

Cortisol ELISA

REF CAN-C-270



IVD

Effective Date: October 17, 2023

Version: CE-13.0

1. INTENDED PURPOSE & USE

For the quantitative measurement of Cortisol in human serum by an ELISA (Enzyme-Linked Immunosorbent Assay).

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

- This test is not intended to be used for screening purposes.
- This test is not intended for home testing or self-testing.
- The kit is calibrated for the determination of cortisol in human serum. The kit is not calibrated for the determination of cortisol in other specimens of human or animal origin.
- There is an observed cross-reactivity of 16.3% with prednisone and 21.6% with prednisolone. Since prednisone is converted to prednisolone *in vivo*, caution must be exercised when assaying the cortisol levels of individuals undergoing either therapy. Under the advice of a physician, prednisolone should be stopped 24 hours before performing a cortisol serum test to ensure no interference with the cortisol assay.
- The results obtained with this kit shall never be used as the sole basis for a clinical diagnosis and for therapeutic decisions.
- 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

Cortisol is the most abundant circulating steroid and the major glucocorticoid secreted by the adrenal cortex. Cortisol is physiologically effective in blood pressure maintenance and anti-inflammatory activity. It is also involved in calcium absorption, gluconeogenesis as well as the secretion of gastric acid and pepsin. Measurement of blood cortisol levels can be used as an indicator of adrenal function and the differential diagnosis of Addison's and Cushing's diseases as well as adrenal hyperplasia. Most circulating cortisol is bound to cortisol binding globulin or transcortin. Cortisol in blood shows a diurnal rhythm with the highest levels in the morning and the lowest levels at night.

4. PRINCIPLE OF THE TEST

The Cortisol ELISA is a competitive immunoassay. Competition occurs between cortisol present in calibrators, controls, specimen samples and an enzyme-labelled antigen (HRP conjugate) for a limited number of anti-cortisol antibody binding sites on the microplate wells. After a washing step that removes unbound materials, the TMB substrate (enzyme substrate) is added which reacts with HRP to form a blue-coloured product that is inversely proportional to the amount of cortisol present. Following an incubation, 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 cortisol in specimen samples and controls can be directly read.

5. PROCEDURAL CAUTIONS AND WARNINGS

- This kit is for use by trained laboratory personnel (professional use only). For laboratory *in vitro* use only.
- 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.
- 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.
- Do not use the kit beyond the expiry date stated on the label.
- If the kit reagents are visibly damaged, do not use the test kit.
- 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.
- 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.
- When the use of water is specified for dilution or reconstitution, use deionized or distilled water.
- Immediately after use, each individual component of the kit must be returned to the recommended storage temperature stated on the label.
- A calibrator curve must be established for every run.
- 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.
- 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.
- When dispensing the substrate and stopping solutions, do not use pipettes in which these liquids will come into contact with any metal parts.
- 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.
- Do not use grossly hemolyzed, grossly lipemic, icteric or improperly stored serum.
- Samples or controls containing azide or thimerosal are not compatible with this kit, they may lead to false results.
- Samples values above the measuring range of the kit may be reported as >40 µg/dL. If further dilution and retesting is required, only calibrator A may be used to dilute serum samples. The use of any other reagent may lead to false results.
- Avoid microbial contamination of reagents.
- To prevent the contamination of reagents, use a new disposable pipette tip for dispensing each reagent, sample, calibrator, and control.
- To prevent the contamination of reagents, do not pour reagents back into the original containers.
- Kit reagents must be regarded as hazardous waste and disposed of according to local and/or national regulations.
- 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.
- 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.
- The use of safety glasses, and disposable plastic, is strongly recommended when manipulating biohazardous or bio-contaminated solutions.
- Proper calibration of the equipment used with the test, such as the pipettes and absorbance microplate reader, is required.

- 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.
- Do not reuse the microplate wells, they are for SINGLE USE only.
- To avoid condensation within the microplate wells in humid environments, do not open the pouch containing the microplate until it has reached room temperature.
- 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.
- 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.

