# QDx Instacheck™ RF IgM

## INTENDED USE

**QDx Instacheck™ RF IgM** is a fluorescence Immunoassay (FIA) for the quantitative determination of RF IgM in human whole blood/serum/ plasma. It is useful as an aid in management and monitoring of rheumatoid arthritis.
For *in vitro* diagnostic use only.

## INTRODUCTION

Rheumatoid arthritis (RA) is the most common chronic autoimmune arthritis worldwide, leading to disability and substantial economic costs. It is a chronic and systemic inflammatory disorder that may affect many tissues and organs, but principally attacks synovial joints. About 1% of the world's population is afflicted by rheumatoid arthritis, women three times more often than men. Onset is most frequent between the ages of 40 and 50, but people of any age can be affected. It can be a disabling and painful condition, which can lead to substantial loss of functioning and mobility if not adequately treated.

## PRINCIPLE

The test uses a sandwich immunodetection method; the detector antibodies in the buffer bind to antigens in the sample, forming antigen-antibody complexes, and these migrate onto the nitrocellulose matrix to be captured by other immobilized-antibodies on the test strip.

The more antigens in the sample, the more antigen-antibody complexes are formed. This then leads to stronger intensity of the fluorescence signal, which is processed by **QDx Instacheck™ Reader** to produce RF IgM concentration in the sample.

## COMPONENTS AND REAGENTS

**QDx Instacheck™ RF IgM** consists of 'Cartridges', 'Detection Buffer Tubes', 'Sample collectors' and an 'ID chip'.

- The cartridge contains a test strip, the membrane which has Human Immunoglobulin 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 and 25 sample collectors.
- The detection buffer contains anti human Immunoglobulin-fluorescence conjugate, BSA-Biotin-fluorescence conjugate, bovine serum albumin (BSA) as a stabilizer and sodium azide as a preservative in potassium phosphate buffer.
- 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™ RF IgM** 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, sample collectors, 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™ RF IgM** will provide accurate and reliable results subject to the following conditions.
  - **QDx Instacheck™ RF IgM** should be used only in conjunction **QDx Instacheck™ Reader**.
  - Any anticoagulants other than **EDTA, sodium citrate, Li-heparin** 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-28**

**Components of QDx Instacheck™ RF IgM**

- Cartridge Box:
  - Cartridges 25
  - Sample collectors 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™ RF IgM**. 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™ RF IgM** 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.
- Fingertip blood sample should be collected as follows:
  - Position the hand such that the palm should be facing upwards.
  - Blood should be normally drawn from the middle or ring finger of the non-dominant hand. Apply intermittent pressure on the least calloused finger towards its tip.
  - Wipe the fingertip clean with an alcohol pad.
  - Allow the finger to dry completely because blood will not form a drop if the puncture site is moist. The residual alcohol at the fingertip may also dilute the blood sample thereby affecting the test result.
  - Hold the finger and puncture the fingertip by firmly pressing a new sterile lancet against it at an off-center position.
  - Wipe away the first drop of blood with a sterile gauze pad or cotton ball.
  - Massage the finger towards its tip to form a new drop of blood. Blood will flow easily if the finger is held lower than the elbow.
  - Hold the handle of a capillary tube and touch the mouth of the capillary to the drop of blood.
  - Let the blood fill the capillary tube completely.
  - It may be sometimes necessary to massage the finger again for an additional drop of blood for filling the capillary tube.

## TEST SETUP

1. Check the components of **QDx Instacheck™ RF IgM**: Sealed Cartridge, Detection Buffer Tube, Sample collectors 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.
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 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.*)

## TEST PROCEDURE

[Single mode]

1. Make a puncture on the top of the detection buffer tube by inserting an empty sample collector.
2. Draw 10 µL (Human whole blood) of sample using a sample collector. If the sample is not whole blood, transfer 5 µL (Human serum / plasma / control) with a pipette to detection buffer tube. (If necessary, wipe out the excess blood outside of the capillary on the sample collector with paper towel.)
3. Assemble the sample collector and the tube into one.
4. Shake the 10 times or more until the sample out of the sample collector by inversion. The mixture of buffer and the sample has to be used within 30 seconds.
5. Remove the cap off the top of assembled tube. Discard two drops of sample mixture onto the paper towel before loading.
6. Load only two drops of the mixture onto the sample well of the cartridge.
7. 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 cartridge holder. An arrow has been marked on the 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 cartridge after 5 minutes.
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 10 µL (Human whole blood) of sample using a sample collector. If the sample is not whole blood, transfer 5 µL (Human serum / plasma / control) with a pipette to detection buffer tube. (If necessary, wipe out the excess blood outside of the capillary on the sample collector with paper towel.)
3. Assemble the sample collector and the tube into one.
4. Shake the 10 times or more until the sample out of the sample collector by inversion. The mixture of buffer and the sample has to be used within 30 seconds.
5. Remove the cap off the top of assembled tube. Discard two drops of sample mixture onto the paper towel before loading.
6. Load only two drops of the mixture onto the sample well of the cartridge.
7. Leave the sample-loaded test cartridge at room temperature for 5 minutes.
8. 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.
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 RF IgM concentration of the test sample in terms of IU/mL.
- The cut-off (reference value) : 20 IU/mL

