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DENGUE VIRUS TESTING SOLUTION

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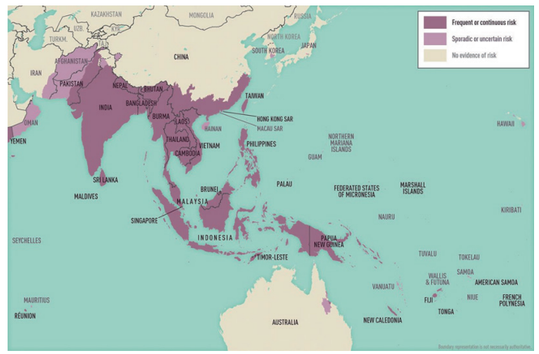
Background:

Dengue, an acute febrile illness, is caused by infection with any of 4 related single-stranded RNA viruses of the genus Flavivirus, dengue virus 1, 2, 3, or 4 (DENV1–4).AImost all DENV transmission occurs through the bite of infected Aedes species mosquitoes, primarily Ae. aegypti and Ae. albopictus. Because of the ≈7-day viremia in humans, bloodborne transmission is possible through exposure to infected blood, organs, or other tissues (e.g., bone marrow).

Dengue is endemic throughout the tropics and subtropics and occurs in >100 countries and destinations worldwide, including Puerto Rico, the US Virgin Islands, and US–affiliated Pacific Islands, and dengue burden is expected to continue to grow in sub-Saharan Africa, Latin America, and Asia, with estimates of >50 million febrile illness cases per year.

Dengue risk in the Americas & the Caribbean

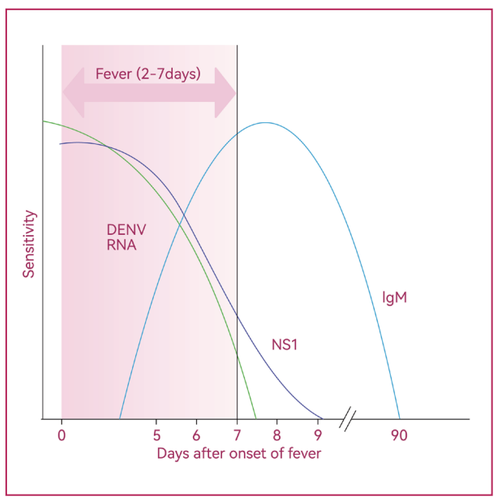
Dengue risk in Africa, Europe, & the Middle East



Dengue risk in Asia & Oceania

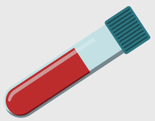
Molecular Diagnosis:

Dengue is a nationally notifiable disease in the United States; report all suspected cases to the state or local health department. Consider dengue in the differential diagnosis of patients who develop onset of symptoms ≤2 weeks after returning from an endemic area. For patients presenting ≤7 days after fever onset, diagnostic testing should include a nucleic acid amplification test for DENV and IgM. For patients presenting >7 days after fever onset, IgM testing is recommended. In the United States, both IgM ELISA and real-time reverse transcription PCR (RT-PCR) are approved as in vitro diagnostic tests.



Nucleic Acid Detection:

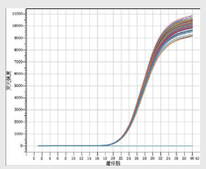
Workflow:



1.Sample Preparation

2.Nucleic Acid Purification

3.Nucleic Acid Detection



4.Data Analysis

Nucleic Acid Purification System:

The GenePure system combined with purification kits help enable efficient, reliable, and easy nucleic acids purification from porcine samples. To accommodate different sample throughputs, we offer two instruments with varying capacities: the 32-throughput GenePure Pro and the 96-throughput GenePure Pro 96, both fully automated nucleic acid extraction instruments. Currently, we provide over a hundred types of extraction kits compatible with these instruments. For the extraction kits, we offer both pre-packaged reagents and bottled reagents to meet diverse customer needs.

