Diagnostics Biochem Canada Inc.
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Anti-Thyroid Peroxidase (Anti-TPO) ELISA

REF CAN-ATP-4160 | CE | **IVD**

Effective Date: August 8, 2024 | Version: CE-2.0

1. INTENDED PURPOSE & USE

For the quantitative measurement of Anti-Thyroid Peroxidase (Anti-TPO) autoantibodies in human serum by an ELISA (Enzyme-Linked Immunosorbent Assay). Results shall be used in combination with other clinical and laboratory data to aid in the diagnosis of autoimmune thyroid diseases in the general population.

This kit is intended for professional use only and is for laboratory use only. For *in vitro* diagnostic use only. Intended to be used manually but may be adaptable to open automated analyzers. The user is responsible for validating the performance of this kit with any automated analyzers.

2. LIMITATIONS RELATED TO INTENDED PURPOSE & USE

1. This test is not intended to be used for screening purposes.
2. This test is not intended for home testing or self-testing.
3. The kit is calibrated for the determination of anti-TPO autoantibodies in human serum. The kit is not calibrated for the determination of anti-TPO autoantibodies in other specimens of human or animal origin.
4. The results obtained with this kit shall never be used as the sole basis for a clinical diagnosis and for therapeutic decisions.
5. Although common interfering substances have been evaluated with this test, other substances that have not been evaluated such as drugs and the occurrence of heterophilic antibodies in individuals regularly exposed to animals or animal products have the potential of causing interferences.

3. SUPPLEMENTAL INFORMATION

Thyroid peroxidase (TPO), a glycoprotein with a molecular weight of 100 kD, is identified as the primary antigenic component of microsomes in thyroid cells. TPO catalyses the iodination of tyrosine in thyroglobulin during the biosynthesis of triiodothyronine and thyroxine (T3 and T4, respectively). Disorders of the thyroid gland are frequently caused by autoimmune reactions. TPO and thyroglobulin are the most important targets for autoimmune attacks. The major thyroid autoimmune diseases are Hashimoto's thyroiditis and Graves' disease. Anti-TPO autoantibodies are detected in 90–95% of autoimmune thyroid disease (AITD) patients, 80% of Graves' disease (GD), and 10–15% of non-AITD patients. A high level of anti-TPO helps to confirm the diagnosis of these thyroid auto-immune disorders. The prevalence of TPO antibodies is higher in elderly (mean age 80 years) women (10%) compared to elderly men (2%).

4. PRINCIPLE OF THE TEST

The Anti-TPO ELISA is a two-step capture or 'sandwich' type immunoassay. Thyroid peroxidase (TPO) antigen is immobilized onto the microplate. In the first incubation step, anti-TPO autoantibodies present in the specimen samples, calibrators and controls is bound to the immobilized antigen. Excess and unbound materials are removed by a washing step. In the second incubation step, anti-human-IgG HRP conjugate is added, which binds specifically to any autoantibodies that are bound to the immobilized antigen. Unbound HRP conjugate is removed by a washing step. Next, the TMB substrate (enzyme substrate) is added which reacts with HRP to form a blue coloured product that is directly proportional to the amount of anti-TPO autoantibodies present. The enzymatic reaction is terminated by the addition of the stopping solution, converting the colour from blue to yellow. The absorbance is measured on a microplate reader at 450 nm. A set of calibrators is used to plot a calibrator curve from which the amount of anti-TPO autoantibodies in specimen samples and controls can be directly read.

