QDx Instacheck™ Dengue NS1 Ag

INTENDED USE

QDx Instacheck™ Dengue NS1 Ag is a fluorescence Immunoassay (FIA) for the qualitative determination of NS1 Antigen in human whole blood/serum/plasma during dengue virus infection. It is useful as an aid in screening of early Dengue virus infection.
For in *vitro* diagnostic use only.

INTRODUCTION

Nonstructural protein 1 (NS1), one of the dengue viral nonstructural proteins, plays a role in supporting the replication complex and attenuating the host immune response against viral infection.[1)] Several lines of evidence show that plasma level of secreted NS1 (sNS1) correlated with viremia levels in dengue virus infected patients. The more generated dengue virus, the higher concentration of sNS1 occurred after onset of illness.[2,3)] The amount of sNS1 is decreased when plasma viral level is reduced. Thus, it is reasonable to detect the sNS1 in patient blood, which makes it possible to early diagnosis of dengue virus infection.

PRINCIPLE

The test uses a sandwich immunodetection method; Conjugators in conjugation pad to antigen in sample, forming antibody-antigen complexes, and migrates onto nitrocellulose matrix to be captured by the other immobilized-antigen on test strip.
The more antigens in the sample, the more antigen-antibody complexes, which leads to stronger fluorescence signal. This signal then is interpreted by the reader to display the 'dengue NS1 Ag positive' in sample.

COMPONENTS AND REAGENTS

QDx Instacheck™ Dengue NS1 Ag consists of 'Cartridge', 'Diluent' and an 'ID chip'.

- The cartridge contains a test strip, the membrane which has streptavidin at the test lines, with chicken IgY antibody at the control line.
- Each cartridge is individually sealed in an aluminum foil pouch containing a desiccant. 25 sealed cartridges are packed in a box which also contains an ID chip.
- The diluent contains a detergent as a stabilizer and sodium azide as a preservative in sodium borate buffer.
- The diluent is dispensed into each diluent tube. 25 diluent tubes are packed in a box.

WARNINGS AND PRECAUTIONS

- For in vitro diagnostic use only.
- 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 diluent) must match 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 incorrect test result(s).
- Do not reuse cartridges or diluent tubes. A diluent tube should be used for processing of one sample only. A cartridge should be used for testing one sample only.
- 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 hemolysis and/or hyperlipidemia must not be used.
- Allow the cartridge, diluent and sample to be at room temperature for approximately 30 minutes before use.
- The instrument for QDx Instacheck™ tests may generate slight vibration during use.
- Used diluent 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™ Dengue NS1 Ag** will provide accurate and reliable results subject to the below conditions.

- **QDx Instacheck™ Dengue NS1 Ag** should be used only in conjunction with **QDx Instacheck™ tests.**
- Have to use recommended anticoagulant sample.

Recommended anticoagulant
EDTA, K_2 EDTA, K_3 EDTA
Sodium heparin, Lithium heparin, Sodium citrate

STORAGE AND STABILITY

Storage condition		
Component	Storage Temperature	Shelf life
Cartridge	4 - 30 °C	20 months
Diluent	4 - 30 °C	20 months

- 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(s) due to the non-responsiveness of the antigen to the antibodies which is most common if the epitope is masked by some unknown components, so therefore not being able to be detected or captured by the antibodies. The instability or degradation of the antigen with time and/or temperature may also cause false negative result 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-33

Components of **QDx Instacheck™ Dengue NS1 Ag.**

- **Cartridge Box:**
  - Cartridges 25
  - ID Chip 1
  - Instruction for Use 1
- **Diluent tube Box:**
  - Diluent 25

MATERIALS REQUIRED BUT SUPPLIED ON DEMAND

Following items can be purchased separately from **QDx Instacheck™ Dengue NS1 Ag.**

Please contact our sales division for more information.

