EN REF QZKA06D

STANDARD Q

Arbo Panel I (Z/D/C/Y)

STANDARD™ Q Arbo Panel I (Z/D/C/Y) Test

PLEASE READ ALL THE INSTRUCTIONS CAREFULLY BEFORE YOU PERFORM THE TEST

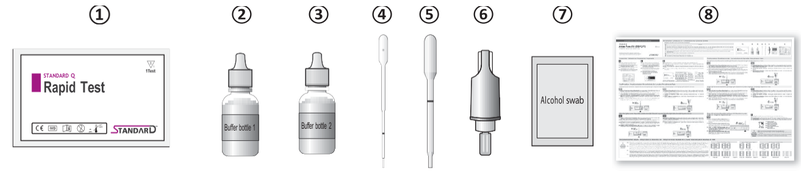
V

SD BIOSENSOR

Kit Contents

STANDARD Q Arbo Panel I (Z/D/C/Y) Test Kit contents the followings.

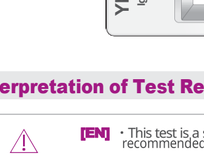
No.	Component
①	Test device
②	Buffer bottle 1 (4ml, Zika, CHIKV, Dengue IgM)
③	Buffer bottle 2 (4ml, YFV IgM)
④	STANDARD™ Ezi tube+(10μl)
⑤	Disposable dropper (100μl)
⑥	Safety lancet
⑦	Alcohol swab
⑧	Instructions for use



Preparation

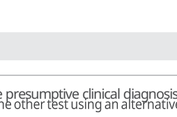
1

[EN] Carefully read the instructions for using the STANDARD Q Arbo Panel I (Z/D/C/Y) Test.



2

[EN] Look at the expiry date at the back of the foil pouch. Do not use the kit, if expiry date has passed.



3

[EN] Open the foil pouch, and check the test device and the desiccant pack within the foil pouch.

<Foil pouch>

<Test device>

[EN] ① Result window
② Specimen well
③ Buffer well

[EN] Yellow : Valid / Green : Invalid

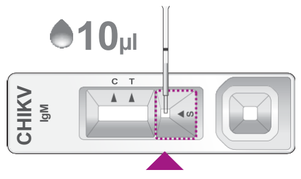
<Desiccant>

Test Procedure

Chikungunya IgM test device

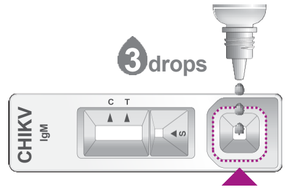
1-1

[EN] Adding of Specimen (Serum/Plasma/Whole blood) Using a STANDARD™ Ezi tube+(10μl), add 10μl of the serum, plasma or whole blood to the specimen well of the test device.



1-2

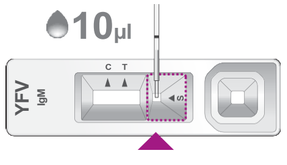
[EN] Dropping of Buffer 1 Add 3 drops(90μl) of buffer 1 to the buffer well of the test device.



Yellow fever IgM test device

1-1

[EN] Adding of Specimen (Serum/Plasma/Whole blood) Using a STANDARD™ Ezi tube+(10μl), add 10μl of the serum, plasma or whole blood to the specimen well of the test device.



1-2

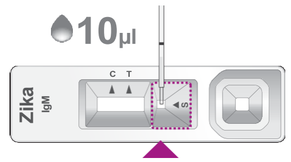
[EN] Dropping of Buffer 2 Add 3 drops(90μl) of buffer 2 to the buffer well of the test device.

Test Procedure

Zika IgM test device

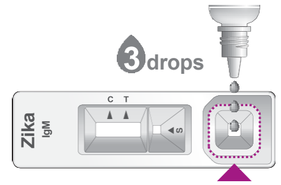
1-1

[EN] Adding of Specimen (Serum/Plasma/Whole blood) Using a STANDARD™ Ezi tube+(10μl), add 10μl of the serum, plasma or whole blood to the specimen well of the test device.