5. PROCEDURAL CAUTIONS AND WARNINGS

1. This kit is for use by trained laboratory personnel (professional use only). For laboratory *in vitro* use only.
2. Practice good laboratory practices when handling kit reagents and specimens. This includes:
   - Do not pipette by mouth.
   - Do not smoke, drink, or eat in areas where specimens or kit reagents are handled.
   - Wear protective clothing and disposable gloves.
   - Wash hands thoroughly after performing the test.
   - Avoid contact with eyes; use safety glasses; in case of contact with eyes, flush eyes with water immediately and contact a doctor.
3. Users should have a thorough understanding of this protocol for the successful use of this kit. Reliable performance will only be attained by strict and careful adherence to the instructions provided.
4. Do not use the kit beyond the expiry date stated on the label.
5. If the kit reagents are visibly damaged, do not use the test kit.
6. Do not use kit components from different kit lots within a test and do not use any component beyond the expiration date printed on the label.
7. All kit reagents and specimens must be brought to room temperature and mixed gently but thoroughly before use. Avoid repeated freezing and thawing of specimens.
8. When the use of water is specified for dilution or reconstitution, use deionized or distilled water.
9. Immediately after use, each individual component of the kit must be returned to the recommended storage temperature stated on the label.
10. A calibrator curve must be established for every run.
11. It is recommended to all customers to prepare their own control materials or serum pools which should be included in every run at a high and low level for assessing the reliability of results.
12. The controls (included in kit) must be included in every run and their results must fall within the ranges stated in the quality control certificate; a failed control result might indicate improper procedural techniques or pipetting, incomplete washing, or improper reagent storage.
13. When dispensing the substrate and stopping solutions, do not use pipettes in which these liquids will come into contact with any metal parts.
14. The TMB Substrate is sensitive to light and should remain colourless if properly stored. Instability or contamination may be indicated by the development of a blue colour, in which case it should not be used.
15. Do not use grossly hemolyzed, grossly lipemic, icteric or improperly stored serum.
16. Samples or controls containing azide or thimerosal are not compatible with this kit, they may lead to false results.
17. Samples values above the measuring range of the kit are reported as >1000 IU/mL. Do not further dilute samples as this may lead to false results.
18. Avoid microbial contamination of reagents.
19. To prevent the contamination of reagents, use a new disposable pipette tip for dispensing each reagent, sample, calibrator, and control.
20. To prevent the contamination of reagents, do not pour reagents back into the original containers.
21. Kit reagents must be regarded as hazardous waste and disposed of according to local and/or national regulations.
22. Consumables used with the kit that are potentially biohazardous (e.g., pipette tips, bottles or containers containing human materials) must be handled according to biosafety practices to minimize the risk of infection and disposed of according to local and/or national regulations relating to biohazardous waste.
23. This kit contains 1 M sulfuric acid in the stopping solution component. Do not combine acid with waste material containing sodium azide or sodium hypochlorite.
24. The use of safety glasses, and disposable plastic, is strongly recommended when manipulating biohazardous or bio-contaminated solutions.
25. Proper calibration of the equipment used with the test, such as the pipettes and absorbance microplate reader, is required.
26. If a microplate shaker is required for the assay procedure, the type and speed of shaker required is stated in the REAGENTS AND EQUIPMENT NEEDED BUT NOT PROVIDED section. Both the type and speed of shaker used can influence the optical densities and test results. If a different type of shaker and/or speed is used, the user is responsible for validating the performance of the kit.
27. Do not reuse the microplate wells, they are for SINGLE USE only.
28. To avoid condensation within the microplate wells in humid environments, do not open the pouch containing the microplate until it has reached room temperature.
29. When reading the microplate, the presence of bubbles in the wells will affect the optical densities (ODs). Carefully remove any bubbles before performing the reading step.
30. Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the European Member State in which the user and/or the patient is established.

6. SAFETY CAUTIONS AND WARNINGS

6.1 BIOHAZARDS

The reagents should be considered a potential biohazard and handled with the same precautions applied to blood specimens. All human specimens should be considered a potential biohazard and handled as if capable of transmitting infections and in accordance with good laboratory practices.

Human serum that is used in the preparation of the calibrators and controls has been tested by approved methods and found to be negative for the presence of HBsAg and antibodies to HCV and HIV 1/2. However, no test method can offer complete assurance that any viable pathogens are absent. Therefore, these components should be considered a potential biohazard and handled with the same precautions as applied to any blood specimen, following good laboratory practices.