- **QDx Instacheck™ II** REF FPRR021
- **Boditech Dengue NS1 Ag Control** REF CFPO-282

SAMPLE COLLECTION AND PROCESSING

The sample type for **QDx Instacheck™ Dengue NS1 Ag** 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.
- The whole blood may be stored for up to a week at 2-8 °C prior to being tested.
- The serum or plasma may be stored for up to a month at 2-8 °C prior to being tested. If testing will be delayed more than a month, it should be frozen at -20 °C.
- Samples stored frozen at -20 °C for 1 year showed no performance difference.
- However, the whole blood sample should not be kept in a freezer in any case.
- Once the sample was frozen, it should be thawed one time and only for test, because repeated freezing and thawing can result in the changed test values.
- Samples containing precipitates must be clarified by centrifugation**.**

TEST SETUP

- Check the components of **QDx Instacheck™ Dengue NS1 Ag**: Sealed Cartridge, Diluent and ID Chip.
- Ensure that the lot number of the test cartridge matches with that of the ID chip as well as the diluent.
- Keep the sealed test 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.
- Turn on the instrument for QDx Instacheck™ tests.
- Insert the ID Chip into the ID chip port of the Instrument for QDx Instacheck™ tests.
  (Please refer to the 'QDx Instacheck™ tests Operation Manual' for complete information and operating instructions.)

TEST PROCEDURE

<Multi test mode>

1. Transfer 75 µL of sample (whole blood/serum/plasma/control) using a pipette to the diluent tube.
2. Mix thoroughly by shaking 2~3 times.
3. Pipette out 75 µL of a sample mixture and dispense it into the sample well on the cartridge.
4. Leave the sample-loaded cartridge at room temperature for 12 minutes.
   ⚠ *Scan the sample-loaded cartridge immediately when the incubation time is over. If not, it will cause inexact test result.*
5. To scan the sample-loaded cartridge, insert it into the cartridge holder of the instrument for QDx Instacheck™ tests. Ensure proper orientation of the cartridge before pushing it all the way inside the cartridge holder. An arrow has been marked on the cartridge especially for this purpose.
6. Tap the 'Start' button on the instrument for QDx Instacheck™ test.
7. Instrument for QDx Instacheck™ tests will start scanning the sample-loaded cartridge immediately.
8. Read the test result on the display screen of the instrument for QDx Instacheck™ tests.

<Single test mode>

1. Transfer 75 µL of sample (whole blood/ serum/ plasma/control) using a pipette to the diluent tube.
2. Mix thoroughly by shaking 2~3 times.
3. Pipette out 75 µL of a sample mixture and dispense it into the sample well on the cartridge.
4. Inserting the cartridge into the holder of the instrument for QDx Instacheck™ tests. Ensure proper orientation of the cartridge before pushing it all the way inside the cartridge holder. An arrow has been marked on the cartridge especially for this purpose.
5. Tap the 'Start' button on the instrument for QDx Instacheck™ test.
6. Instrument for QDx Instacheck™ tests will automatically start scanning the sample-loaded cartridge after 12 minutes.
7. Read the test result on the display screen of the instrument for QDx Instacheck™ tests.

INTERPRETATION OF TEST RESULT

- The QDx Instacheck™ tests calculates the test result automatically and displays "Positive / Negative / Indeterminate".
- Ancillary value is served in the form of a cut-off index (COI).

Cut-off index (COI)	Result	Note
< 0.9	Negative for Dengue NS1 Ag	No need to additional test.
≥ 0.9, < 1.1	Indeterminate	Need to retest. If test results are shown 'Negative' or 'Indeterminate' repeatedly, these samples are considered dengue NS1 antigen negative.
≥ 1.1	Positive for Dengue NS1 Ag	Need to confirmation test.

QUALITY CONTROL

- Quality control tests are a part of the good testing practice to confirm the expected results and validity of the assay and should be performed at regular intervals.
- The control tests should be performed immediately after opening a new test lot to ensure the test performance is not altered.
- 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™ Dengue NS1 Ag. For more information regarding obtaining the control standards, contact the technical section at Diasys Diagnostics India Private Limited.
  (Please refer to the instruction for use of control material.)