Nucleic Acid Purification System

- NPA-16H
- NPA-32E
- NPA-96E

Extraction Kit Introduction:

Dengue fever is a mosquito-borne viral infection that causes flu-like symptoms, including high fever, severe headache, pain behind the eyes, joint and muscle pain, rash, and mild bleeding. Nucleic acid testing, due to its rapid speed and high sensitivity, can be widely used for dengue nucleic acid detection. The commonly used sample types for dengue nucleic acid testing are plasma and serum. We offer three kits for extracting viral nucleic acids: BSC86, BSC71 and BSC110.

MagaBio plus Virus DNA/RNA Purification Kit II

BSC71 CE IVD

The MagaBio plus Virus DNA/RNA Purification Kit II is designed for the rapid, efficient and automatic isolation and purification of high quality virus nucleic acid from a variety of samples on the automatic nucleic acid extraction system. It takes about only 35minutes for the total procedure. The obtained virus nucleic acid can be used directly for a broad range of downstream applications, such as qPCR, NGS, etc.

Product Features:

- **Sample types:** Serum, Plasma, Whole blood, Swabs, Saliva, Body fluid, Tissue, Feces, etc.
- **Rapid and Reliable:** Nucleic acid extraction can be completed in as little as 35 minutes.
- **High Extraction Efficiency:** High purity viral DNA or viral RNA.
- **Safe and Non-toxic:** Ensures user safety and environmental protection.

MagaBio Plus Virus DNA/RNA Purification Kit III

BSC86 CE IVD

MagaBio Plus virus DNA/RNA Purification kit III compared to the previous two generations, this product uses a unique lysis system to rapidly lyse the virus, combined with a new magnetic bead technology for the purification of nucleic acids. The sample types cover tissue, feces, whole blood, serum, plasma, body fluid samples and swabs, which are more common and do not require protease K. 96 samples can be easily extracted in only 15 minutes. The purified nucleic acid can be used for detection of NGS, qPCR, etc.

Product Features:

- **Wide application:** Suitable for samples of tissue, feces, whole blood, serum, plasma, body fluid samples and swabs.
- **Easy to use:** No need to add protease K, just add samples to complete whole extraction.
- **Rapid extraction:** 96 samples can be extracted in 15 minutes.
- **High sensitivity:** The sensitivity of DNA virus extraction was up to 10 IU/mL and RNA virus extraction was up to 50 IU/mL.

MagaBio plus Virus DNA/RNA Purification Kit VI

BSC110

MagaBio plus Virus DNA /RNA Purification Kit VI is used for extraction and purification of viral nucleic acid DNA or RNA from the biological specimens. Depending on the sample type, we provide extraction buffers with or without PK along with corresponding protocols. For complex samples like whole blood and tissue, we recommend using extraction buffers with PK. For simpler samples like serum, plasma, and throat swabs, we recommend using extraction buffers without PK.

Product Features:

- **Sample types:** plasma, serum, ascites, swabs, tissue, whole blood.
- **Rapid and Reliable:** Without PK 14min, With PK 24min completed the purification.
- **High Extraction Efficiency:** High purity viral DNA or viral RNA.
- **High Sensitivity:** HBV DNA: 10 IU/mL; HCV: 50 IU/mL.

Ordering Information:

Cat. No.	Product Name	Package	Storage Condition
BSC71	MagaBio plus Virus DNA/RNA Purification Kit II	16T/32T/48T/96T	2-8℃
BSC86	MagaBio Plus Virus DNA/RNA Purification Kit III	16T/32T/48T/96T	2-8℃
BSC110	MagaBio plus Virus DNA/RNA Purification Kit VI	16T/32T/48T/96T	2-8℃

Fluorescent Quantitative Detection System:

Bioer Technology has been dedicated to the field of molecular detection for many years. Beyond nucleic acid extraction and its related products, we also offer real-time quantitative PCR (qPCR) instruments and corresponding animal disease detection kits. Our qPCR instruments include the latest QuantGene 9600, featuring a large touchscreen for standalone operation; the LineGene 9600 Plus, known for its stable performance and high market share.

