA performed on the BioCLIA® 1200 and BioCLIA® 6500.

Catalog Numbers

MY00342 (2 X 1 mL)

My00393 (4 X 1 mL)

Summary and Explanation

Tissue transglutaminase (abbreviated as tTG or TG2) is a 78-kDa, calcium-dependent enzyme of the protein-glutamine γ -glutamyltransferases family (or simply transglutaminase family).^{1,2} It is best known for its link with celiac disease. Three tTG is particularly notable for being the autoantigen in celiac disease, a lifelong illness in which the consumption of dietary gluten causes a pathological immune response resulting in the inflammation of the small intestine and subsequent villous atrophy.³⁻⁵

Anti-transglutaminase antibodies result in a form of gluten sensitivity in which a cellular response to Triticeae glutes that are crosslinked to tTG, which are able to stimulate transglutaminase specific B-cell responses that eventually result in the production of anti-transglutaminase antibodies IgA and IgG. 6 Serology for anti-tTG antibodies has superseded older serological tests (anti-endomysium, anti-gliadin, and anti-reticulins) and has a strong sensitivity (99%) and specificity (>90%) for identifying celiac disease.

Materials supplied

- **tTG IgA Control 1**

h-tTG-A	Control	L
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A tube contains 1mL, ready to use reagent. Control contains human antibodies to tTG IgA in stabilizers and preservatives (Low).

Preservatives: 0.0015% < Proclin 300 < 0.6%.

- **tTG IgA Control 2**

h-tTG-A	Control	H
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A tube contains 1mL, ready to use reagent. Control contains human antibodies to tTG IgA in stabilizers and preservatives (High).

Preservatives: 0.0015% < Proclin 300 < 0.6%.

Target value and acceptable range for the controls are indicated on control information sheet in each kit.

Warnings and Precautions

The human derived material in this product was tested by FDA approved methods and found nonreactive for Hepatitis B Surface Antigen (HBsAg), Anti-HCV and HIV 1/2 antibodies. Handle as if potentially infectious.⁷ Avoid contacting with skin and eyes. Do not empty into drains. Wear suitable protective clothing.

Precautions:



Human serum is added in the controls.



Proclin 300 is added in the controls at concentration between 0.0015% - 0.6%.

- The product is for *in vitro* diagnostic use only.
- Do not use any controls beyond their expiration dates. Do not mix controls from different lots unless specified.
- Instructions must be carefully followed for using and storing of controls. Any modification in procedure may interfere with the results. Controls and contaminated vials must be handled strictly following safety guidelines or rules of biological hazards to ensure the users' and environmental safety.
- Controls contain chemical and biological components. Avoid ingesting or splashing onto skin and mucous membrane. If direct contact with controls happens, rinse the contact surface with plenty of water immediately and see a doctor if necessary.

Storage Conditions

The kit is stable until the expiration date, if it is stored and handled as directed. Routine store the kit in refrigerator (2-8°C). Once a control tube is opened, it is good for a total of 15 times, no more than 2 hours per time when kept uncapped, onboard the instrument, after which the reagent must be discarded. Three freeze-thaw cycles before testing has no effect on the kit reagents.

Assay Procedure

Note that, for obtaining optimal performance, it is important to perform all routine maintenance procedures as defined in the BioCLIA® 1200 and BioCLIA® 6500 User Manual.

See the BioCLIA® 1200 and BioCLIA® 6500 User Manual for preparation, setup, dilutions, adjustment, assay and quality control procedures.

The control procedure can be done before running the specimens each day. Users also can adjust the control procedure period according to their own lab frequency.

Limitations

This product is designed as controls for monitoring the performance of the BioCLIA tTG IgA. These controls are subjected to the limitations of the assay system. Deviations may indicate possible problems with one or more components in the test system.

References

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2. Klöck C, Diraimondo TR, Khosla C. Role of transglutaminase 2 in celiac disease pathogenesis. *Seminars in Immunopathology*; 2012.
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4. Griffin M, Casadio R, Bergamini CM. Transglutaminases: nature's biological glues. *Biochemical Journal* 2002;368:377-96.
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6. Dieterich W, Ehnis T, Bauer M, Donner P, Volta U, Riecken EO, Schuppan D. Identification of tissue transglutaminase as the autoantigen of celiac disease. *Nature Medicine* 1997;3:797-801.
7. Richmond JY, McKinney RW. Biosafety in microbiological and biomedical laboratories: U.S.GPO. 1999.



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Technical Assistance

For technical assistance, contact your National Distributor.

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