

QDx InstaCheck™ Cortisol

INTENDED USE

QDx InstaCheck™ Cortisol along with QDx InstaCheck™ Reader is a fluorescence immunoassay (FIA) for the quantitative determination of Cortisol in human whole blood/serum/plasma. It is useful as an aid in management and monitoring of concentration of cortisol.

INTRODUCTION

Cortisol is a potent hormone known as a glucocorticoid that affects the metabolism of carbohydrates, proteins, and fats, but especially glucose. Cortisol test is performed on patients who may have malfunctioning adrenal glands. Cortisol level normally rises and falls during the day. It peaks its highest level between 6 and 8 AM and gradually falls, reaching its lowest point around midnight. When cortisol level is measured, blood specimen is usually collected at 8 AM and again at 4 PM. It should be noted that normal values may be adjusted in individuals who have worked during the night and slept during the day for long periods of time. QDx InstaCheck™ Cortisol quantitatively measures the cortisol concentration of whole blood, serum and plasma.

PRINCIPLE

The test uses a competitive immunodetection method; In this method, the target material in the sample bind to the fluorescence (FL)-labeled detection antibodies in the detection buffer, to form the complex as sample mixture. This complex is loaded to migrate onto the nitrocellulose matrix, where the covalent couple of cortisol and bovine serum albumin (BSA) is immobilized on the test strip, and interferes with the binding of target material and FL-labeled antibody. If the more target material exists in blood, the less detection antibody is accumulated, resulting in the less fluorescence signal.

COMPONENTS AND REAGENTS

QDx InstaCheck™ Cortisol consists of 'Cartridges', 'Detection Buffer Tubes' and an 'ID chip'.

- The cartridge contains a test strip, the membrane which has BSA-human cortisol at the test line, with streptavidin at the control line.
- Each cartridge is individually sealed in an aluminum foil pouch containing of a desiccant. 25 sealed cartridges are packed in a box which also contains an ID chip.
- The detection buffer contains anti human cortisol-fluorescence conjugate, biotin-BSA-fluorescence conjugate, bovine serum albumin (BSA) as a stabilizer and sodium azide as a preservative in phosphate buffered saline.
- The detection buffer is pre-dispensed in a tube. 25 detection buffer tubes are packaged in a box and further packed in a Styrofoam box with ice-packs for shipping.

WARNINGS AND PRECAUTIONS

- For *in vitro* diagnostic use only.
- Carefully follow the instructions and procedures described in this 'Instruction for use'.
- Use only fresh samples and avoid direct sunlight.
- Lot numbers of all the test components (Cartridge, ID chip and detection buffer) must agree each other.
- Do not interchange the test components between different lots or use the test components after the expiration date, either of which might yield misleading test result(s).
- Do not reuse. A detection buffer tube should be used for processing one sample only. So should a cartridge.
- The cartridge should remain sealed in its original pouch before use.

- Do not use the cartridge, if is damaged or already opened.
- Frozen sample should be thawed only once. For shipping, samples must be packed in accordance with the regulations. Sample with severe hemolytic and hyperlipidemia cannot be used and should be recollected.
- Just before use, allow the cartridge, detection buffer and sample to be at room temperature for approximately 30 minutes.
- QDx InstaCheck™ Cortisol as well as the QDx InstaCheck™ Reader should be used away from vibration and/or magnetic field. During normal usage, it can be noted the QDx InstaCheck™ Reader may produce minor vibration.
- Used detection buffer tubes, pipette tips and cartridges should be handled carefully and discarded by an appropriate method in accordance with relevant local regulations.
- An exposure to larger quantities of sodium azide may cause certain health issues like convulsions, low blood pressure and heart rate, loss of consciousness, lung injury and respiratory failure.
- QDx InstaCheck™ Cortisol will provide accurate and reliable results subject to the following conditions.
 - QDx InstaCheck™ Cortisol should be used only in conjunction QDx InstaCheck™ Reader.
 - Any anticoagulants other than EDTA should be avoided.

STORAGE AND STABILITY

- The cartridge is stable for 20 months (while sealed in an aluminum foil pouch) if stored at 4-30 °C.
- The detection buffer pre-dispensed in a tube is stable for 20 months if stored at 2-8 °C.
- After the cartridge pouch is opened, the test should be performed immediately.

LIMITATIONS OF THE TEST SYSTEM

- The test may yield false positive result(s) due to the cross-reactions and/or non-specific adhesion of certain sample components to the capture/detector antibodies.
- The test may yield false negative result. The non-responsiveness of the antigen to the antibodies is most common where the epitope is masked by some unknown components, so as not to be detected or captured by the antibodies. The instability or degradation of the antigen with time and/or temperature may cause the false negative as it makes antigen unrecognizable by the antibodies.
- Other factors may interfere with the test and cause erroneous results, such as technical/procedural errors, degradation of the test components/reagents or presence of interfering substances in the test samples.
- Any clinical diagnosis based on the test result must be supported by a comprehensive judgment of the concerned physician including clinical symptoms and other relevant test results.

