


















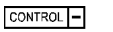











## REF ORG 540A Anti-Tissue-Transglutaminase IgA

### INTENDED PURPOSE

Anti-Tissue-Transglutaminase IgA is an ELISA test system for the quantitative measurement of IgA class autoantibodies to tissue transglutaminase (tTG) in human serum or plasma. This product is intended for professional in vitro diagnostic use only.

Autoantibodies against tissue transglutaminase (tTG) during a gluten containing diet are the most obvious serologic feature of coeliac disease (CD). Determination of serum levels of IgA against tTG is the first choice in suspected CD. In subjects with either primary or secondary humoral IgA deficiency, at least one additional test measuring IgG class CD-specific antibodies is recommended. The clinical relevance of a positive anti-tTG result should be confirmed by histology of the small intestinal mucosa.

### SYMBOLS USED ON LABELS

	In vitro diagnostic medical device		Microplate
	Manufacturer		Calibrator
	Catalogue number		Calibrator
	Sufficient for ... determinations		Calibrator
	Batch code		Calibrator
	Use by		Calibrator
	Temperature limitation		Calibrator
	Keep away from sunlight		Control positive
	Do not reuse		Control negative
	Date of manufacture		Sample Buffer P
	CE marked according to 98/79/EC		Enzyme Conjugate
	Consult electronic Instructions For Use		TMB Substrate
	Electronic Instruction For Use: version		Stop solution
			Wash Buffer
			Ready to use
			50 x concentrate

### PRINCIPLE OF THE TEST

Human recombinant tissue transglutaminase is bound to microwells.

The determination is based on an indirect enzyme linked immune reaction with the following steps:

Specific antibodies in the patient sample bind to the antigen coated on the surface of the reaction wells. After incubation, a washing step removes unbound and unspecifically bound serum or plasma components. Subsequently added enzyme conjugate binds to the immobilized antibody-antigen-complexes. After incubation, a second washing step removes unbound enzyme conjugate. After addition of substrate solution the bound enzyme conjugate hydrolyses the substrate forming a blue coloured product. Addition of an acid stops the reaction generating a yellow end-product. The intensity of the yellow color correlates with the concentration of the antibody-antigen-complex and can be measured photometrically at 450 nm.

### WARNINGS AND PRECAUTIONS

- All reagents of this kit are intended for professional in vitro diagnostic use only.
- Components containing human serum were tested and found negative for HBsAg, HCV, HIV1 and HIV2 by FDA approved methods. No test can guarantee the absence of HBsAg, HCV, HIV1 or HIV2, and so all human serum based reagents in this kit must be handled as though capable of transmitting infection.
- Bovine serum albumin (BSA) used in components has been tested for BSE and found negative.
- Avoid contact with the substrate TMB (3,3',5,5'-Tetramethyl-benzidine).
- Stop solution contains acid, classification is non-hazardous. Avoid contact with skin.
- Control, sample buffer and wash buffer contain sodium azide 0.09% as preservative. This concentration is classified as non-hazardous.
- Enzyme conjugate contains ProClin 300 0.05% as preservative. This concentration is classified as non-hazardous.

During handling of all reagents, controls and serum samples observe the existing regulations for laboratory safety regulations and good laboratory practice:

- First aid measures: In case of skin contact, immediately wash thoroughly with water and soap. Remove contaminated clothing and shoes and wash before reuse. If system fluid comes into contact with skin, wash thoroughly with water. After contact with the eyes carefully rinse the opened eye with running water for at least 10 minutes. Get medical attention if necessary.
- Personal precautions, protective equipment and emergency procedures:

Observe laboratory safety regulations. Avoid contact with skin and eyes. Do not swallow. Do not pipette by mouth. Do not eat, drink, smoke or apply makeup in areas where specimens or kit reagents are handled. When spilled, absorb with an inert material and put the spilled material in an appropriate waste disposal.

- Exposure controls / personal protection: Wear protective gloves of nitril rubber or natural latex. Wear protective glasses. Used according to intended use no dangerous reactions known.
- Conditions to avoid: Since substrate solution is light-sensitive. Store in the dark.
- For disposal of laboratory waste the national or regional legislation has to be observed.