1-2

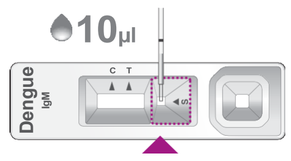
[EN] Dropping of Buffer 1 Add 3 drops(90μl) of buffer 1 to the buffer well of the test device.



Dengue IgM test device

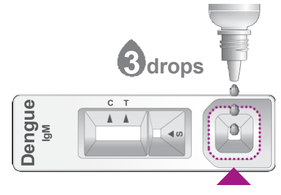
1-1

[EN] Adding of Specimen (Serum/Plasma/Whole blood) Using a STANDARD™ Ezi tube+(10μl), add 10μl of the serum, plasma or whole blood to the specimen well of the test device.



1-2

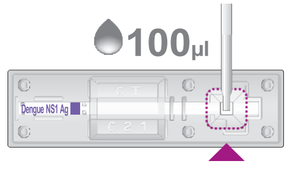
[EN] Dropping of Buffer 1 Add 3 drops(90μl) of buffer 1 to the buffer well of the test device.



Dengue NS1 test device

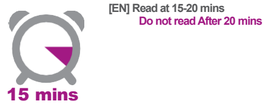
1-1

[EN] Adding of Specimen (Serum/Plasma/Whole blood) Using a Disposable dropper (100μl), add 100μl of the serum, plasma or whole blood to the specimen well of the test device.



2

[EN] Reading Time Read the test results at 15-20 minutes. Do not read after 20 minutes.



[EN] Read at 15-20 mins
Do not read After 20 mins

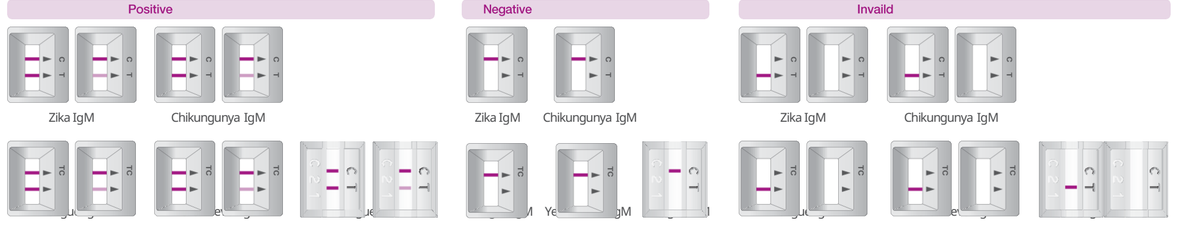
CAUTION

[EN] Do not read test results after 20 minutes, it may give false results.

Interpretation of Test Results

CAUTION

[EN] • This test is a screening tool for the presumptive clinical diagnosis of viral infection by Zika, Dengue, Chikungunya and/or Yellow fever virus. Therefore, even though the test result is positive, it is recommended to perform at least one other test using an alternative method such as PCR, EIAs, IFA or PRNT (Plaque-reduction neutralization test) in parallel to confirm the viral infection by Zika, Dengue, Chikungunya and/or Yellow fever virus. It is also recommended that a physician determines the result with help of confirmatory tests (such as PCR test), patient's symptoms and medical history.



English

EXPLANATION AND SUMMARY

■ Introduction

Arboviruses are transmitted by arthropods, including those responsible for the current pandemic, flaviviruses (Zika, Dengue, Yellow Fever and Encephalitis viruses, etc) and alphavirus (Chikungunya, Mayaro and Ross River, etc). The main vectors are Aedes aegypti and A. albopictus. The illnesses caused by Zika, Dengue, Chikungunya and Yellow fever virus have very similar clinical presentation with prominent fever, headache, rash, myalgias (muscle aches) and arthralgias (joint aches). In fact, serological tests have demonstrated that outbreaks attributed to Zika in the past have actually turned out to be Dengue, Chikungunya or Yellow fever infections. Therefore, great efforts to establish best practice to be recognized and distinguished them promptly are required in order to treat in time and to prevent further spread and recurrence of their infections. STANDARD Q Arbo Panel I (Z/D/C/Y) Test, with a high degree of both sensitivity and specificity, would enhance the accuracy of the diagnosis in distinguishing of the infections with these viruses and thus make clinical treatment decisions effectively.