MATERIALS SUPPLIED

REF IFPC-19

Components of QDx InstaCheck™ Cortisol

- Cartridge Box:
 - Cartridges 25
 - ID Chip 1
 - Instruction For Use 1
- Box containing Detection Buffer Tubes
 - Detection Buffer tubes 25

MATERIALS REQUIRED BUT SUPPLIED ON DEMAND

Following items can be purchased separately from **QDx Instacheck™ Cortisol**. Please contact our sales division for more information.

- **QDx Instacheck™ Reader REF** FPRR010
- Thermal Printer

SAMPLE COLLECTION AND PROCESSING

The sample type for **QDx Instacheck™ Cortisol** is human whole blood/serum /plasma.

- It is recommended to test the sample within 24 hours after collection.
- The serum or plasma should be separated from the clot by centrifugation within 3 hours after the collection of whole blood. If longer storage is required, e.g. if the test could not be performed within 24 hours, serum or plasma should be immediately frozen below -20 °C. The freezing storage of sample up to 3 months does not affect the quality of results
- However, the whole blood sample should not be kept in a freezer in any case.
- Once the sample was frozen, it should be used one time only for test, because repeated freezing and thawing can result in the change of test values.

TEST SETUP

1. Check the components of **QDx Instacheck™ Cortisol**: Sealed Cartridge, Detection Buffer Tube and ID Chip.
2. Ensure that the lot number of the test cartridge matches with that of the ID chip as well as the detection buffer.
3. Keep the sealed cartridge (if stored in refrigerator) and detection buffer tube at room temperature for at least 30 minutes just prior to performing the test. Place the cartridge on a clean, dust-free and flat surface.
4. Turn on power supply of the **QDx Instacheck™ Reader**.
5. Insert the ID chip into the 'ID Chip Port' of the **QDx Instacheck™ Reader**.
6. Press 'Select' button on the **QDx Instacheck™ Reader**.
(Please refer to the '**QDx Instacheck™ Reader Operation Manual**' for complete information and operating instructions.)

CAUTION

- To minimize erroneous test results, we suggest that the ambient temperature of the cartridge should be 25 °C during the reaction time after loading sample mixture to the cartridge.
- To maintain the ambient temperature to 25 °C, you can use various devices such as an i-Chamber or an incubator and so on.

TEST PROCEDURE

[Multi mode]

1. Transfer 30 µL (Human serum/plasma/control) or 50 µL (Human whole blood) of sample using a transfer pipette to a tube containing the detection buffer.
2. Close the lid of the detection buffer tube and mix the sample thoroughly by shaking it about 10 times. (The sample mixture must be used immediately.)
3. Pipette out 75 µL of a sample mixture and load it into the sample well on the cartridge.
4. Insert the sample-loaded cartridge into the slot of the i-Chamber or an incubator (25 °C).
5. Leave the sample-loaded cartridge in the i-Chamber or an incubator for 10 minutes.
6. For scanning the sample-loaded cartridge, insert it into the test cartridge holder of the **QDx Instacheck™ Reader**. Ensure proper

orientation of the test cartridge before pushing it all the way inside the test cartridge holder. An arrow has been marked on the test cartridge especially for this purpose.

7. Press 'Select' button on the **QDx Instacheck™ Reader** to start the scanning process.
8. **QDx Instacheck™ Reader** will start scanning the sample-loaded test cartridge immediately.
9. Read the test result on the display screen of the **QDx Instacheck™ Reader**.

INTERPRETATION OF TEST RESULT

- **QDx Instacheck™ Reader** calculates the test result automatically and displays cortisol concentration of the test sample in terms of nmol/L.
- **Reference range**
 - Morning: 140-700 nmol/L
 - Midnight: 80-350 nmol/L
- Working range: 80-800 nmol/L

QUALITY CONTROL

- Quality control tests should be performed as a part of the good testing practice to confirm the expected quality control results and validity of the assay as well as to ensure accuracy of the test results with clinical samples.
- A quality control test should be performed at regular intervals. Before testing a clinical sample using a new test lot, control reagents should be tested to confirm the test procedure, and to verify whether the test produces the expected quality control results. Quality control tests should also be performed whenever there is any question concerning the validity of the test results.
- Control reagents are not provided with **QDx Instacheck™ Cortisol**. For more information regarding obtaining the control reagents, contact the technical section at **Diasys Diagnostics India Private Limited**.
- **Internal Control:** **QDx Instacheck™ Cortisol** test has an in-built quality control indicator that satisfies the routine quality control requirements. This internal control test is performed automatically each time a clinical sample is tested. An invalid result from the internal control leads to display an error message on the **QDx Instacheck™ Reader** indicating that the test should be repeated.