Observe the guidelines for performing quality control in medical laboratories by assaying control sera.



## CONTENTS OF THE KIT

ORG 540A	▽ 96	Sufficient for 96 determinations
MICROPLATE	1	One divisible microplate consisting of 12 modules of 8 wells each. Ready to use. Product code on module: <b>tTG</b>
CALIBRATOR A	1x 1.5 ml	Calibrator A 0 U/ml, containing serum/buffer matrix (PBS, BSA, detergent, NaN3 0.09%), yellow. Ready to use.
CALIBRATOR B	1x 1.5 ml	Calibrator B 5 U/ml, containing tTG antibodies in a serum/buffer matrix (PBS, BSA, detergent, NaN3 0.09%), yellow. Ready to use.
CALIBRATOR C	1x 1.5 ml	Calibrator C 10 U/ml, containing tTG antibodies in a serum/buffer matrix (PBS, BSA, detergent, NaN3 0.09%), yellow. Ready to use.
CALIBRATOR D	1x 1.5 ml	Calibrator D 25 U/ml, containing tTG antibodies in a serum/buffer matrix (PBS, BSA, detergent, NaN3 0.09%), yellow. Ready to use.
CALIBRATOR E	1x 1.5 ml	Calibrator E 75 U/ml, containing tTG antibodies in a serum/buffer matrix (PBS, BSA, NaN3 0.09%), yellow. Ready to use.
CALIBRATOR F	1x 1.5 ml	Calibrator F 200 U/ml, containing tTG antibodies in a serum/buffer matrix (PBS, BSA, detergent, NaN3 0.09%), yellow. Ready to use.
CONTROL +	1x 1.5 ml	Control positive, containing tTG antibodies in a serum/buffer matrix (PBS, BSA, detergent, NaN3 0.09%), yellow. Ready to use. The concentration is specified on the certificate of analysis.
CONTROL -	1x 1.5 ml	Control negative, containing tTG antibodies in a serum/buffer matrix (PBS, BSA, detergent, NaN3 0.09%), yellow. Ready to use. The concentration is specified on the certificate of analysis.
DILUENT	20 ml	Sample Buffer P, containing PBS, BSA, detergent, preservative sodium azide 0.09%, yellow, concentrate (5 x).
CONJUGATE	15 ml	Enzyme Conjugate; light red, containing anti-human IgA antibodies, HRP labelled; PBS, BSA, detergent, preservative PROCLIN 0.05%. Ready to use.
TMB	15 ml	TMB Substrate; containing 3,3', 5,5'- Tetramethylbenzidin, colorless. Ready to use.
STOP	15 ml	Stop solution; contains acid. Ready to use.
WASH	20 ml	Wash Buffer, containing Tris, detergent, preservative sodium azide 0.09%; 50 x conc.

## MATERIALS REQUIRED

- Microplate reader capable of endpoint measurements at 450 nm; optional: reference filter at 620 nm
- Data reduction software
- Multi-channel dispenser or repeatable pipette for 100 µl
- Vortex mixer
- Pipettes for 10 µl, 100 µl and 1000 µl
- Laboratory timing device
- Distilled or deionised water
- Measuring cylinder for 1000 ml and 100 ml
- Plastic container for storage of the wash solution

This ELISA assay is suitable for use on open automated ELISA processors. Each assay has to be validated on the respective automated system. Detailed information is provided upon request.

## SPECIMEN COLLECTION, STORAGE AND HANDLING

- Collect whole blood specimens using acceptable medical techniques to avoid hemolysis.
- Allow blood to clot and separate the serum or plasma by centrifugation.
- Test serum should be clear and non-hemolyzed. Contamination by hemolysis or lipemia should be avoided, but does not interfere with this assay.
- Specimens may be refrigerated at 2-8°C for up to five days or stored at -20°C up to six months.
- Avoid repetitive freezing and thawing of serum or plasma samples. This may result in variable loss of antibody activity.
- Testing of heat-inactivated sera is not recommended.

