QDx Instacheck™ hsCRP - All in one

INTENDED USE

QDx Instacheck™ hsCRP - All in one in conjunction with **QDx Instacheck™ Reader** is a fluorescence immunoassay for quantitative measurement of C-reactive protein (CRP) in human whole blood/serum/plasma. The test is used as an aid to predict future cardiovascular diseases (CDC) as well as to see infection inflammation.

INTRODUCTION

C-reactive protein (CRP) is a protein found in blood; the level of which rises in response to inflammation. CRP is first acute-phase protein to be described and is an exquisitely sensitive systemic marker of inflammation and tissue damage. The serum CRP level may rise from a normal level of < 5 mg/L to 500 mg/L during the body's general, non-specific response to infections and other acute inflammatory conditions. Measurement of CRP concentration has been widely used as a clinical tool for monitoring the status of inflammation, effectiveness of treatment of various infections and autoimmune diseases such as rheumatoid arthritis. High sensitive C-reactive protein (hsCRP) has recently been suggested, as a marker for diagnosis in CVD such as to predict acute coronary events in the general population of all groups.

PRINCIPLE

QDx Instacheck™ hsCRP - All in one is an immunoassay system based on antigen-antibody reaction and fluorescence technology. When a test sample (human serum, plasma, or whole blood) is processed with the detection buffer in the detection buffer tube, the fluorochrome-labeled detector antibodies (anti-CRP) in the detection buffer binds with CRP in the test sample.

When this processed test sample is loaded into the sample well on the test cartridge as per the prescribed test procedure, it migrates through the nitrocellulose matrix of the test strip.

The fluorochrome-labeled detector antibody-analyte (CRP) complexes get captured on to the capture antibodies (anti-CRP) which have been immobilized at the test line on the test strip.

As a result, the complexes of the capture antibody-analyte (CRP)-detector antibody get accumulated at the test line on test cartridge membrane.

Thus, more the CRP in the test sample, more the complexes that get accumulated at the test line on the test cartridge membrane.

Upon inserting the sample-loaded test cartridge in the **QDx Instacheck™ Reader**, the laser light illuminates the test cartridge membrane thereby triggering fluorescence from the fluorochrome- labeled complexes of CRP.

Intensity of the fluorescence is scanned and converted into an electric signal. The on-board microprocessor computes the CRP concentration based on a pre-programmed calibration.

The computed and converted result is display **QDx Instacheck™ Reader** quantitatively in terms of mg/L.

COMPONENTS AND REAGENTS

QDx Instacheck™ hsCRP - All in one consists of a 'Cartridge', a 'Detection Buffer Tube', a 'Sample collector' and an 'ID Chip'.

- The cartridge contains a test strip, the membrane of which, murine antibodies against human CRP and rabbit immunoglobulin -G have been immobilized at the test line and the control line respectively.
- Each test cartridge is individually sealed in an aluminum foil pouch containing a desiccant. 25 sealed test cartridges are packed in a box which also contains an ID chip and 25 sample collectors for collecting fingertip blood samples.
- The detection buffer pre-dispensed in a plastic tube contains fluorochrome-labeled anti-CRP murine antibodies, fluorochrome-labeled anti-rabbit immunoglobulin-G, bovine serum albumin (BSA) as a stabilizer and sodium azide in phosphate buffered saline (PBS) as a preservative.
- The detection buffer is dispensed in each detection buffer tube. 25 detection buffer tubes are packed in a separate box which is further packed in a Styrofoam box provided with ice packs for the purpose of shipment.

WARNINGS AND PRECAUTIONS

- For *in vitro* diagnostic use only.
- Carefully follow the instructions and procedures described in this insert as well as the **QDx Instacheck™ Reader** operation manual.
- Lot numbers of all the test components (test cartridge, ID chip and detection buffer tube) must match with each other.
- Neither interchange the test components form different lots nor use the test components beyond expiration date.
- Test performed by using any test component of mismatching lot number or that beyond the expiration date may yield misleading test result(s).
- **QDx Instacheck™ hsCRP - All in one** is compatible only with **QDx Instacheck™ Reader**.
- The test cartridge should remain sealed in its original pouch until just prior to use. Do not use the test cartridge should it be damaged or the pouch found already opened.
- Allow a minimum of 30 minutes for the test cartridge (if stored in a refrigerator) and the detection buffer tube to attain room temperature prior to performing the test.
- **QDx Instacheck™ hsCRP - All in one** as well as the **QDx Instacheck™ Reader** should be used away from vibration and/or magnetic field. During normal usage, **QDx Instacheck™ Reader** may produce minor vibrations which should be regarded as normal.
- A sample collector and a detection buffer tube should be used for collecting and processing one test sample only. Similarly a test cartridge should be used for testing one processed test sample only. All these test components should be discarded after single use.
- Being potentially infectious, used sample collector(s), detection buffer tube(s) and test cartridge(s) should be handled carefully and disposed of by appropriate method in accordance with relevant local regulations.