6.2 CHEMICAL HAZARDS

Avoid direct contact with any of the kit reagents. Specifically avoid contact with the TMB Substrate (contains tetramethylbenzidine) and Stopping Solution (contains sulfuric acid). If contacted with any of these reagents, wash with plenty of water and refer to SDS for additional information.

7. SPECIMEN COLLECTION, STORAGE AND PRE-TREATMENT

7.1 Specimen Collection & Storage

Approximately 0.05 mL of serum is required per duplicate determination. Collect 4–5 mL of venous blood into an appropriately labelled tube and allow it to clot at room temperature. Centrifuge at room temperature and carefully transfer the serum into a new labelled storage tube or container. Serum samples may be stored at room temperature and at 2-8°C for up to 24 hours and at or below -20°C for up to 1 month. Specimens may be more stable than indicated. Consider all human specimens as possible biohazardous materials and take appropriate precautions when handling.

7.2 Specimen Pre-Treatment & Storage

All serum specimens must be diluted 1:20 in the provided Assay Buffer before being used in the test. Follow the specimen pre-treatment procedure as stated below for each specimen that is to be tested:

1. Pipette 0.475 mL of the Assay Buffer into a new polypropylene microcentrifuge tube.
2. Pipette 25 µL of the serum specimen into the tube from step 1 that contains 0.475 mL of assay buffer.
3. Close the tube and label with specimen identification information.
4. Mix the contents of the tube by vortexing.

Do not pre-treat the calibrators and kit controls; they are provided in a ready to use format.

Diluted serum specimens (1:20 dilution used in the test) are stable for up to 8 hours at room temperature. Do not use any diluted specimens that have been stored beyond this time limit or at different temperatures.

8. REAGENTS AND EQUIPMENT NEEDED BUT NOT PROVIDED

1. Calibrated single-channel pipette to dispense 25 µL, 100 µL and 475 µL.
2. Calibrated multi-channel pipettes to dispense 50 µL and 100 µL.
3. Calibrated multi-channel pipettes to dispense 350 µL (if washing manually).
4. Automatic microplate washer (recommended).
5. Disposable pipette tips.
6. Distilled or deionized water.
7. Calibrated absorbance microplate reader with a 450 nm filter and an upper OD limit of 3.0 or greater.
8. Polypropylene or HDPE tubes for sample dilution (e.g., polypropylene microcentrifuge tubes).

9. REAGENTS PROVIDED

1. MPL — Microplate

Contents:	One thyroid peroxidase antigen-coated 96-well (12x8) microplate in a resealable pouch with desiccant.
Format:	Ready to Use
Storage:	2–8°C
Stability:	Unopened: Stable until the expiry date printed on the label. After Opening: Stable for four weeks.

2. HRP CONJ — HRP Conjugate

Contents:	One bottle containing Anti-Human IgG-Horse Radish Peroxidase (HRP) conjugate in a protein-based buffer with a non-mercury preservative.
Format:	Ready to Use
Volume:	13 mL/bottle
Storage:	2–8°C
Stability:	Unopened: Stable until the expiry date printed on the label. After Opening: Stable for four weeks.

3. CAL | A – G — Calibrator A – G

Contents:	Seven bottles of calibrator containing specified anti-TPO autoantibody concentrations. Protein-based buffer with a non-mercury preservative. Prepared by spiking buffer with defined quantities of human serum. Listed below are approximate concentrations, please refer to vial labels for exact concentrations. Concentrations: 0, 10, 30, 100, 250, 500, 1000 IU/mL.
Format:	Ready to Use
Volume:	Calibrator A-G: 1.0 mL/bottle
Storage:	2–8°C
Stability:	Unopened: Stable until the expiry date printed on the label. After Opening: Stable for four weeks.

4. CONTROL | 1 – 2 — Control 1 – 2

Contents:	Two bottles of control containing different anti-TPO autoantibody concentrations. Protein-based buffer with a non-mercury preservative. Prepared by spiking buffer with defined quantities of human serum. Refer to the QC certificate for the target values and acceptable ranges.
Format:	Ready to Use
Volume:	1.0 mL/bottle
Storage:	2–8°C
Stability:	Unopened: Stable until the expiry date printed on the label. After Opening: Stable for four weeks.

