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 **604_4**

ORG 604 Anti-dsDNA

INTENDED PURPOSE

Anti-dsDNA is an ELISA test system for the quantitative measurement of IgG class autoantibodies against double-stranded DNA in human serum or plasma. This product is intended for professional in vitro diagnostic use only.

The test is used as an aid in the differential diagnosis of inflammatory autoimmune diseases, especially systemic lupus erythematosus (SLE). Autoantibodies to dsDNA are diagnostic markers for SLE and levels may be elevated during active disease. Evaluation of a test result should always take into account all clinical and laboratory diagnostic findings.

SYMBOLS USED



In vitro diagnostic medical device



Manufacturer



Catalogue number



Sufficient for 96 determinations



Batch code



Use by



Temperature limitation



Keep away from sunlight



Do not reuse



Date of manufacture



CE marked according to 98/79/EC



Consult instructions for use

604_4

Electronic Instruction For Use: version



Microplate



Calibrator



Calibrator



Calibrator



Calibrator



Calibrator



Calibrator



Control positive



Control negative



Sample Buffer



Enzyme Conjugate



TMB Substrate



Stop solution



Wash Buffer



Ready to use

PRINCIPLE OF THE TEST

Highly purified double-stranded DNA (dsDNA) 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 604	▽ 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: dsD
CALIBRATOR A	1x 1.5 ml	Calibrator A 0 IU/ml, containing no serum/buffer matrix (PBS, BSA, detergent, NaN3 0.09%), yellow. Ready to use.
CALIBRATOR B	1x 1.5 ml	Calibrator B 12.5 IU/ml, containing dsDNA antibodies in a serum/buffer matrix (PBS, BSA, detergent, NaN3 0.09%), yellow. Ready to use.
CALIBRATOR C	1x 1.5 ml	Calibrator C 25 IU/ml, containing dsDNA antibodies in a serum/buffer matrix (PBS, BSA, detergent, NaN3 0.09%), yellow. Ready to use.
CALIBRATOR D	1x 1.5 ml	Calibrator D 50 IU/ml, containing dsDNA antibodies in a serum/buffer matrix (PBS, BSA, detergent, NaN3 0.09%), yellow. Ready to use.
CALIBRATOR E	1x 1.5 ml	Calibrator E 100 IU/ml, containing dsDNA antibodies in a serum/buffer matrix (PBS, BSA, NaN3 0.09%), yellow. Ready to use.
CALIBRATOR F	1x 1.5 ml	Calibrator F 200 IU/ml, containing dsDNA antibodies in a serum/buffer matrix (PBS, BSA, detergent, NaN3 0.09%), yellow. Ready to use.
CONTROL +	1x 1.5 ml	Control positive, containing dsDNA 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 dsDNA 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 PD, containing PBS, BSA, detergent, preservative sodium azide 0.09%, yellow, concentrate (5 x).
CONJUGATE	15 ml	Enzyme Conjugate containing anti-human IgG antibodies, HRP labelled; PBS, BSA, detergent, preservative PROCLIN 0.05%, light red. 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 PD 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.

TEST PROCEDURE

Prepare enough microplate modules for all calibrators / controls and patient samples.

1. Pipette **100 µl** of calibrators, controls and prediluted patient samples into the wells.
Incubate for **30 minutes** at room temperature (20-28 °C).
Discard the contents of the microwells and **wash 3 times** with **300 µl** of wash solution.
2. Dispense **100 µl** of enzyme conjugate into each well.
Incubate for **15 minutes** at room temperature.
Discard the contents of the microwells and **wash 3 times** with **300 µl** of wash solution.
3. Dispense **100 µl** of TMB substrate solution into each well.
Incubate for **15 minutes** at room temperature
4. **Add 100 µl** of stop solution to each well of the modules
Incubate for **5 minutes** at room temperature.
Read the optical density at 450 nm (reference 600-690nm) and calculate the results.
The developed colour is stable for at least 30 minutes. Read during this time.