LineGene 9600 Plus

LineGene 9600 Plus is a fluorescence quantitative PCR instrument designed specifically for research and medical users. The instrument adopts the latest custom-made semiconductor cooler (Peltier) by Ferrotec. Advanced optical fiber technology and a brand-new globally wide voltage switch power supply, combined with a unique module heat dissipation proprietary technology and a bottom detection proprietary mode, give LineGene 9600 Plus faster heating and cooling rates, better temperature control accuracy, uniformity, and stability.

QuantGene 9600

Building on the consistent high-quality of the LineGene family, QuantGene 9600 incorporates highly mature Peltier cooling technology, a new light source and optical design, a unique constant current power supply, and a 6-zone independent temperature control system. These features ensure faster, more accurate, and stable fluorescence quantitative analysis, all while maintaining outstanding energy efficiency. The product is modular in design, offering various configuration options, including temperature gradient, sample preservation at 4°C, automatic dehumidification, and other functions. Compared to the previous generation, Bioer will comprehensively achieve automatic gain, enhancing user experience, and accepting personalized system customization to fully meet the needs of scientific research and clinical medicine.

Dengue Virus Nucleic Acid Detection Kit (Fluorescent PCR)

BSJ43

This kit uses fluorescent PCR and is compatible with the real-time fluorescence quantitative PCR analyzer (model: FQD-96C, FQD-96A) and the Automated Nucleic Acid Purification and Real Time PCR System (model: FQD-A1600). The kit features rapid detection, high specificity, and high sensitivity. The kit targets highly conserved regions of the dengue virus, with specifically designed primers and probes that bind to the target sequence. Under the action of reverse transcriptase and hot-start Taq DNA polymerase, the specific fragment is amplified. During the amplification process, the fluorescent probe is hydrolyzed, producing fluorescence. The detection system includes dUTP-UDG enzyme contamination prevention measures to fully degrade potential product contamination and avoid false-positive results. Additionally, an internal control is set for a highly conserved region of the human genome. This internal control monitors the entire process of sample collection, transportation, nucleic acid extraction, and PCR amplification, ensuring the validity of the entire process and avoiding false-negative results.

Specification:

Parameters	Description
Sample Type	Human serum and/or plasma
Serotypes	DEN-1 to -4
Sensitivity	500 copies/mL
Precision	The coefficients of variation for inter-batch, intra-batch, inter-day, and intra-day precision are all less than 5%.
Accuracy	Testing with positive reference samples from the company shows a positive agreement rate of 100%, and testing with negative reference samples shows a negative agreement rate of 100%.
Specificity	No cross-reactivity with Hepatitis B Virus, Hepatitis C Virus, Influenza A Virus, Influenza B Virus, Herpes Simplex Virus, Encephalitis Virus, Human Cytomegalovirus, etc.
Compatible Platform	FQD-96A, FQD-96C, FQD-A1600
Time	45min
Storage Condition	-20 ± 5 °C

Application Cases:

Case 1

Accuracy: Positive reference samples (P1-P4) and negative reference samples (N1-N8) provided by Hangzhou Bioer Technology Co., Ltd. were reconstituted as required and then extracted using the Bioer extraction reagent BSC86S1E (Zhejiang Medical Device Registration No. 20200872) for subsequent testing.

results: The results indicate accurate detection of dengue virus nucleic acid. The testing of company reference samples shows a 100% positive agreement rate and a 100% negative agreement rate.

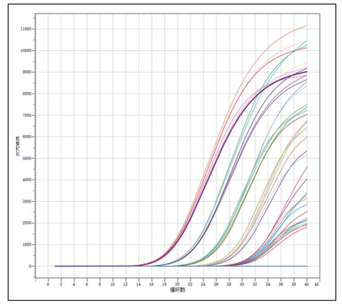


Figure 1: Detection of Negative/Positive Reference Samples

Case 2

Precision: The precision reference samples (J1-J2) of the dengue fever virus nucleic acid detection kit (fluorescent PCR method) were reconstituted according to the instructions for use. After extraction with the Bioer extraction reagent BSC86S1E (Zhejiang Medical Device Registration No. 20200872), testing was conducted using three batches of reagents, with each sample tested 10 times.

results: The results indicate that the inter-batch and intra-batch precision coefficients of variation for the three batches of reagents are all less than 5%, demonstrating good reagent precision.