5. ASY | BUFF — Assay Buffer

Contents:	One bottle containing a protein-based buffer with a non-mercury preservative.
Format:	Ready to Use
Volume:	55 mL/bottle
Storage:	2–8°C
Stability:	Unopened: Stable until the expiry date printed on the label. After Opening: Stable for four weeks.

6. TMB | SUB — TMB Substrate

Contents:	One bottle containing tetramethylbenzidine and hydrogen peroxide in a non-DMF or DMSO containing buffer.
Format:	Ready to Use
Volume:	18 mL/bottle
Storage:	2–8°C
Stability:	Unopened: Stable until the expiry date printed on the label. After Opening: Stable for four weeks.

7. STOP — Stopping Solution

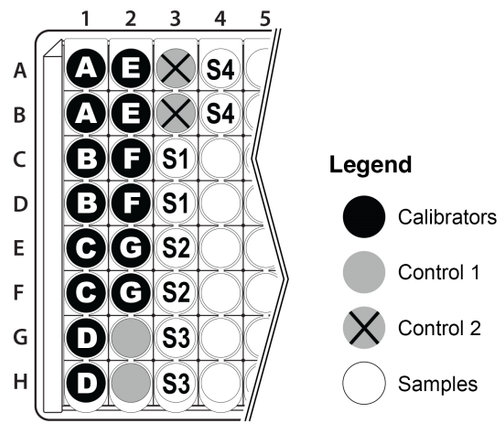
Contents:	One bottle containing 1M sulfuric acid.
Format:	Ready to Use
Volume:	6 mL/bottle
Storage:	2–8°C
Stability:	Unopened: Stable until the expiry date printed on the label. After Opening: Stable for four weeks.
Safety:	Refer to product SDS.

Warning

8. WASH | BUFF | CONC — Wash Buffer Concentrate

Contents:	One bottle containing buffer with a non-ionic detergent and a non-mercury preservative.
Format:	Concentrated; Requires Preparation
Volume:	50 mL/bottle
Storage:	2–8°C
Stability:	Unopened: Stable until the expiry date printed on the label. After Opening: Stable for four weeks. Following Preparation: The wash buffer working solution is stable for 2 weeks following preparation, assuming Good Laboratory Practices are adhered to. To prevent microbial growth, prepare the wash buffer working solution in a clean container and store under refrigerated conditions (2-8°C) when not in use.
Preparation of Wash Buffer Working Solution:	**X10 — Dilute 1:10 Before Use** Dilute 1:10 in distilled or deionized water before use. If the whole microplate is to be used dilute 50 mL of the wash buffer concentrate in 450 mL of distilled or deionized water.

10. RECOMMENDED ASSAY LAYOUT



11. ASSAY PROCEDURE

Specimen Pre-Treatment:

All specimens that will be tested must be pre-treated before being tested (see section *7.2. Specimen Pre-Treatment & Storage*). Do not pre-treat the calibrators and kit controls as they are provided ready to use.

All kit components, controls and specimen samples must reach room temperature prior to use. Calibrators, controls, and specimen samples should be assayed in duplicate. Once the procedure has been started, all steps should be completed without interruption.

1. After all kit components have reached room temperature, **mix** gently by inversion.
2. **Prepare** the Wash Buffer Working Solution (See section *9. Reagents Provided, 8. Wash Buffer Concentrate*).
3. **Prepare** all specimen samples that will be tested. Refer to section *7.2. Specimen Pre-Treatment & Storage*.
4. **Plan** the microplate wells to be used for calibrators, controls, and samples. See section *10. Recommended Assay Layout.* Remove the strips from the microplate frame that will not be used and place them in the bag with desiccant. Reseal the bag with the unused strips and return it to the refrigerator.
5. Pipette **100 µL** of each calibrator, control, and pre-treated specimen sample into assigned wells.
6. Incubate the microplate at room temperature (no shaking) for **30 minutes.** Do not tap the microplate and avoid placing in intense light or air currents.
7. **Wash** the microplate wells with an automatic microplate washer (preferred) or manually as stated below.