■ Intended use

STANDARD Q Arbo Panel I (Z/D/C/Y) Test is a rapid chromatographic immunoassay for the detection of Zika IgM, Chikungunya IgM, Dengue IgM, Yellow fever IgM and Dengue NS1 Ag in human serum, plasma or whole blood specimens. This test is for *in vitro* professional diagnostic use and intended as an aid to early diagnosis of the infection by Zika, Dengue, Chikungunya or Yellow fever in patient with clinical symptoms. It provides only an initial screening test result. In case of Zika virus, alternative diagnosis methods by the WHO algorithm, the CDC guideline or laboratory testing from the regulatory authorities should be performed in order to obtain the confirmation of the virus infections.

■ Test principle

STANDARD Q Arbo Panel I (Z/D/C/Y) Test contains five devices, the first device for the Zika IgM, the second device for the Chikungunya (CHIKV) IgM, the third device for the Dengue IgM, the fourth device for Yellow fever (YFV) IgM and the fifth device for Dengue NS1 Ag. Zika IgM, CHIKV IgM, Dengue IgM and YFV IgM test devices have two pre-coated lines, "T" (Test line) and "C" (Control line) on the surface of the nitrocellulose membrane. During testing, the test specimens are added directly to the specimen well and the 3 drops of buffer are added into the buffer well. The immunoglobulins in the specimen interact with monoclonal anti-human IgM and monoclonal anti-human IgM that is coated on the individual test line. If any Zika IgM, Chikungunya IgM, Dengue IgM or Yellow fever IgM is present, the solution moves through the inactivated Zika, Chikungunya, Dengue or Yellow fever virus and then, reacts with its specific monoclonal anti-Zika, anti-Chikungunya, anti-Dengue or anti-yellow fever env conjugated to gold colloid in turn. Dengue NS1 test device contains two pre-coated lines, "T" (Test line) and "C" (Control line) on the surface of the nitrocellulose membrane. During the test, Dengue NS1 in the specimen interacts with monoclonal anti-Dengue NS1 conjugated to gold colloid making antigen-antibody gold particle complex. This complex moves on the membrane until the test line, where it will be captured by monoclonal anti-Dengue NS1. A violet test line would be visible in the result window of the each test device if Zika IgM, Chikungunya IgM, Dengue IgM, Yellow fever IgM or Dengue NS1 Ag is included in the specimens. Absence of this violet indicates a negative result. The control line is used for procedural control, and should always appear if the test procedure is performed properly and the test reagents of the control line are working.

■ Kit contents

① Test device
② Buffer bottle 1 (4ml, Zika IgM/CHIKV IgM/Dengue IgM)
③ Buffer bottle 2 (4ml, YFV IgM)
④ STANDARD™ Ezi tube+(10μl)
⑤ Disposable dropper (100μl)

⑥ Safety lancet ⑦ Alcohol swab ⑧ Instruction for use

KIT STORAGE AND STABILITY

Store the kit at room temperature, 2-40°C / 36-104°F, out of direct sunlight. Kit materials are stable until the expiration date printed on the outer box. Do not freeze the kit.

WARNINGS

1. Do not re-use the test kit.
2. Do not use the test kit if the pouch is damaged or the seal is broken.
3. Do not use Buffer bottle of another lot.
4. Do not smoke, drink or eat while handling specimen.
5. Wear personal protective equipment, such as gloves and lab coats when handling kit reagents. Wash hands thoroughly afterwards.
6. Clean up spills thoroughly using an appropriate disinfectant.
7. Handle all specimens as if they contain infectious agents.
8. Observe established precautions against microbiological hazards throughout testing procedures.
9. Dispose of all specimens and materials used to perform the test as bio-hazard waste. Laboratory chemical and bio-hazard wastes must be handled and discarded in accordance with all local, state, and national regulations.
10. Desiccant in foil pouch is to absorb moisture and keep humidity from affecting products. If the moisture indicating desiccant beads change from yellow to green, the pouch should be discarded.
11. CHIKV IgM may show serologically cross-reactivity within the flavivirus group (dengue virus, St, Lewis encephalitis and / or Zika virus).
12. YFV IgM may show serologically cross-reactive within the flavivirus group (Dengue virus, West Nile virus, St, Lewis encephalitis virus and / or Zika virus).