PERFORMANCE CHARACTERISTICS

1. Analytical Sensitivity

Limit of Blank (LoB)	4.79 nmol/L
Limit of Detection (LoD)	6.63 nmol/L
Limit of Quantification (LoQ)	80.0 nmol/L

2. Analytical Specificity

- Cross-reactivity

There was no significant cross-reactivity from these materials with the **QDx Instacheck™ Cortisol** test measurements.

Material	Cross-reactivity (%)
Cortisone (100 nmol/L)	2.3
Corticosterone (1,000 nmol/L)	2.5
Progesterone (100 nmol/L)	4.0
Prednisone (100 nmol/L)	3.3
Testosterone (1,000 nmol/L)	2.5
Prednisolone (100 nmol/L)	3.9
Deoxycortisol (100 nmol/L)	3.9
DHEA (1,000 nmol/L)	1.2
Dexamethasone (100 nmol/L)	3.6

- Interference

There was no significant interference from these materials with the **QDx InstaCheck™ Cortisol** test measurements.

Material	Interference (%)
D-Glucose (60 mM/L)	2.8
L-Ascorbic acid (0.2 mM/L)	1.1
Bilirubin (unconjugated, 0.4 mM/L)	4.1
Hemoglobin (2 g/L)	1.0
Cholesterol (13 mM/L)	2.4
Triglyceride (10 mg/mL)	4.0

3. Precision

- Between lot

One person tested three different lots of **QDx InstaCheck™ Cortisol**, ten times at each concentration of the control standard.

- Between person

Three different persons tested **QDx InstaCheck™ Cortisol**; ten times at each concentration of the control standard.

- Between day

One person tested **QDx InstaCheck™ Cortisol** during five days; five times at each concentration of the control standard.

- Between site

One person tested **QDx InstaCheck™ Cortisol** at three different sites; five times at each concentration of the control standard.

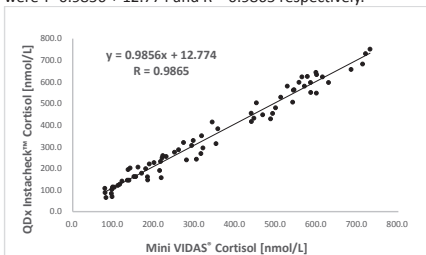
conc. (nmol/L)	Between-lot		Between-person		Between-day		Between-site	
	AVG	CV(%)	AVG	CV(%)	AVG	CV(%)	AVG	CV(%)
270.00	277.98	3.0	282.61	2.8	279.50	3.1	282.01	2.8
550.00	538.80	3.7	540.36	4.0	537.43	3.5	543.39	4.0
650.00	645.93	3.5	651.63	3.5	653.44	4.4	654.28	4.3

4. Accuracy

The accuracy was confirmed by 3 different lots testing six times each different concentrations.

expected value [nmol/L]	Lot 1	Lot 2	Lot 3	AV	Recovery (%)
120.00	112.14	114.85	114.74	113.91	99.0
180.00	183.22	177.37	177.13	179.24	102.4
320.00	315.53	321.34	311.69	316.19	100.4
410.00	414.78	422.23	415.82	417.61	101.9
600.00	620.39	636.94	626.39	627.91	104.7

5. **Comparability:** Cortisol concentrations of 72 clinical samples were independently with **QDx InstaCheck™ Cortisol** and Mini VIDAS® (BioMérieux Inc. France) as per prescribed test procedures. Test results were compared and their comparability was investigated with linear regression and coefficient of correlation (R). Linear regression and coefficient of correlation between the two tests were $Y=0.9856x + 12.774$ and $R = 0.9865$ respectively.



REFERENCES

- Gustavo, E.T. Correlation between cortisol level and serotonin uptake in patients with chronic stress and depression. *Cognitive, Affective, & Behavioral Neuroscience* 2001, 1(4): 388-393.
- Sonia, J.L., Mony, L., Susan, S., Antonio, A., Chaim, T., Mira, T., Bruce, S., M., Richard, L.H., and Michael, J.M. Cortisol levels during human aging predict hippocampal atrophy and memory deficits. *Nature* 1998, 1:69-73.
- Bartels, M., Van den Berg, M., Sluyter, F., Boomsma, D.I., de Geus, E.J.C. Heritability of cortisol levels: review and simultaneous analysis of twin studies. *Psychoneuroendocrinology* 2003, 28:121-137.

Note: Please refer to the table below to identify various symbols.

	Sufficient for <n> tests
	Read instruction for use
	Use by Date
	Batch code
	Catalog number
	Caution
	Manufacturer
	Authorized representative of the European Community
	In vitro diagnostic medical device
	Temperature limit
	Do not reuse
	This product fulfills the requirements of the Directive 98/79/EC on in vitro diagnostic medical devices



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Revision No. 01
Date of last revision: September 7, 2018

