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DENV Detect™ IgM Capture ELISA Frequently Asked Questions

How many unknown samples can be tested with the kit? 44

Why are 2 wells per sample needed?

In addition to Dengue recombinant antigen (DENRA), samples are screened with a normal cell antigen (NCA). This step optimizes the specificity by helping eliminate any false positives that may occur in the assay because of non-specific interactions of the antigen with the sample. This is similar to what is done in the Centers for Disease Control (CDC) developed MAC ELISA for Dengue IgM.

How long is the incubation time? 196 minutes (60+60+60+5+10+1)

What is the total time it takes to process a sample? 256 minutes

What antigen(s) are used in the assay?

InBios uses a mixture of recombinant DENV antigens in a pre-determined ratio capable of detecting IgM against all serotypes

What serotypes does the assay detect? Dengue 1-4

What is the storage of the kit? 2-8 degrees Celsius

What is the shelf life of the kit? 12 months from the manufacture date.

Is the kit CLIA waived? No

Is the kit FDA 510k cleared? Yes. The 510K number is: k100534

Do you need to perform the Enwash step?

Our kit performance was validated with the Enwash step. This helps to clear the background reactivity. Some end users consider this unnecessary and eliminate it at their own risk.

What is the CPT code?

At this time, the generic code of 86790 (antibody virus not elsewhere specified) is in use. There may be a more specific code in the future.

What is the sensitivity and specificity of the assay?

Positive Percent Agreement: 91.7% (95% CI: 84.9-95.8%)

Negative Percent Agreement: 92.8% (95% CI: 85.6-96.7%)

(Based on WHO panel study. See package insert for details)

Do you also have IgG and NS1?

Yes, we offer Dengue IgG and Dengue NS1 ELISA kits available for research use within the US and kits for export use only outside the US.