Example for a pipetting scheme:

	1	2	3	4	5	6	7	8	9	10	11	12
A	A	P1										
B	B	P2										
C	C	P3										
D	D											
E	E											
F	F											
G	C+											
H	C-											

P1, ... patient sample A-F calibrators C+, C- controls

VALIDATION

Test results are valid if the optical densities at 450 nm for calibrators / controls and the results for controls comply with the reference ranges indicated on the Certificate of Analysis enclosed in each test kit.
If these quality control criteria are not met the assay run is invalid and should be repeated.

CALCULATION OF RESULTS

For quantitative results plot the optical density of each calibrator versus the calibrator concentration to create a calibration curve. The concentration of patient samples may then be estimated from the calibration curve by interpolation.

Using data reduction software a 4-Parameter-Fit with lin-log coordinates for optical density and concentration is the data reduction method of choice.

PERFORMANCE CHARACTERISTICS

Calibration

The assay system is calibrated against the international reference preparation WHO Wo/80 for human anti-dsDNA IgG antibodies as 200 IU/ml.

Measuring range

The calculation range of this ELISA assay is 0 - 200 IU/ml

Expected values

In a normal range study with samples from healthy blood donors the following ranges have been established with this ELISA assay: Cut-off 20 IU/ml

Interpretation of results

Negative: < 20 IU/ml
Positive: ≥ 20 IU/ml

Linearity

Patient samples containing high levels of specific antibody were serially diluted in sample buffer to demonstrate the dynamic range of the assay and the upper / lower end of linearity. Activity for each dilution was calculated from the calibration curve using a 4-Parameter-Fit with lin-log coordinates.

Sample	Dilution	Observed IU/ml	Expected IU/ml	O/E [%]
1	1:100	104.2	104.2	100
.	1:200	50.6	52.1	97
.	1:400	24.9	26.1	95
.	1:800	11.2	13.0	86
2	1:100	135.3	135.3	100
.	1:200	68.9	67.7	102
.	1:400	35.2	33.8	104
.	1:800	18.2	16.9	108

Limit of detection

Functional sensitivity was determined to be: 1 IU/ml

Reproducibility

Intra-assay precision: Coefficient of variation (CV) was calculated for each of three samples from the results of 24 determinations in a single run. Results for precision-within-assay are shown in the table below.

Inter-assay precision: Coefficient of variation (CV) was calculated for each of three samples from the results of 6 determinations in 5 different runs. Results for run-to-run precision are shown in the table below.

Intra-Assay		
Sample	Mean IU/ml	CV %
1	26.0	4.5
2	61.0	3.1
3	114.0	6.4

Inter-Assay		
Sample	Mean IU/ml	CV %
1	29.0	12.4
2	68.0	7.3
3	138.0	5.2

Interfering substances

No interference has been observed with haemolytic (up to 1000 mg/dl) or lipemic (up to 3 g/dl triglycerides) sera or plasma, or bilirubin (up to 40 mg/dl) containing sera or plasma. Nor have any interfering effects been observed with the use of anticoagulants (Citrate, EDTA, Heparine). However for practical reasons it is recommended that grossly hemolyzed or lipemic samples should be avoided.

Study results

<u>Study population</u>	<u>n</u>	<u>n pos</u>	<u>%</u>
SLE	202	164	81.2
Other autoimmune diseases	33	1	3.0
Normal human sera	115	1	0.9

Clinical Diagnosis

		POS	NEG	
ORG 604	POS	164	2	
	NEG	38	146	
		202	148	350
Sensitivity: 81.2 %				
Specificity: 98.6 %				
Overall agreement: 88.6 %				

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 604_IFU_DE_QM112991_2018-01-02_3

Reason for revision: *updated description of coating material.*

- 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

Safety Data Sheet

ORG 604



1. Product identifier

Code **ORG 604**

Name **Anti-dsDNA**

Anti-dsDNA is a medical device for the quantitative detection of IgG class autoantibodies against dsDNA in human serum or plasma. Intended for professional in vitro diagnostic use only.

Manufacturer / Supplier

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2. Hazards identification

Product is **not classified as hazardous** according to the European Regulation 1999/45/EC or 1272/2008/EC.
Human health hazards: No specific hazard.