## STORAGE AND STABILITY

- Store test kit at 2-8°C in the dark.
- Do not expose reagents to heat, sun, or strong light during storage and usage.
- Store microplate sealed and dessicated in the clip bag provided.
- Shelf life of the unopened test kit is 18 months from day of production.  
Unopened reagents are stable until expiration of the kit. See labels for individual batch.
- Diluted Wash Buffer and Sample Buffer are stable for at least 30 days when stored at 2-8°C.  
We recommend consumption on the same day.

## PROCEDURAL NOTES

- Do not use kit components beyond their expiration dates.
- Do not interchange kit components from different lots and products.
- All materials must be at room temperature (20-28°C) prior to use.
- Prepare all reagents and samples. Once started, perform the test without interruption.
- Double determinations may be done. By this means pipetting errors may become obvious.
- Perform the assay steps only in the order indicated.
- Always use fresh sample dilutions.
- Pipette all reagents and samples into the bottom of the wells.
- To avoid carryover or contamination, change the pipette tip between samples and different kit controls.
- Wash microwells thoroughly and remove the last droplets of wash buffer.
- All incubation steps must be accurately timed.
- Do not re-use microplate wells.

## PREPARATION OF REAGENTS

### WASH

Dilute the contents of one vial of the buffered wash solution concentrate (50x) with distilled or deionised water to a final volume of 1000 ml prior to use.

### DILUENT

Sample Buffer P: Prior to use dilute the contents (20 ml) of one vial of sample buffer 5x concentrate with distilled or deionised water to a final volume of 100 ml.

### Preparation of samples

Dilute patient samples 1:100 before the assay: Put 990 µl of prediluted sample buffer in a polystyrene tube and add 10 µl of sample. Mix well. Note: Calibrators / Controls are ready to use and need not be diluted.







Sensitivity: 100.0 %  
Specificity: 97.8 %  
Overall agreement: 98.4 %

## LIMITATIONS OF THE PROCEDURE

This assay is a diagnostic aid. A definite clinical diagnosis should not be based on the results of a single test, but should be made by the physician after all clinical and laboratory findings have been evaluated concerning the entire clinical picture of the patient. Also every decision for therapy should be taken individually.

The above pathological and normal reference ranges for antibodies in patient samples should be regarded as recommendations only. Each laboratory should establish its own ranges according to ISO 15189 or other applicable laboratory guidelines.

## REFERENCES

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2. Cummins AG, Roberts-Thomson IC: Prevalence of celiac disease in the Asia-Pacific region. J Gastroenterol. Hepatol. 2009, 24:1347-1351.
3. Giersiepen K, Leigemann M, Stuhldreher N, Ronfani L, Husby S, Koletzko S, Korponay-Szabo IR: Accuracy of diagnostic antibody tests for coeliac disease in children: summary of an evidence report. J Pediatr. Gastroenterol. Nutr. 2012, 54:229-241.
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5. Gupta R, Reddy DN, Makharia GK, Sood A, Ramakrishna BS, Yachha SK, Thapa BR, Banerjee R, Anuradha S, Dutta U, Puri AS, Jain AK, Mulder CJ, Kumar A, Boindala S: Indian task force for celiac disease: current status. World J Gastroenterol. 2009, 15:6028-6033.
6. Husby S, Koletzko S, Korponay-Szabo IR, Mearin ML, Phillips A, Shamir R, Troncone R, Giersiepen K, Branski D, Catassi C, Leigeman M, Maki M, Ribes-Koninckx C, Ventura A, Zimmer KP: European Society for Pediatric Gastroenterology, Hepatology, and Nutrition guidelines for the diagnosis of coeliac disease. J Pediatr. Gastroenterol. Nutr. 2012, 54:136-160.
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10. Rubio-Tapia A, Murray JA: Celiac disease. Curr. Opin. Gastroenterol. 2010, 26:116-122.
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12. Tjon JM, van BJ, Koning F: Celiac disease: how complicated can it get? Immunogenetics 2010, 62:641-651.
13. van der Windt DA, Jellema P, Mulder CJ, Kneepkens CM, van der Horst HE: Diagnostic testing for celiac disease among patients with abdominal symptoms: a systematic review. JAMA 2010, 303:1738-1746.
14. Villalta D, Tonutti E, Prause C, Koletzko S, Uhlig HH, Vermeersch P, Bossuyt X, Stern M, Laass MW, Ellis JH, Ciclitira PJ, Richter T, Daehrich C, Schlumberger W, Mothes T: IgG antibodies against deamidated gliadin peptides for diagnosis of celiac disease in patients with IgA deficiency. Clin. Chem. 2010, 56:464-468.

