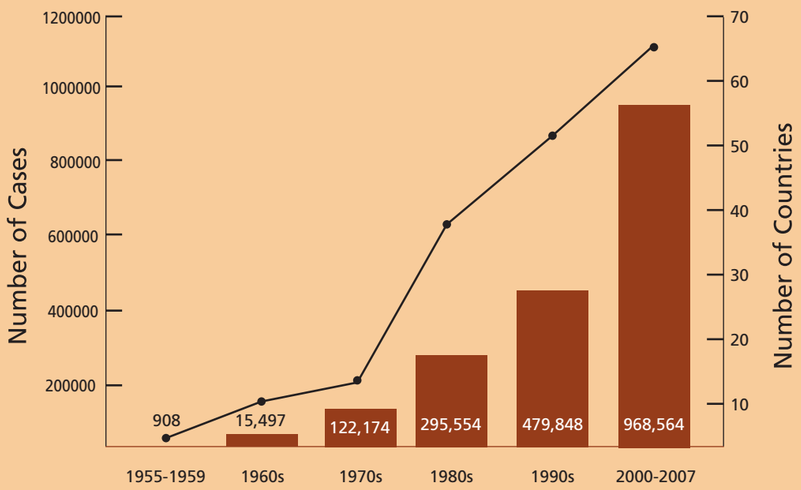
Impact of Dengue

Reported cases of DHF are increasing worldwide.

Specific and sensitive diagnostic assays for early detection will be critical to our understanding and control of this disease.



Source: WHO, www.who.int/csr/disease/dengue/impact/en/

Dengue is endemic in the tropics and subtropics, worldwide,

where an estimated 100,000,000 cases occur annually (1). During 2002, more than 30 Latin American countries reported over 10,000,000 (DF) cases with a large number of DHF cases. This has been followed by extensive epidemics of DHF in several parts of India during 2003 through 2005. In the Americas, the reported incidence more than tripled from 1996 to 2002. Dengue outbreaks have been reported in Hawaii (2), and in Laredo, Texas.

References

1. Gubler DJ, Dengue and dengue hemorrhagic fever. Clin Microbiol Rev 1998; 11(3):480-496.
2. Effler PV, Pang L, Kitsutani P, Vorndam V, Nakata M, Ayers T, Elm J, Tom T, Reiter P, Rigau-Perez JG, Hayes JM, Mills K, Napier M, Clark GG, Gubler DJ; Hawaii Dengue Outbreak Investigation Team. Dengue fever, Hawaii, 2001-2002. Emerg Infect Dis 2005; 11(5):742-9
3. Hunsperger EA, Yoksan S, Buchy P, Nguyen VC, Sekaran SD, Enria DA, et al. Evaluation of Commercially Available Anti–dengue Virus Immunoglobulin M Tests. Emerg Infect Dis. 2009; 15:436-440.

InBios International, Inc. presents

A New FDA Cleared *In Vitro* Diagnostic Test for Dengue Virus Infection

Ordering Information:

Catalog No.	Product	Regulatory Status	No. of Tests	Total Incubation Time Req.
DDMS-1	DENV *Detect*™ IgM Capture ELISA	FDA Cleared, CE	44	196 minutes
DDGS-1	DENV *Detect*™ IgG ELISA	Export Only, CE	44	196 minutes
DNS1-1	DENV *Detect*™ NS1 ELISA	Export Only, CE	90	111 minutes

To place an order, contact your local distributor or InBios directly.

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InBios

DENV *Detect*™ IgM Capture ELISA

For the qualitative detection of IgM antibodies to dengue virus in human serum to aid in the presumptive diagnosis of individuals with dengue fever or dengue hemorrhagic fever.

CE | FDA | Made in USA.

InBios

Easy to use and accurate.

- 1st in vitro assay for dengue to receive FDA clearance.
- Performance thoroughly evaluated with clinically confirmed cases of dengue 1-4 serotypes.
- Developed with a new generation of CDC licensed recombinants expressed in mammalian cells.
- Excellent positive and negative agreement with WHO reference panel (>90%).
- Includes a normal cell antigen to improve accuracy by monitoring background reactivity that can lead to false positive results.
- Employs a simple, one step ratio method of interpretation.