3. Composition / Information on ingredients

Coated microplate: Purified antigen coated onto polystyrene microwells.
Calibrators/controls: Human antibodies < 1% in phosphate buffered saline with Tween 20 as detergent, sodium azide 0.09% as preservative and BSA for stabilization.
Enzyme conjugate: Peroxidase conjugated anti-human antibody < 0.0001% in phosphate buffered saline with ProClin 300 as preservative and bovine serum albumin (BSA) for stabilization.
Sample buffer: Phosphate buffered saline with sodium azide 0.09% as preservative and BSA for stabilization.
Wash buffer: Tris buffered saline with Tween 20 as detergent and sodium azide 0.09% as preservative.
Substrate solution: Aqueous solution of TMB (3,3',5,5'-Tetramethylbenzidine) 0.032% with organic solvent 2-pyrrolidone < 10%, sodium perborate, citrate, EDTA, and Kathon CG as preservative.
Stop solution: Aqueous solution of phosphoric acid 4.5%.
Active substances in all mixtures do not meet the criteria for classification according to 1272/2008/EC.

4. First aid measures

Skin Contact: In case of skin contact, immediately wash thoroughly with water and soap. Remove contaminated clothing and shoes and wash before reuse. If stop solution comes into contact with skin, wash thoroughly with water.
Eye Contact: After contact with the eyes carefully rinse the opened eye with running water for at least 10 minutes. Get medical attention if necessary. Remove contact lenses if this can be done easily.
Respiratory tract: Take person to the fresh air.
Swallowing: Rinse the mouth and spit the fluids out. Drink 1 - 2 glasses of water immediately. During spontaneous vomiting hold the head of the casualty low with the body in a prone position in order to avoid the penetration of vomit into the air tube.

5. Firefighting measures

Extinguishing Media: Use dry chemical powder, water spray, foam or carbon dioxide.

6. 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.

7. Handling and storage

Handling: Special measures are not required.
Storage: Store at 2 to 8 °C. Protect from light.

8. Exposure controls / personal protection

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Safety Data Sheet

ORG 604



Respiratory protection: Not required
Hand protection: Wear protective gloves of nitril rubber or natural latex.
Eye protection: Wear protective glasses.

9. Physical and chemical properties

Coated microplate: Polystyrol microwells in foil pouch.
Calibrators: Yellow fluid in glass bottle.
Enzyme conjugate: Red fluid in polyethylene bottle.
Sample buffer: Yellow fluid in polyethylene bottle.
Wash buffer: Colorless fluid in polyethylene bottle.
Substrate solution: Colorless fluid in polyethylene bottle.
Stop solution: Colorless fluid in polyethylene bottle.

10. Stability and reactivity

Stability of components is given on the labels. Used according to intended use no dangerous reactions known.
Conditions to avoid: Substrate solution is light-sensitive. Store substrate solution in the dark.

11. Toxicological information

Used according to intended use no toxicological reactions known.

12. Ecological information

Used according to intended use no ecological reactions known.

13. Disposal considerations

Waste should be disposed of in accordance with federal, state and local environmental control regulations.
When disposing of conjugate solution, sample buffer or wash buffer flush drains with copious amounts of water.
Disposal of packaging according to the instructions of the public authorities.

14. Transport information

This product is not subject to official transport regulations.

15. Regulatory information

1907/2006/EC Registration, evaluation and authorization of chemicals regulation (REACH)
1272/2008/EC Classification, labelling and packaging regulation (CLP, globally harmonized system GHS)
replaces 67/548/EEG and 1999/45/EEG, amending 1907/2006/EC
453/2010/EC Compilation of safety data sheets regulation (SDS), amending 1907/2006/EC
This product is not classified according to the EU regulations 1272/2008. No labeling requirement.

16. Other information

Revision: prolonging validity for 3 years; editorial corrections.
Safety data for product including all components. This product is intended for professional laboratory use only.

Notice to Reader

To the best of our knowledge, the information contained herein is accurate. However, neither the above named supplier assumes any liability whatsoever for the accuracy or completeness of the information contained herein. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.