Notice to the user (European Union):

Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the EU Member State in which the user and/or the patient is established .

Change Control

Former version: ORG 540A\_IFU\_EN\_QM113174\_2018-01-02\_4      Reason for revision: *Definition of symbols used and symbols updated*



- ① **100 µl** Standards, Kontrollen und verdünnte Patientenproben pipettieren  
→ **30 Minuten** bei Raumtemperatur inkubieren  
→ Inhalt der Platte verwerfen und  
3 mal mit **300 µl** Waschpuffer waschen
- ② **100 µl** Enzymkonjugatlösung pipettieren  
→ **15 Minuten** bei Raumtemperatur inkubieren  
→ Inhalt der Platte verwerfen und  
3 mal mit **300 µl** Waschpuffer waschen
- ③ **100 µl** Substratlösung pipettieren  
→ **15 Minuten** bei Raumtemperatur inkubieren
- ④ **100 µl** Stopplösung zugeben  
→ Platte **5 Minuten** stehenlassen  
→ Bei **450 nm** messen








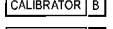

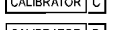

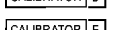

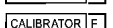

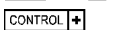

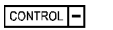













## REF ORG 540G Anti-Tissue-Transglutaminase IgG

### INTENDED PURPOSE

Anti-Tissue-Transglutaminase IgG is an ELISA test system for the quantitative measurement of IgG class autoantibodies to tissue-transglutaminase (tTG) in human serum or plasma. This product is intended for professional in vitro diagnostic use only.

Autoantibodies against tissue transglutaminase (tTG) during a gluten containing diet are the most obvious serologic feature of coeliac disease (CD). Determination of serum levels of IgA against tTG is the first choice in suspected CD. In subjects with either primary or secondary humoral IgA deficiency, at least one additional test measuring IgG class CD-specific antibodies is recommended. The clinical relevance of a positive anti-tTG result should be confirmed by histology of the small intestinal mucosa.

### SYMBOLS USED ON LABELS

	In vitro diagnostic medical device		Microplate
	Manufacturer		Calibrator
	Catalogue number		Calibrator
	Sufficient for ... determinations		Calibrator
	Batch code		Calibrator
	Use by		Calibrator
	Temperature limitation		Calibrator
	Keep away from sunlight		Control positive
	Do not reuse		Control negative
	Date of manufacture		Sample Buffer P
	CE marked according to 98/79/EC		Enzyme Conjugate
	Consult electronic Instructions For Use		TMB Substrate
	Electronic Instruction For Use: version		Stop solution
			Wash Buffer
			Ready to use
			50 x concentrate

### PRINCIPLE OF THE TEST

Human recombinant tissue transglutaminase is bound to microwells.

The determination is based on an indirect enzyme linked immune reaction with the following steps:

Specific antibodies in the patient sample bind to the antigen coated on the surface of the reaction wells. After incubation, a washing step removes unbound and unspecifically bound serum or plasma components. Subsequently added enzyme conjugate binds to the immobilized antibody-antigen-complexes. After incubation, a second washing step removes unbound enzyme conjugate. After addition of substrate solution the bound enzyme conjugate hydrolyses the substrate forming a blue coloured product. Addition of an acid stops the reaction generating a yellow end-product. The intensity of the yellow color correlates with the concentration of the antibody-antigen-complex and can be measured photometrically at 450 nm.

### WARNINGS AND PRECAUTIONS

- All reagents of this kit are intended for professional in vitro diagnostic use only.
- Components containing human serum were tested and found negative for HBsAg, HCV, HIV1 and HIV2 by FDA approved methods. No test can guarantee the absence of HBsAg, HCV, HIV1 or HIV2, and so all human serum based reagents in this kit must be handled as though capable of transmitting infection.
- Bovine serum albumin (BSA) used in components has been tested for BSE and found negative.
- Avoid contact with the substrate TMB (3,3',5,5'-Tetramethyl-benzidine).
- Stop solution contains acid, classification is non-hazardous. Avoid contact with skin.
- Control, sample buffer and wash buffer contain sodium azide 0.09% as preservative. This concentration is classified as non-hazardous.
- Enzyme conjugate contains ProClin 300 0.05% as preservative. This concentration is classified as non-hazardous.