The calibrators and controls provided with the kit contain processed human serum/plasma that has been tested by approved methods and found to be negative for the presence of HBsAg and antibodies to HCV, HIV 1/2 and HIV NAT. 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 0.1 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. Centrifuge at room temperature and carefully transfer the serum into a new storage tube or container. Serum samples may be stored at room temperature for up to 24 hours, 2–8°C for up to 5 days or at -20°C or lower for up to 30 days. 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

Specimen pre-treatment is not required.

8. REAGENTS AND EQUIPMENT NEEDED BUT NOT PROVIDED

- Calibrated single-channel pipette to dispense 20 µL.
- Calibrated multi-channel pipettes to dispense 50 µL and 150 µL.
- Calibrated multi-channel pipettes to dispense 350 µL (if washing manually).
- Automatic microplate washer (recommended).
- Disposable pipette tips.
- Distilled or deionized water.
- Calibrated absorbance microplate reader with a 450 nm filter and an upper OD limit of 3.0 or greater.

9. REAGENTS PROVIDED

1. MPL Microplate

Contents:	One anti-cortisol polyclonal antibody-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 Cortisol-Horse Radish Peroxidase (HRP) conjugate in a protein-based buffer with a non-mercury preservative.
Format:	Ready to Use
Volume:	20 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 – F Calibrator A – F

Contents:	Six bottles of calibrator containing specified cortisol concentrations. Human serum-based matrix with a non-mercury preservative. Prepared by spiking matrix with defined quantities of cortisol. Listed below are approximate concentrations, please refer to vial labels for exact concentrations. Concentrations: 0, 0.4, 1, 4, 10, 40 µg/dL.
Format:	Ready to Use
Volume:	Calibrator A-F: 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 cortisol concentrations. Human serum-based matrix with a non-mercury preservative. Prepared by spiking matrix with defined quantities of cortisol. 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. 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:	16 mL/bottle
Storage:	2–8°C
Stability:	Unopened: Stable until the expiry date printed on the label. After Opening: Stable for four weeks.

6. 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

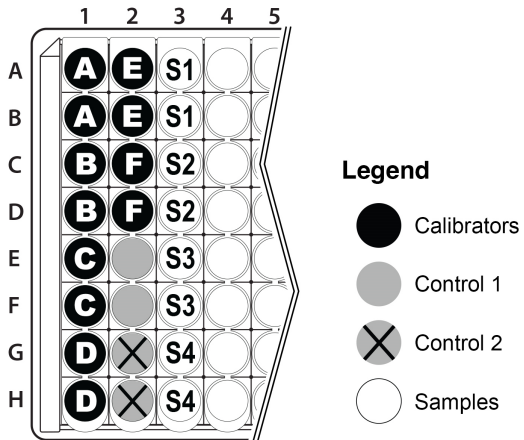
7. WASH BUFF CONC Wash Buffer Concentrate

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.

X10 Dilute 1:10 Before Use

Preparation of Wash Buffer Working Solution:	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.
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10. RECOMMENDED ASSAY LAYOUT



11. ASSAY PROCEDURE

Specimen Pre-Treatment: None	
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. <i>Reagents Provided, 7. Wash Buffer Concentrate</i>).
3.	Plan the microplate wells to be used for calibrators, controls, and samples. See section 10. <i>Recommended Assay Layout</i> . 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.
4.	Pipette 20 µL of each calibrator, control, and specimen sample into assigned wells.
5.	Pipette 150 µL of the HRP Conjugate into each well (the use of a multi-channel pipette is recommended).
6.	Gently tap the microplate frame for 10 seconds to mix the contents of the wells and incubate the microplate at room temperature (no shaking) for 45 minutes .
7.	Wash the microplate wells with an automatic microplate washer (preferred) or manually as stated below. <i>Automatic:</i> 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. <i>Manually:</i> 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 150 µL of TMB Substrate into each well (the use of a multi-channel pipette is recommended).
9.	Gently tap the microplate frame for 10 seconds to mix the contents of the wells and incubate the microplate at room temperature (no shaking) for 15 minutes .
10.	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.
11.	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

- Calculate the mean optical density for each calibrator, control and specimen sample duplicate.
- Use a 4-parameter or 5-parameter curve fit with immunoassay software to generate a calibrator curve.
- The immunoassay software will calculate the concentrations of the controls and specimen samples using the mean optical density values and the calibrator curve.
- If a sample reads more than 40 µg/dL and needs to be diluted and retested, dilute it with calibrator A not more than 1:10. The result obtained must be multiplied by the dilution factor.