   Automatic: Using an automatic microplate washer, perform a **3-cycle** wash using **350 µL/well** of Wash Buffer Working Solution (3 x 350 µL). One cycle consists of aspirating all wells then filling each well with 350 µL of Wash Buffer Working Solution. After the final wash cycle, aspirate all wells and then tap the microplate firmly against absorbent paper to remove any residual liquid.

   Manually: For manual washing, perform a **3-cycle** wash using **350 µL/well** of Wash Buffer Working Solution (3 x 350 µL). One cycle consists of aspirating all wells by briskly emptying the contents of the wells over a waste container, then pipetting 350 µL of Wash Buffer Working Solution into each well using a multi-channel pipette. After the final wash cycle, aspirate all wells by briskly emptying the contents over a waste container and then tap the microplate firmly against absorbent paper to remove any residual liquid.
8. Pipette **100 µL** of the HRP Conjugate into each well (the use of a multi-channel pipette is recommended).
9. Incubate the microplate at room temperature (no shaking) for **30 minutes.** Do not tap the microplate and avoid placing in intense light or air currents.
10. **Wash** the microplate wells again as stated in step 7.
11. Pipette **100 µL** of TMB Substrate into each well (the use of a multi-channel pipette is recommended).
12. Incubate the microplate at room temperature (no shaking) for **15 – 20 minutes** (until calibrator G attains dark blue colour for desired OD). Do not tap the microplate and avoid placing in intense light or air currents.
13. Pipette **50 µL** of Stopping Solution into each well (the use of a multi-channel pipette is recommended) in the same order and speed as was used for addition of the TMB Substrate. Gently tap the microplate frame to mix the contents of the wells.
14. **Measure** the optical density (absorbance) in the microplate wells using an absorbance microplate reader set to 450 nm, within 20 minutes after addition of the Stopping Solution.

12. CALCULATIONS

1. Calculate the mean optical density for each calibrator, control and specimen sample duplicate.
2. Use a 4-parameter or 5-parameter curve fit with immunoassay software to generate a calibrator curve.
3. The immunoassay software will calculate the concentrations of the controls and specimen samples using the mean optical density values and the calibrator curve.

Do not apply any dilution factor to the controls or specimen sample results. The calibrators are provided in a pre-diluted (1:20), ready to use format in the kit which automatically compensates for the dilution of specimen samples.

4. If a sample value is greater than 1000 IU/mL then report as >1000 IU/mL; do not further dilute and retest.

13. QUALITY CONTROL

When assessing the validity of the test results, the following criteria should be evaluated:

1. The calibrator A mean optical density meets the acceptable range as stated in the QC Certificate.
2. The calibrator with the highest concentration meets the optical density acceptable range as stated in the QC Certificate.
3. The values obtained for the kit controls are within the acceptable ranges as stated in the QC certificate.
4. The results of any external controls that were used meet the acceptable ranges.

14. TYPICAL DATA

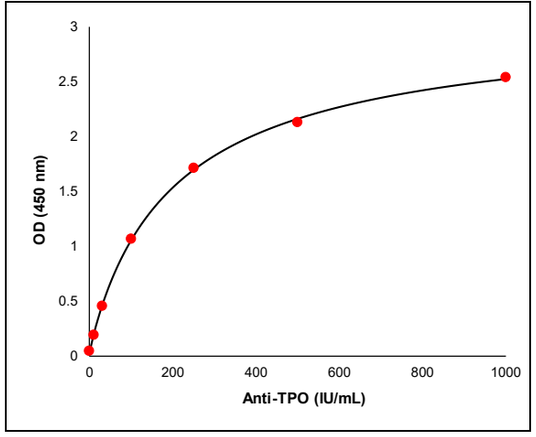
14.1 TYPICAL TABULATED DATA

Sample data only. **Do not** use to calculate results.