During handling of all reagents, controls and serum samples observe the existing regulations for laboratory safety regulations and good laboratory practice:

- First aid measures: In case of skin contact, immediately wash thoroughly with water and soap. Remove contaminated clothing and shoes and wash before reuse. If system fluid comes into contact with skin, wash thoroughly with water. After contact with the eyes carefully rinse the opened eye with running water for at least 10 minutes. Get medical attention if necessary.
- Personal precautions, protective equipment and emergency procedures:

Observe laboratory safety regulations. Avoid contact with skin and eyes. Do not swallow. Do not pipette by mouth. Do not eat, drink, smoke or apply makeup in areas where specimens or kit reagents are handled. When spilled, absorb with an inert material and put the spilled material in an appropriate waste disposal.

- Exposure controls / personal protection: Wear protective gloves of nitril rubber or natural latex. Wear protective glasses. Used according to intended use no dangerous reactions known.
- Conditions to avoid: Since substrate solution is light-sensitive. Store in the dark.
- For disposal of laboratory waste the national or regional legislation has to be observed.

Observe the guidelines for performing quality control in medical laboratories by assaying control sera.



## CONTENTS OF THE KIT

ORG 540G	▽ 96	Sufficient for 96 determinations
<b>MICROPLATE</b>	1	One divisible microplate consisting of 12 modules of 8 wells each. Ready to use. Product code on module: <b>tTG</b>
<b>CALIBRATOR A</b>	1x 1.5 ml	Calibrator A 0 U/ml, containing serum/buffer matrix (PBS, BSA, detergent, NaN3 0.09%), yellow. Ready to use.
<b>CALIBRATOR B</b>	1x 1.5 ml	Calibrator B 5 U/ml, containing tTG antibodies in a serum/buffer matrix (PBS, BSA, detergent, NaN3 0.09%), yellow. Ready to use.
<b>CALIBRATOR C</b>	1x 1.5 ml	Calibrator C 10 U/ml, containing tTG antibodies in a serum/buffer matrix (PBS, BSA, detergent, NaN3 0.09%), yellow. Ready to use.
<b>CALIBRATOR D</b>	1x 1.5 ml	Calibrator D 25 U/ml, containing tTG antibodies in a serum/buffer matrix (PBS, BSA, detergent, NaN3 0.09%), yellow. Ready to use.
<b>CALIBRATOR E</b>	1x 1.5 ml	Calibrator E 75 U/ml, containing tTG antibodies in a serum/buffer matrix (PBS, BSA, NaN3 0.09%), yellow. Ready to use.
<b>CALIBRATOR F</b>	1x 1.5 ml	Calibrator F 200 U/ml, containing tTG antibodies in a serum/buffer matrix (PBS, BSA, detergent, NaN3 0.09%), yellow. Ready to use.
<b>CONTROL +</b>	1x 1.5 ml	Control positive, containing tTG antibodies in a serum/buffer matrix (PBS, BSA, detergent, NaN3 0.09%), yellow. Ready to use. The concentration is specified on the certificate of analysis.
<b>CONTROL -</b>	1x 1.5 ml	Control negative, containing tTG antibodies in a serum/buffer matrix (PBS, BSA, detergent, NaN3 0.09%), yellow. Ready to use. The concentration is specified on the certificate of analysis.
<b>DILUENT</b>	20 ml	Sample Buffer P, containing PBS, BSA, detergent, preservative sodium azide 0.09%, yellow, concentrate (5 x).
<b>CONJUGATE</b>	15 ml	Enzyme Conjugate containing anti-human IgG antibodies, HRP labelled; PBS, BSA, detergent, preservative PROCLIN 0.05%, light red. Ready to use.
<b>TMB</b>	15 ml	TMB Substrate; containing 3,3', 5,5'- Tetramethylbenzidin, colorless. Ready to use.
<b>STOP</b>	15 ml	Stop solution; contains acid. Ready to use.
<b>WASH</b>	20 ml	Wash Buffer, containing Tris, detergent, preservative sodium azide 0.09%; 50 x conc.