SPECIMEN COLLECTION AND PREPARATION

■ Serum

1. Collect the whole blood into the commercially available plain tube NOT containing anti-coagulant such as heparin, EDTA or sodium citrate by venipuncture and leave to settle for 30 minutes for blood coagulation and then centrifuge blood to get serum specimen of supernatant.
2. If serum in the plain tube is stored in a refrigerator at 2-8°C / 36-46°F, the specimen can be used for testing within 1 week after collection. Using the specimen in the long-term keeping more than 1 week can cause non-specific reaction. For prolonged storage, it should be at below -40°C / -40°F .
3. It should be brought to room temperature prior to use.

■ Plasma

1. Collect the venous whole blood into the commercially available anti-coagulant tube such as heparin, EDTA or sodium citrate by venipuncture and centrifuge blood to get plasma specimen.
2. If plasma in an anti-coagulant tube is stored in a refrigerator at 2-8°C/ 36-46°F, the specimen can be used for testing within 1 week after collection. Using the specimen in the long-term keeping more than 1 week can cause non-specific reaction. For prolonged storage, it should be at below -40°C/ -40°F.
3. It should be brought to room temperature prior to use.

■ Whole blood

[Capillary whole blood]

1. Capillary whole blood should be collected aseptically by fingertip.
2. Clean the area to be lanced with an alcohol swab.
3. Squeeze the end of the fingertip and pierce with a sterile lancet.
4. Collect the capillary whole blood to the black line of the STANDARD™ Ezi tube+(10μl) for the testing.
5. The capillary whole blood must be tested immediately after collection.

[Venous Whole blood]

1. Collect the venous whole blood into the commercially available anti-coagulant tube such as heparin, EDTA or sodium citrate by venipuncture.
2. If venous whole blood in an anti-coagulant tube is stored in a refrigerator at 2-8°C/ 36-46°F, the specimen can be used for testing within 1-2 days after collection.
3. Do not use hemolyzed blood specimens.

- Anticoagulants such as heparin, EDTA or sodium citrate do not affect the test result.
- As known relevant interference, hemolytic specimen, rheumatoid factors-contained specimen and lipaemic, icteric specimen can lead to impair the test results.
- Use separate disposable materials for each specimen in order to avoid cross-contamination which can cause erroneous results.

TEST PROCEDURE

■ Preparation

1. Carefully read the instruction for using the STANDARD Q Arbo Panel I (Z/D/C/Y) Test.
2. Look at the expiry date at the back of the foil pouch. Do not use the kit, if expiry date has passed.
3. Open the foil pouch, and check the test device and the desiccant pack within the foil pouch.

■ Test Procedure

[Zika IgM, Chikungunya (CHIKV) IgM and Dengue IgM test devices.]

1. Using a STANDARD™ Ezi tube+(10μl), add 10μl of the serum, plasma or whole blood to the specimen well of the test device.
2. Add 3 drops (90μl) of buffer 1 into the buffer well of the test device.
3. Read the test results at 15-20 minutes. Do not read after 20 minutes.

[Yellow fever (YFV) IgM test devices.]

1. Using a STANDARD™ Ezi tube+(10μl), add 10μl of the serum, plasma or whole blood to the specimen well of the test device.
2. Add 3 drops (90μl) of buffer 2 into the buffer well of the test device.
3. Read the test results at 15-20 minutes. Do not read after 20 minutes.