STORAGE AND STABILITY

- The test cartridge is stable for 20 months (while sealed in the aluminum foil pouch) if stored at 4~30 °C.
- The detection buffer dispensed in the detection buffer tube is stable for 20 months if stored at 2~8°C.
- Allow a minimum of 30 minutes for the test cartridge (if stored in a refrigerator) and the detection buffer tube to attain room temperature prior to performing the test.
- Do not remove the test cartridge from the aluminum foil pouch until just prior to use.
- After the test cartridge pouch and the detection buffer tube are opened, the test should be performed within 30 minutes.

LIMITATIONS OF THE TEST SYSTEM

QDx Instacheck™ hsCRP - All in one provides accurate and reliable test results subject to the following constraints:

- **QDx Instacheck™ hsCRP - All in one** should be used only in conjunction with **QDx Instacheck™ Reader**.
- The test should always be performed on freshly collected blood sample(s). If testing cannot be performed within an hour, the serum/plasma sample(s) should be immediately stored at -20 °C until being tested.
- Anticoagulants other than EDTA (like heparin, citrate etc.) have not been evaluated for obtaining the plasma samples for the purpose of this test. Hence their use should be avoided.
- The test samples must be allowed to attain room temperature prior to testing. Frozen plasma/serum samples must be completely thawed and thoroughly mixed prior to testing. If the test samples are to be shipped for the purpose of this test, appropriate precautions must be exercised.
- The test should not be performed on hemolysed samples. If a test sample appears to be hemolysed, fresh blood sample should be obtained, processed and tested.
- Effectiveness of the test is highly dependent on storage of test components and test samples at prescribed optimal conditions.
- The test may yield false positive result(s) due to cross-reactions of some components of blood with the capture/detector antibodies and/or non-specific adhesion of certain components having similar epitopes to bind with these antibodies.
- The test may also yield false negative results; the most common factor being non-responsiveness of the antigen to the antibodies due to its epitopes being masked by some unknown components such that the antigen cannot be detected or captured by the antibodies. False negative results may also be obtained due to instability or degradation of the CRP antigen with time and/or temperature making it unrecognizable by the antibodies.
- Other factors interfering with the test and causing erroneous results include technical/procedural errors, degradation of the test components/reagents as well as 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-1**

Components of QDx Instacheck™ hsCRP - All in one

- **Cartridge Box:**
  - Cartridges 25
  - ID Chip 1
  - Package Insert 1
  - Sample Collector* 25
    (*For collecting blood samples in case the test is to be performed on fingertip blood.)
- **Detection Buffer Box:**
  - Detection Buffer Tubes 25

MATERIALS REQUIRED BUT SUPPLIED ON DEMAND

Following items can be purchased separately from **QDx Instacheck™ hsCRP - All in one**. 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™ hsCRP - All in one** 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.
- In case of the whole blood sample, it 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 test values.

TEST SETUP

1. Check the components of **QDx Instacheck™ hsCRP - All in one**: Sealed Cartridge, Detection Buffer Tube, Sample collector and ID Chip.
2. Ensure that the lot number of the cartridge matches with that of the ID chip as well as the detection buffer tube.
3. Keep the sealed cartridge (if stored in refrigerator) and the detection buffer tube at room temperature for at least 30 minutes just prior to the test. Place the test cartridge on a clean, dust-free and flat surface.
4. Turn on 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.*)

TEST PROCEDURE

[Single mode]

1. Make a puncture on the top of the detection buffer tube by inserting an empty sample collector.
2. Draw the test sample (fingertip blood or serum or plasma) in to the sample collector (10 µL capacity). If a quality control test is to be performed, draw the control reagent instead of the test sample.
3. Assemble the sample collector (filled with the test sample) on to the detection buffer tube.
4. Shake this assembled detection buffer tube by inverting it about 10 times to ensure that entire test sample in the sample collector has been mixed thoroughly with the detection buffer.
5. Remove the cap at the top of the assembled detection buffer tube and discard first two drops by inverting and squeezing the tube.
6. Further squeeze out two drops into the sample well on the test cartridge. (Please refer to the diagram below.)
7. For scanning the sample-loaded test 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.
8. Press 'Select' button on the **QDx Instacheck™ Reader** to start the scanning process.
9. **QDx Instacheck™ Reader** will start scanning the sample-loaded test cartridge after 3min.
10. Read the test result on the display screen of the **QDx Instacheck™ Reader.**