## MATERIALS REQUIRED

- Microplate reader capable of endpoint measurements at 450 nm; optional: reference filter at 620 nm
- Data reduction software
- Multi-channel dispenser or repeatable pipette for 100 µl
- Vortex mixer
- Pipettes for 10 µl, 100 µl and 1000 µl
- Laboratory timing device
- Distilled or deionised water
- Measuring cylinder for 1000 ml and 100 ml
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This ELISA assay is suitable for use on open automated ELISA processors. Each assay has to be validated on the respective automated system. Detailed information is provided upon request.

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- Allow blood to clot and separate the serum or plasma by centrifugation.
- Test serum should be clear and non-hemolyzed. Contamination by hemolysis or lipemia should be avoided, but does not interfere with this assay.
- Specimens may be refrigerated at 2-8°C for up to five days or stored at -20°C up to six months.
- Avoid repetitive freezing and thawing of serum or plasma samples. This may result in variable loss of antibody activity.
- Testing of heat-inactivated sera is not recommended.

## STORAGE AND STABILITY

- Store test kit at 2-8°C in the dark.
- Do not expose reagents to heat, sun, or strong light during storage and usage.
- Store microplate sealed and dessicated in the clip bag provided.
- Shelf life of the unopened test kit is 18 months from day of production.  
Unopened reagents are stable until expiration of the kit. See labels for individual batch.
- Diluted Wash Buffer and Sample Buffer are stable for at least 30 days when stored at 2-8°C.  
We recommend consumption on the same day.

## PROCEDURAL NOTES

- Do not use kit components beyond their expiration dates.
- Do not interchange kit components from different lots and products.
- All materials must be at room temperature (20-28°C) prior to use.
- Prepare all reagents and samples. Once started, perform the test without interruption.
- Double determinations may be done. By this means pipetting errors may become obvious.
- Perform the assay steps only in the order indicated.
- Always use fresh sample dilutions.
- Pipette all reagents and samples into the bottom of the wells.
- To avoid carryover or contamination, change the pipette tip between samples and different kit controls.
- Wash microwells thoroughly and remove the last droplets of wash buffer.
- All incubation steps must be accurately timed.
- Do not re-use microplate wells.

## PREPARATION OF REAGENTS

**WASH**  
Dilute the contents of one vial of the buffered wash solution concentrate (50x) with distilled or deionised water to a final volume of 1000 ml prior to use.

**DILUENT**  
Sample Buffer P: Prior to use dilute the contents (20 ml) of one vial of sample buffer 5x concentrate with distilled or deionised water to a final volume of 100 ml.

### Preparation of samples

Dilute patient samples 1:100 before the assay: Put 990 µl of prediluted sample buffer in a polystyrene tube and add 10 µl of sample. Mix well. Note: Calibrators / Controls are ready to use and need not be diluted.







Sensitivity: 72.1 %  
Specificity: 100.0 %  
Overall agreement: 91.0 %

## LIMITATIONS OF THE PROCEDURE

This assay is a diagnostic aid. A definite clinical diagnosis should not be based on the results of a single test, but should be made by the physician after all clinical and laboratory findings have been evaluated concerning the entire clinical picture of the patient. Also every decision for therapy should be taken individually.

The above pathological and normal reference ranges for antibodies in patient samples should be regarded as recommendations only. Each laboratory should establish its own ranges according to ISO 15189 or other applicable laboratory guidelines.

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Notice to the user (European Union):

Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the EU Member State in which the user and/or the patient is established .