[Dengue NS1 test device]

1. Using a Disposable dropper (100μl) , add 100μl of the serum, plasma or whole blood to the specimen well of the test device.
2. Read the test results at 15-20 minutes. Do not read after 20 minutes.

BIBLIOGRAPHY

1. Neurological Syndrome, congenital malformations and Zika virus infection. Implications for public health in the Americas. Pan American Health Organization WHO. 2016.
2. Dick GWA, Kitchen SF, Haddow AJ. Zika virus. I. Isolations and serological specificity. Trans R Soc Trop Med Hyg. 1952; 46:509–20.
3. Lanciotti RS, Kosoy OL, Laven JJ, Velez JO, Lambert AJ, Johnson AJ. Genetic and serologic properties of Zika virus associated with an epidemic, Yap State, Micronesia, 2007. Emerg Infect Dis. 2008; 14:1232–9.

Product Disclaimer

- **Product Disclaimer:** Whilst every precaution has been taken to ensure the diagnostic ability and accuracy of this product, the product is used outside of the control of the manufacturer and distributor and the result may accordingly be affected by environmental factors and/or user error. A person who is the subject of the diagnosis should consult a doctor for further confirmation of the result.
- **Warning:** The manufacturers and distributors of this product shall not be liable for any losses, liability, claims, costs or damages whether direct or indirect of consequential arising out of or related to an incorrect diagnosis, whether positive or negative, in the use of this product.

CE IVD

EC REP **Authorized Representative**
MT Promedt Consulting GmbH
Ernst-Heckel-Straße 7 66386 St. Ingbert Germany
Phone : +49 6894 581020, Fax : +49 6894 581021

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REF Reference number / Numéro de référence / Número de referência
EC REP Authorised representative in the european community
IVD In vitro Diagnostic / Diagnostic in vitro / Diagnóstico in Vitro / Diagnóstico in Vitro
Consult Instructions for Use / Consulter le mode d'emploi / Consultar Instrucciones de Uso / Consultar instruções de uso
Contains Sufficient for <n> Tests / Contient <n> tests / Contiene suficiente para <n> pruebas / Contém o suficiente para <n> testes
Caution / Avertissement / Precaución / Atenção
Do not re-use / Usage unique / No volver a usar / Não reutilizar
2°C - 30°C (36°F - 104°F) - To indicate the temperature limitations in which the transport package has to be kept and handled. / Veuillez bien conserver et manipuler le test pour indiquer les limites de température dans laquelle le pack de transport. / Indicar las limitaciones de temperatura en las que debe mantenerse y manipularse el paquete de transporte. / Indica as limitações de temperatura relativas a como deve ser manuseado durante transporte.
Use by / Utiliser par / Usar por / Usado por
LOT Batch code / Code du lot / Código de lote / Código de lote
CE Fulfill the requirements of Directive 98/79/EC on in vitro diagnostic medical devices / Veuillez respecter les exigences de la directive 98/79/CE relative aux appareils médicaux de diagnostic in vitro / Cumplir con los requisitos de la Directiva 98/79 / CE relativa a los dispositivos médicos de diagnóstico in vitro / Preencha os requisitos da Diretriz 98/79/EC sobre dispositivos de diagnóstico médico in vitro
Manufacturer / Fabricant / Fabricante / Fabricante
Date of manufacture / Date de fabrication / Fecha de fabricación / Data de fabricação
Keep away from sunlight / Tenir ce produit éloigné de la lumière du soleil / Evitar luz solar directa / Não utilize se a embalagem estiver danificada
Do not use if packaging is damaged / Ne pas utiliser si l'emballage est endommagé / No utilizar si el empaque está dañado / Não utilize se a embalagem estiver danificada

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Head office: C-4th&5th, 16, Deogyeong-daero 1556beon-gil, Yeongtong-gu, Suwon-si, Gyeonggi-do, 16690, REPUBLIC OF KOREA
Manufacturing site: 74, Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, 28161, REPUBLIC OF KOREA
Contact e-mail: ts@sdbiosensor.com
Website: www.sdbiosensor.com