- Working range : 8-200 IU/mL

## 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™ RF IgM**. For more information regarding obtaining the control reagents, contact the technical section at **Diasys Diagnostics India Private Limited.**
- **Internal Control**: **QDx Instacheck™ RF IgM** 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): | 2.6 IU/mL |
| Limit of Detection (LoD): | 3.28 IU/mL |
| Limit of Quantification (LoQ): | 7.78 IU/mL |

2. **Analytical Specificity**

- Cross-reactivity
  Cross-reactivity test is not considered because RF is non-specific for non-rheumatic and healthy persons.
- Interference
  There, in test samples, are biomolecules such as hemoglobin, bilirubin, triglyceride in higher concentration than their normal physiological levels. But this doesn't interfere with the **QDx Instacheck™ RF IgM** test measurements.

| Interference material | Standard material conc. (IU/mL) | | |
|---|---|---|---|
| | 14 | 54 | 109 |
| | Interference rate (%) | | |
| Hemoglobin (500 mg/dL) | 1.9 | 3.2 | 4.0 |
| Bilirubin (40 mg/dL) | 3.9 | 0.7 | 1.8 |
| Triglyceride (2,000 mg/dL) | 1.3 | 3.3 | 5.5 |

3. **Precision**

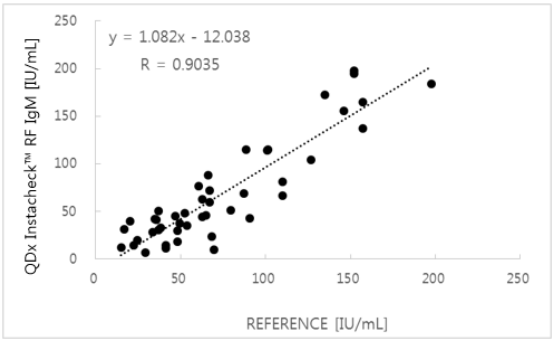
- Between lot
  One person tested three different lots of **QDx Instacheck™ RF IgM,** ten times at each concentration of the control standard.
- Between person
  Three different persons tested **QDx Instacheck™ RF IgM,** ten times at each concentration of the control standard.
- Between day
  One person tested **QDx Instacheck™ RF IgM** during five days**,** five times at each concentration of the control standard.
- Between site
  One person tested **QDx Instacheck™ RF IgM** at three different sites, five times at each concentration of the control standard.

| RF IgM | Between lot | | Between person | | Between day | | Between site | |
|---|---|---|---|---|---|---|---|---|
| [IU/mL] | AVG | CV (%) | AVG | CV (%) | AVG | CV (%) | AVG | CV (%) |
| 14 | 13.46 | 5.7 | 13.20 | 5.9 | 13.70 | 5.5 | 13.69 | 5.8 |
| 54 | 51.82 | 3.7 | 52.20 | 4.3 | 52.04 | 3.6 | 52.63 | 3.1 |
| 109 | 100.31 | 3.3 | 101.88 | 6.5 | 99.38 | 3.2 | 100.80 | 3.2 |

4. **Accuracy**
   The accuracy was confirmed by testing with 3 different lots of **QDx Instacheck™ RF IgM.** The tests are repeated 6 times in each different concentration.

| RF IgM [IU/mL] | Lot 1 | Lot 2 | Lot 3 | Mean | CV (%) | Bias (%) |
|---|---|---|---|---|---|---|
| 15.75 | 16.29 | 16.49 | 16.37 | 16.38 | 0.55 | 4.0 |
| 20.25 | 20.92 | 20.63 | 20.90 | 20.82 | 1.33 | 2.8 |
| 33.75 | 36.37 | 36.86 | 35.83 | 36.36 | 1.61 | 7.7 |
| 61.00 | 62.43 | 61.13 | 61.40 | 61.65 | 4.93 | 1.5 |
| 81.25 | 73.66 | 74.54 | 73.45 | 73.88 | 1.61 | -8.8 |

5. **Comparability**
   RF IgM concentrations of 89 clinical samples were quantified independently with **QDx Instacheck™ RF IgM** and HITACHI 7020 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=1.082 X - 12.038 and R = 0.9035 respectively.

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

| | |
|---|---|
| | 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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