Change Control

Former version: ORG 540G\_IFU\_EN\_QM113175\_2018-01-02\_4 Reason for revision: Definition of symbols used and symbols updated



- 1 **100 µl** Standards, Kontrollen und verdünnte Patientenproben pipettieren  
→ **30 Minuten** bei Raumtemperatur inkubieren  
→ Inhalt der Platte verwerfen und  
3 mal mit **300 µl** Waschpuffer waschen
- 2 **100 µl** Enzymkonjugatlösung pipettieren  
→ **15 Minuten** bei Raumtemperatur inkubieren  
→ Inhalt der Platte verwerfen und  
3 mal mit **300 µl** Waschpuffer waschen
- 3 **100 µl** Substratlösung pipettieren  
→ **15 Minuten** bei Raumtemperatur inkubieren
- 4 **100 µl** Stopplösung zugeben  
→ Platte **5 Minuten** stehenlassen  
→ Bei **450 nm** messen



## EG Konformitätserklärung

### EC Declaration of Conformity

ORGENTEC Diagnostika GmbH  
Carl-Zeiss-Straße 49-51, 55129 Mainz, GERMANY

Wir erklären in eigener Verantwortung, dass das ORGENTEC Produkt  
*We declare in our sole responsibility that the ORGENTEC product*

#### **ORG 540A Anti-Tissue-Transglutaminase IgA**

zur quantitativen in-vitro-Bestimmung bestimmt ist und entsprechend Art. 9 Abs. Satz 1 der Europäischen Richtlinie 98/79/EG als „Sonstige Produkte“ (non-A, non-B, keine Selbstanwendung) klassifiziert ist.

*as intended for use in quantitative in vitro determination is classified as "Other Devices" (non-A, non-B, no self-testing device) according to article 9 paragraph 1 sentence 1 of the European directive 98/79/EC.*

Das Produkt stimmt mit den Grundlegenden Anforderungen und allen zutreffenden Bestimmungen der Richtlinie 98/79/EG des Europäischen Parlaments und des Rates vom 27. Oktober 1998 über in-vitro-Diagnostika überein. Die Konformität zur Richtlinie wurde durch ein Konformitätsbewertungsverfahren nach Anhang III der Richtlinie festgestellt.

*This product is conform with the essential requirements and meet the appropriate provisions of the Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices. Conformity was proved by a conformity assessment procedure referred to in annex III of the directive.*

Liste angewendeter Normen:

List of standards applied for CE marking:

EN ISO 13485, EN ISO 14971, EN ISO 18113, EN ISO 15223, EN ISO 23640, EN 13612.

Mainz, 2021-02-05

**René Betz**  
Head of Regulatory Affairs




Gültig ab / Valid from 2021-02-05 bis / until 2024-02-28

Notification pursuant to §25 Abs. 3 Nr. 3 Medical Devices Act, MPG

Type: Reagent

EDMS 12-10-90-21-00

GMDN 55223

ORG 540A\_CE declaration of conformity\_QM120359\_2021-02-05\_8

F4.01B Declaration of conformity



## EG Konformitätserklärung

### EC Declaration of Conformity

ORGENTEC Diagnostika GmbH  
Carl-Zeiss-Straße 49-51, 55129 Mainz, GERMANY

Wir erklären in eigener Verantwortung, dass das ORGENTEC Produkt

*We declare in our sole responsibility that the ORGENTEC product*

#### **ORG 540G Anti-Tissue-Transglutaminase IgG**

zur quantitativen in-vitro-Bestimmung bestimmt ist und entsprechend Art. 9 Abs. Satz 1 der Europäischen Richtlinie 98/79/EG als „Sonstige Produkte“ (non-A, non-B, keine Selbstanwendung) klassifiziert ist.

*as intended for use in quantitative in vitro determination is classified as "Other Devices" (non-A, non-B, no self-testing device) according to article 9 paragraph 1 sentence 1 of the European directive 98/79/EC.*

Das Produkt stimmt mit den Grundlegenden Anforderungen und allen zutreffenden Bestimmungen der Richtlinie 98/79/EG des Europäischen Parlaments und des Rates vom 27. Oktober 1998 über in-vitro-Diagnostika überein. Die Konformität zur Richtlinie wurde durch ein Konformitätsbewertungsverfahren nach Anhang III der Richtlinie festgestellt.

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René Betz  
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Notification pursuant to §25 Abs. 3 Nr. 3 Medical Devices Act, MPG

Type: Reagent

EDMS 12-10-90-21-00

GMDN 55223

ORG 540G\_CE declaration of conformity\_QM120360\_2021-02-05\_8

F4.01B Declaration of conformity