Performance Data

Reactivity of WHO Reference Panel samples with the InBios DENV Detect IgM ELISA

Category	Number tested	DENV Detect IgM ELISA Result	Count	Category	Number Tested	DENV Detect IgM ELISA Result	Count
Dengue IgM Negative	27	Negative	27	St. Louis encephalitis (SLE)	2	Negative	1
		Equivocal	0			Equivocal	1
		Positive	0			Positive	0
Dengue IgM Positive	109	Negative	4	Lyme IgG	9	Negative	9
		Equivocal	5			Equivocal	0
		Positive	100			Positive	0
West Nile Virus IgG	11	Negative	10	Rheumatoid factor (RF)	10	Negative	10
		Equivocal	1			Equivocal	0
		Positive	0			Positive	0
West Nile Virus IgM	25	Negative	21	Systemic lupus erythematosus (SLE)	2	Negative	2
		Equivocal	2			Equivocal	0
		Positive	2			Positive	0
Yellow Fever (YF) IgM	4	Negative	3	New World hantavirus (HTN) IgM	7	Negative	7
		Equivocal	1			Equivocal	0
		Positive	0			Positive	0

Who Panel Study

Positive Percent Agreement: (100/109) 91.7% (95% CI: 84.9-95.8%)
Negative Percent Agreement: (90/97) 92.8% (95% CI: 85.6-96.7%)

A well characterized reference panel of samples was created by a joint effort of the United Nations International Children's Emergency Fund / United Nations Development Programme / World Bank / World Health Organization Special Programme for Research and Training in Tropical Diseases and the Pediatric Dengue Vaccine Initiative. The reference panel was created by establishing a network of seven laboratories which contributed serum specimens and evaluated the samples (3).

A subset of the reference panel was available for screening with the InBios DENV Detect IgM Capture ELISA. The panel was tested by the CDC in Puerto Rico and the results are shown below.

The positive percent agreement (PPA) and negative percent agreement (NPA) are tabulated throughout by considering the "worst-case scenario." That is, equivocal samples are considered false negative for the PPA and equivocal samples are considered false positive for the NPA.

Clinical Study

This retrospective study utilized serially collected archived samples from individuals displaying signs and symptoms of dengue infection. Samples were collected from a select date onwards until a predetermined number of reactive samples were reached. The study was conducted using 197 subjects' sera obtained from a reference laboratory in Southeast Asia. Two sample draws (394 total samples collected 1-2 weeks apart) were available and confirmation of DENV was assessed by different methods in the reference laboratory. The final diagnosis for each subject was determined by the reference laboratory using a diagnostic algorithm (validated in-house IgM test result, and/or PCR result, and/or a rising IgG titer, and/or a four-fold rise of HAI titer between acute and convalescent blood draw). Any one test was used to confirm a positive diagnosis.

All the above samples were sequentially collected and tested by the InBios DENV Detect IgM Capture ELISA kit. Positive and negative percent agreements with the reference laboratory final diagnosis are tabulated below as a function of the number of days post onset of fever.

The positive percent agreement (PPA) and negative percent agreement (NPA) are tabulated throughout by considering the "worst-case scenario." That is, equivocal samples are considered false negative for the PPA and equivocal samples are considered false positive for the NPA.

Note: The above summary compares the InBios assay test results to the final diagnosis determined by the reference lab using PCR, HAI, rise in IgG titer and the in-house IgM ELISA.

DENV Detect Performance from Study Site 1

Days post onset fever	Positive Percent Agreement	Negative Percent Agreement	# of Equivocal Samples with final diagnosis of Positive	# of Equivocal Samples with final diagnosis of Negative
2-3 days	28.6% (2/7)	100.0% (4/4)	1	0
4-5 days	40.3% (27/67)	78.8% (26/33)	19	7
6-7 days	75.9% (63/83)	88.6% (31/35)	14	3
8-10 days	88.8% (71/80)	97.1% (33/34)	7	1
11-15 days	91.7% (22/24)	100.0% (21/21)	2	0
16-19 days	100.0% (5/5)	100.0% (1/1)	0	0

Product Info

DENV Detect™ IgM Capture ELISA

Catalog Number:
DDMS-1

No. of Tests:
96 well plate processes 44 unknown samples

Total Incubation Time Required:
196 minutes

Storage:
2-8° Celsius

See package insert for full range of studies performed.

Also Available:

Product	Catalog No.
DENV *Detect*™ IgG ELISA	DDGS-1
DENV *Detect*™ NS1 ELISA	DNS1-1

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