Calibrator	Mean OD (450 nm)	% Binding	Value (IU/mL)
A	0.049	1.9	0
B	0.197	7.7	10
C	0.458	18.0	30
D	1.067	42.0	100
E	1.714	67.5	250
F	2.132	83.9	500
G	2.540	100	1000
Unknown	0.509	-	34.0

14.2 TYPICAL CALIBRATOR CURVE

Sample curve only. **Do not** use to calculate results.



15. PERFORMANCE CHARACTERISTICS

15.1 SENSITIVITY

The analytical sensitivity study was performed according to the CLSI EP17-A2 guideline. The Limit of Background (LoB), Limit of Detection (LoD) and Limit of Quantitation (LoQ) are summarized in the table below:

Parameter	Anti-TPO (IU/mL)
LoB	0.074
LoD	0.819
LoQ	2.89

15.2 SPECIFICITY (CROSS-REACTIVITY)

Three serum samples were spiked with 1000 µg/mL of Thyroglobulin (Tg). No significant cross-reactivity was observed. The results are summarized in the table below.

Sample	Unspiked (Anti-TPO, IU/mL)	Spiked 1000 µg/mL Tg (Anti TPO, IU/mL)	Recovery %
1	359.347	357.987	99.6%
2	156.887	169.173	107.8%
3	342.303	359.094	104.9%

15.3 INTERFERENCES

An interference study was performed according to the CLSI EP07-A3 guideline. No significant interference was observed for concentrations of up to 2 g/L haemoglobin, 40 mg/dL Bilirubin (conjugated and unconjugated), 15 mg/mL triglycerides, 1.2 µg/mL HAMAS, 2.4 µg/mL Biotin and 1688 IU/mL Rheumatoid Factor.

15.4 HIGH-DOSE HOOK EFFECT

No high-dose hook effect was observed for anti-TPO concentrations up to 8689.7 IU/mL.

15.5 PRECISION

The precision study was performed according to the CLSI EP5-A3 guideline.
The experimental protocol used a nested components-of-variance design with 9 serum samples, 10 testing days, two lots and two scientists per day. Each scientist ran two tests with two lots per day and two replicate measurements per run (a 10 x 2 x 2 x 2 design) for each sample. The results were analyzed with a two-way nested ANOVA and summarized in the table below.

Sample	Mean (IU/mL)	Within Run SD (IU/mL)	Within Run CV%	Between Run SD (IU/mL)	Between Run CV%	Total SD (IU/mL)	Total CV%
1	15.4	0.8	5.1	2.3	15.2	2.5	16.1
2	73.8	4.0	5.4	8.0	10.9	9.2	12.5
3	188.1	11.5	6.1	22.5	12.0	25.3	13.4
4	484.8	43.7	9.0	66.1	13.6	79.2	16.3
5	72.7	3.4	4.7	6.9	9.5	7.7	10.6
6	90.7	3.6	3.9	7.7	8.4	8.5	9.3
7	272.3	18.9	6.9	35.3	13.0	40.1	14.7
8	282.5	19.9	7.0	48.5	17.2	52.8	18.7
9	222.0	11.5	5.2	24.1	17.2	27.0	12.2

15.6 RECOVERY

Low value samples and high value samples were mixed at different ratios. The measured values were compared to the expected values and the recovery % for each sample was calculated. The results are summarized in the table below.

	Sample	Measured (IU/mL)	Expected (IU/mL)	Recovery %
Low value: S1	100% S1	25.6	25.6	-
	50% S1 / 50% S2	214.6	191.7	111.9
	30% S1 / 70% S2	303.8	258.2	117.7
High value: S2	10% S1 / 90% S2	283.1	324.6	87.2
	100% S2	357.8	357.8	-
Low value: S3	100% S3	33.7	33.7	-
	50% S3 / 50% S4	215.3	181.2	118.8
	30% S3 / 70% S4	255.3	240.2	106.3
High value: S4	10% S3 / 90% S4	360.6	299.3	120.5
	100% S4	328.8	328.8	-
Low value: S5	100% S5	8.8	8.8	-
	50% S5 / 50% S6	436.0	428.0	101.9
	30% S5 / 70% S6	543.1	595.6	91.2
High value: S6	10% S5 / 90% S6	817.1	763.3	107.0
	100% S6	847.2	847.2	-