13. QUALITY CONTROL

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

- The calibrator A mean optical density meets the acceptable range as stated in the QC Certificate.
- The calibrator with the highest concentration meets the % binding acceptable range as stated in the QC Certificate. % Binding = (OD of calibrator/OD of calibrator A) x 100.
- The values obtained for the kit controls are within the acceptable ranges as stated in the QC certificate.
- The results of any external controls that were used meet the acceptable ranges.

14. TYPICAL DATA

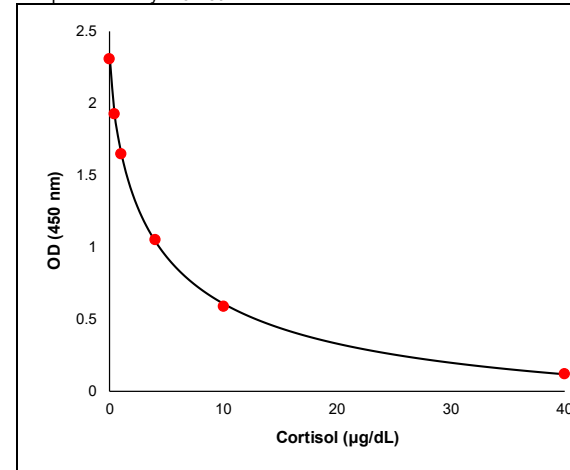
14.1 TYPICAL TABULATED DATA

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

Calibrator	Mean OD (450 nm)	% Binding	Value (µg/dL)
A	2.307	100	0
B	1.926	84	0.4
C	1.651	72	1
D	1.056	46	4
E	0.593	26	10
F	0.123	5	40
Unknown	0.738	-	7.5

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	Cortisol (µg/dL)
LoB	0.143
LoD	0.298
LoQ	0.300

15.2 SPECIFICITY (CROSS-REACTIVITY)

The following compounds were tested for cross-reactivity with cortisol cross-reacting at 100%. ND=Not detected.

Compound	% Cross-Reactivity
Cortisol	100
11-Deoxycorticosterone	3.8
11-Deoxycortisol	8.7
17-OH-progesterone	10.2
21-Deoxycortisol	ND
Aldosterone	0.8
Allopregnanolone	2.0
Androstenedione	1.0
Androsterone	ND
Corticosterone	14.2
Cortisone	8.8
Dehydroepiandrosterone	ND
DHEAS	ND
Dihydrotestosterone	ND
Estradiol	ND
Estrilol	ND
Estrone	ND
Prednisolone	21.6
Prednisone	16.3
Pregnenolone	0.5
Testosterone	3.3

15.3 INTERFERENCES

An interference study was performed according to the CLSI EP07 guideline. No significant interference was observed for concentrations of up to 2 g/L haemoglobin, 20 mg/dL Bilirubin (conjugated and unconjugated), 5.0 mg/mL triglycerides, 1.2 µg/mL HAMAS, 2.4 µg/mL Biotin and 1500 IU/mL Rheumatoid Factor.