PERFORMANCE CHARACTERISTICS

- Analytical sensitivity

- Cut-off
  The **QDx Instacheck™ Dengue NS1 Ag** test result indicates 'positive' or 'negative' of a sample defined by the algorithm of QDx Instacheck™ reader based on COI (cut-off index).

Cut-off index (COI)	Result
COI ≥ 1.1	Positive
0.9 ≤ COI < 1.1	Indeterminate
COI < 0.9	Negative

- Analytical specificity

- Cross-reactivity
  There was no significant cross-reactivity from these materials with the **QDx Instacheck™ Dengue NS1 Ag** test measurements.

Cross reactants	No. of reactivity			Cross-reactivity (%)
	LOT 1	LOT 2	LOT 3	

HAV	0/25	0/25	0/25	ND
HBV	0/25	0/25	0/25	ND
HCV	0/25	0/25	0/25	ND
EBV	0/25	0/25	0/25	ND
CMV	0/25	0/25	0/25	ND
ANA	0/25	0/25	0/25	ND
RF	0/25	0/25	0/25	ND
Zika	0/18	0/18	0/18	ND

- Interference
  There was no significant cross-reactivity from these materials with the **QDx Instacheck™ Dengue NS1 Ag** test measurements.

Materials	Concentration
Sodium heparin	100,000 U/L
EDTA_K2	2 mg/mL, 5 µM
Sodium citrate	25 mg/mL, 0.085 M
Bilirubin	0.3 mg/mL, 500 µM
Hemoglobin	2 g/L
Triglycerides	1.5 g/L
Cholesterol	7.7 mg/mL, 20 mM
BSA	30 g/L

- **Precision**
  - Between lot
    One person tested three different lots of **QDx Instacheck™ Dengue NS1 Ag,** five times at each concentration of the control standard.
  - Between person
    Three different persons tested same lot of **QDx Instacheck™ Dengue NS1 Ag**, five times at each concentration of the control standard.
  - Between day
    One person tested same lot of **QDx Instacheck™ Dengue NS1 Ag** for three days, five times at each concentration of the control standard.
  - Between site
    One person tested **QDx Instacheck™ Dengue NS1 Ag** at three different sites, five times at each concentration of the control standard.

Dengue NS1 Ag Cal	Between lot		Between person	
	Positive/ Number of tests	Positive rate	Positive/ Number of tests	Positive rate
Negative	0/15	0 %	0/15	0 %
Positive	15/15	100 %	15/15	100 %
Dengue NS1 Ag Cal	**Between day**		**Between site**	
	Positive/ Number of tests	Positive rate	Positive/ Number of tests	Positive rate
Negative	0/15	0 %	0/15	0 %
Positive	15/15	100 %	15/15	100 %

- **Clinical performance evaluation**

		FDA-cleared NS1 ELISA		
		Positive	Negative	Total
QDx Instacheck™ Dengue NS1 Ag	Positive	51	1	52
	Negative	1	116	117
	Total	52	117	169

  - Clinical sensitivity = 98.1 %
  - Clinical specificity = 99.1 %

REFERENCES

1. High circulating levels of the dengue virus nonstructural protein NS1 early in dengue illness correlate with the development of dengue hemorrhagic fever. Daniel H. Library et al., The Journal of Infectious Diseases, 2002.
2. Potential application of nonstructural protein NS1 serotype-specific immunoglobulin G enzyme-linked immunosorbent assay in the seroepidemiologic study of dengue virus infection: Correlation of results with those of the plaque reduction neutralization test. Pei-Yun S. et al., Journal of Clinical Microbiology, 2002.
3. Evaluation of diagnostic tests: Dengue, Rosanna W. P. et. al., Nature, 2010.

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. 00
Date of last revision: January 25, 2021

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