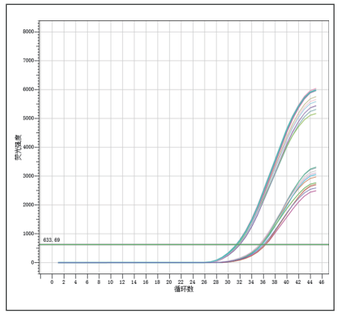


Figure 2: Intra-batch and Inter-batch Precision

Ordering Information:

Cat. No.	Product Name	Package	Storage Condition
BSJ43	Dengue Virus Nucleic Acid Detection Kit (Fluorescent PCR)	48T/96T	-25~-15℃

Dengue IgM/IgG Rapid Test Kit (Colloidal Gold Method)

BSK14 CE IVD

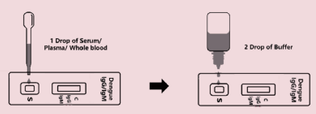
The Dengue IgM/IgG Rapid Test Kit (Colloidal Gold Method) is a lateral flow immunoassay assay designed for qualitative detection of dengue IgM/IgG in human serum, plasma, or whole blood as an aid in the diagnosis of primary and secondary Dengue infections. The operation steps are simple and test results are interpreted visually at 15-20 minutes based on the presence or absence of visually colored lines. The diagnosis can be achieved within 3-5 days after infection, which is of great significance for prognosis and targeted treatment.

Test Procedure:

- **Specimen:** Whole Blood/Serum/Plasma.
- **Specimen collection:** Specimens of all types are collected by conventional methods.
- **Test method:**

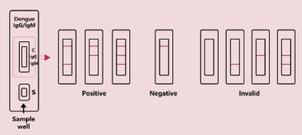
1

Hold the dropper vertically, draw the specimen up to the Fill Line (approximately 10 μL), and transfer the specimen to the specimen well (S) of the test device, then add 2 drops of buffer (approximately 80 μL) and start the timer. Avoid trapping air bubbles in the specimen well (S).



2

Wait for the reddish-purple line(s) to appear. The test result should be read at between 15 and 20 minutes. Result may be read up to 30 minutes.



Dengue NS1 Antigen Rapid Test Kit (Colloidal Gold Method)

BSK10 CE IVD

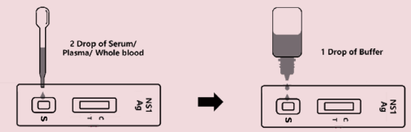
The Dengue NS1 Antigen Rapid Test Kit (Colloidal Gold Method) is a rapid, qualitative immunochromatographic assay designed for qualitative detection of the presence of NS1 Antigen of dengue virus in human serum, plasma, or whole blood. The operation steps are simple and test results are interpreted visually at 15-20 minutes based on the presence or absence of visually colored lines. The diagnosis can be achieved within 1-9 days after infection, which is of great significance for prognosis and targeted treatment.

Test Procedure:

- **Specimen:** Whole Blood/Serum/Plasma.
- **Specimen collection:** Specimens of all types are collected by conventional methods.
- **Test method:**

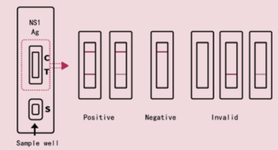
1

Add 2 drops (about 60 μl) of serum / plasma into the sample well (S) using dropper provided then add 1 drop of buffer (approximately 40 μl).



2

Wait for the reddish-purple line(s) to appear. The test result should be read at between 15 and 20 minutes. Result may be read up to 30 minutes.



Ordering Information:

Cat. No.	Product Name	Package	Storage Condition
BSK10	Dengue NS1 Antigen Rapid Test Kit (Colloidal Gold Method)	25T/50T	2℃~30℃
BSK14	Dengue IgM/IgG Rapid Test Kit (Colloidal Gold Method)	25T/50T	2℃~30℃