15.7 COMPARATIVE STUDIES

The DBC Anti-TPO ELISA kit (y) was compared against a competitor's ECLIA method (x). The comparison of 101 serum samples yielded the following linear regression results:
y = 0.90x - 7.36, r = 0.92

16. REFERENCE RANGES

Serum samples from healthy individuals of diverse races, were screened for serum TSH levels between 0.5 and 3.0 µIU/mL. After completing the screen, 166 samples were selected and tested. Sample details:
100 x female, 66 x male, age range: 18–62 years old, average age: 34 years old. Results are summarized below.
Each laboratory shall establish their own reference ranges.

N	95% Range	Negative for Anti-TPO Autoantibodies	Positive for Anti-TPO Autoantibodies
166	5.3–58.8 IU/mL	≤ 58.8 IU/mL	> 58.8 IU/mL

17. LITERATURE

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18. SYMBOLS GLOSSARY

Symbol	Definition	Symbol	Definition
REF	Catalogue number		Manufacturer
LOT	Batch code		Date of manufacture
IVD	In vitro diagnostic medical device		Biological risks
UDI	Unique Device Identifier		Consult instructions for use
X #	Dilute 1:# Before Use	Rx ONLY	Prescription only: Device restricted to use by or on the order of a physician
QTY	Quantity		Keep away from sunlight
	Use-by date	EC REP	Authorized representative in the European Community/ European Union
	Do not re-use		Temperature limit
	Caution		Contains sufficient for <n> tests
LYO	Lyophilized	RUO	For Research Use Only. Not for use in diagnostic procedures.

The definitions of symbols used for kit component names are described in the *Reagents Provided* section.

19. CHANGE HISTORY

Previous Version:	CE-1.1	New Version:	CE-2.0
Changes:	**4. PRINCIPLE OF THE TEST** **Change:** **From:** The enzymatic reaction is terminated by the addition of the stopping solution, converting the blue colour to a yellow colour. **To:** The enzymatic reaction is terminated by the addition of the stopping solution, converting the colour from blue to yellow. **5. PROCEDURAL CAUTIONS AND WARNINGS** **Addition:** 29. When reading the microplate, the presence of bubbles in the wells will affect the optical densities (ODs). Carefully remove any bubbles before performing the reading step. **Change:** 30. Specified 'European' member State.		
	11. ASSAY PROCEDURE **Correction:** 12. Corrected from '(until calibrator F attains dark blue colour for desired OD)' to '(until calibrator G attains dark blue colour for desired OD)'. **15.3 INTERFERENCES** **Correction:** The concentration of HAMAS that was tested was corrected from 2.4 µg/mL to 1.2 µg/mL. **18. SYMBOLS GLOSSARY** **Addition:** • Date of Manufacture • Lyophilized Build: *v1.4D* BASE: *v3.0*		

20. GENERAL INFORMATION

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www.dbc-labs.com

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MedEnvoy Global B.V.
Prinses Margrietplantsoen 33, Suite 123
2595AM The Hague
The Netherlands

Product Complaints

In the case of product complaints, the user shall submit in writing to the distributor or manufacturer a description of the complaint and provide accompanying data and/or information.

Warranty

DBC guarantees that the product is free of defects and will perform within the product specifications when the product is used prior to the expiration date, according to the intended purpose and use, and according to the instructions for use provided with the product. Any deviations from the intended purpose and use, instructions for use, modifications to kit components or use beyond the expiration date will invalidate any warranty claims.

Limitation of Liability

DBC liability in all circumstances whether in tort (including negligence) or at common law, and for any damage or loss, including but not limited to loss of profit and loss of sales, suffered whether direct, indirect, consequential, incidental or special is limited to the purchase price of the product(s) in question.