15.4 PRECISION

The precision study was performed according to the CLSI EP5-A3 guideline. The experimental protocol used a nested components-of-variance design with 8 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 (µg/dL)	Within Run SD (µg/dL)	Within Run CV%	Between Run SD (µg/dL)	Between Run CV%	Total SD (µg/dL)	Total CV%
1	3.520	0.097	2.7	0.188	5.3%	0.220	6.3
2	12.640	0.206	1.6	0.389	3.1%	0.440	3.5
3	32.347	0.349	1.1	0.551	1.7%	0.652	2.0
4	0.829	0.072	8.7	0.079	9.5%	0.107	12.8
5	15.358	0.341	2.2	0.350	2.3%	0.502	3.3
6	32.274	0.493	1.5	0.546	1.7%	0.736	2.3
7	9.461	0.179	1.9	0.295	3.1%	0.361	3.8
8	4.568	0.208	4.5	0.162	3.5%	0.274	6.0

15.5 LINEARITY

The linearity study was according to the CLSI EP06-A guideline using three human serum samples covering the range of the assay. The samples were diluted in calibrator A at several equidistant concentration levels and up to a 1:10 dilution. Samples were tested in duplicate, and the regression equation of the results (y) compared to the concentration (x) predicted from the dilution factor was: $y = 0.98x + 0.17$, $r = 0.99$. The relative non-linearity was $\leq 4.8\%$ at a dilution ratio up to 1:10 for all samples. The statistical analysis demonstrates that the assay is sufficiently linear throughout the dynamic range of the kit.

15.6 RECOVERY

Spiked samples were prepared by adding defined amounts of cortisol (2, 10 and 30 µg/dL) in a human serum matrix to three human serum samples (1:1 volume). The results (in µg/dL) are tabulated below:

Sample	Observed Result	Expected Result	Recovery %
S1 Unspiked	12.374	-	-
+2 µg/dL (1:1)	7.125	7.187	99.1
+10 µg/dL (1:1)	10.941	11.187	97.8
+30 µg/dL (1:1)	22.519	21.187	106.3
S2 Unspiked	10.44	-	-
+2 µg/dL (1:1)	6.571	6.22	105.6
+10 µg/dL (1:1)	9.689	10.22	94.8
+30 µg/dL (1:1)	20.155	20.22	99.7
S3 Unspiked	8.488	-	-
+2 µg/dL (1:1)	5.845	5.244	111.5
+10 µg/dL (1:1)	8.308	9.244	89.9
+30 µg/dL (1:1)	18.47	19.244	96.0

15.7 COMPARATIVE STUDIES

The DBC Cortisol ELISA kit (y) was compared to a competitor's commercial Cortisol ELISA kit (x). The comparison of 71 human serum samples yielded the following linear regression results: $y = 1.17x - 0.73$, $r = 0.99$

16. REFERENCE RANGES

Reference ranges (95%) were estimated using male and female human serum samples collected during the AM and PM. Samples were obtained from adult individuals of diverse races. Results are summarized below. Each laboratory shall establish their own reference ranges.

Group	N	Median (µg/dL)	95% Confidence Range (µg/dL)
AM Collection	52	11.46	4.94 -18.32
PM Collection	52	6.82	3.23 -13.82

17. LITERATURE

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18. SYMBOLS GLOSSARY

Symbol	Definition	Symbol	Definition
	Catalogue number		Manufacturer
	Batch code		Date of manufacture
	In vitro diagnostic medical device		Biological risks
	Unique Device Identifier		Consult instructions for use
	Dilute 1:# Before Use		Prescription only: Device restricted to use by or on the order of a physician
	Quantity		Keep away from sunlight
	Use-by date		Authorized representative in the European Community/ European Union
	Do not re-use		Temperature limit
	Caution		Contains sufficient for <n> tests
	Lyophilized		For Research Use Only. Not for use in diagnostic procedures.
The definitions of symbols used for kit component names are described in the <i>Reagents Provided</i> section.			

19. CHANGE HISTORY

Previous Version:	CE-12.0	New Version:	CE-13.0
Changes:	20. GENERAL INFORMATION Change: EC REP changed from Emergo Europe to MedEnvoy Global B.V. Build: v1.4D BASE: v12.0		

20. GENERAL INFORMATION

	Diagnosics Biochem Canada (DBC) Inc. 384 Neptune Crescent London, Ontario, Canada N6M 1A1 Tel: (519) 681-8731 Fax: (519) 681-8734 e-mail: dbc@dbc-labs.com www.dbc-labs.com
	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.