[Multi mode]

1. Make a puncture on the top of the detection buffer tube by inserting an empty sample collector.
2. Draw the test sample (fingertip blood or serum or plasma) in to the sample collector (10 µL capacity). If a quality control test is to be performed, draw the control reagent instead of the test sample.
3. Assemble the sample collector (filled with the test sample) on to the detection buffer tube.
4. Shake this assembled detection buffer tube by inverting it about 10 times to ensure that entire test sample in the sample collector has been mixed thoroughly with the detection buffer.
5. Remove the cap at the top of the assembled detection buffer tube and discard first two drops by inverting and squeezing the tube.
6. Further squeeze out two drops into the sample well on the test cartridge. (Please refer to the diagram below.)
7. Leave the sample-loaded test cartridge at room temperature for 3 minutes.
8. For scanning the sample-loaded test 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.
9. Press 'Select' button on the **QDx Instacheck™ Reader** to start the scanning process.
10. **QDx Instacheck™ Reader** will start scanning the sample-loaded test cartridge immediately.
11. 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 CRP concentration of the test sample in terms of mg/L.
- Working range of **QDx Instacheck™ hsCRP - All in one** is 0.5-200 mg/L.
  - CRP range between 5-200 mg/L.
    - Cut-off range of CRP is 10 mg/L.
    - If the test result is > 10 mg/L, consult the physician for diagnosis and/or further investigation.
    - CRP test result of > 10 mg/L, may reflect an acute phase response to infectious diseases or disorders characterized by acute inflammation.
  - hsCRP range between 0.5-5 mg/L.
    - Cut-off range of hsCRP are as followings:
      - ✓ Between 0.5 and 1.0 mg/L, low risk
      - ✓ Between 1.0 and 3.0 mg/L, average risk
      - ✓ Between 3.0 and 5.0 mg/L, high risk
    - If the test result is < 5 mg/L, consult the physician for diagnosis and/or further investigation.
    - hsCRP test result of <5 mg/L may reflect an predictor of future cardiovascular disease.
- **QDx Instacheck™ hsCRP - All in one** test should be considered as a screening tool only. In case of a positive result (above 10 mg/L or below 5 mg/L), consult the physician to discuss the test result. The physician may decide further course of action.

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 standards are not provided with **QDx Instacheck™ hsCRP - All in one**. For more information regarding obtaining the control standards, contact the technical section at **Diasys Diagnostics India Private Limited**.
- Internal Control: **QDx Instacheck™ hsCRP - All in one** 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.

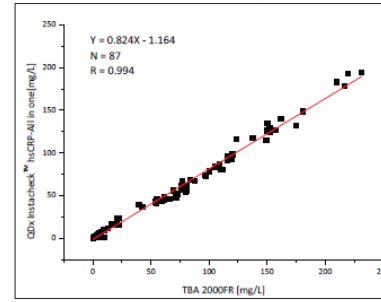
PERFORMANCE CHARACTERISTICS

1. **Specificity/Interference:** Biomolecules such as Hemoglobin (Hb), Carcinoembryonic antigen (CEA), ?-Fetoprotein (AFP), Alanine transaminase (ALT), Troponin-I, Creatine Kinase Isoenzyme-MB (CK-MB), Albumin and Serum amyloid-P component were added to the test samples at concentrations much higher than their normal physiological levels. **QDx Instacheck™ hsCRP - All in one** test results showed neither any significant interference from these biomolecules nor any significant cross-reactivity with the same.

2. **Precision**: For studying intra-assay imprecision, 20 replicates of each of the three concentrations of control reagent were tested. For studying inter-assay imprecision, 10 replicates of each of the three concentrations of control reagent were tested every day for 10 successive days.

hsCRP concentration (mg/L)	Intra-assay			Inter-assay		
	Mean	SD	CV (%)	Mean	SD	CV (%)
1.5	1.14	0.06	4.9	1.11	0.07	6.6
40	31.21	0.83	2.7	30.58	0.88	2.9
100	86.39	5.04	5.8	81.66	4.02	4.9
150	128.43	10.02	7.8	124.54	5.95	4.7

3. **Comparability (Correlation):** CRP concentrations of 87 clinical samples were quantified independently with **QDx Instacheck™ hsCRP - All in one** using whole blood samples as well as with TBA-2000FR Automated Clinical Chemistry Analyzer of Toshiba Corporation, Japan using serum samples. The test results were compared and their compatibilities were investigated with linear regression and coefficient of correlation (*R*). Excellent correlation was observed between the two test systems.



QDx insta check™

DiaSys Diagnostic Systems
CHOOSING QUALITY.

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

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

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