West Nile Detect™ IgM Capture ELISA
For In Vitro Diagnostic Use

Intended Use
The West Nile Detect™ IgM Capture ELISA is for the qualitative presumptive detection of IgM antibodies to WNV recombinant antigens (WNRA) in serum as an aid in the clinical laboratory diagnosis of West Nile Virus infection in patients with clinical symptoms consistent with encephalitis/meningitis.

Description
InBios’ West Nile Detect IgM Capture ELISA consists of one enzymatically amplified “two-step” sandwich-type immunoassay.

In this assay, controls and unknown serum samples are incubated in microtiter wells which have been coated with anti-human IgM antibodies, followed by incubation with West Nile Virus derived recombinant WNRA protein and a control preparation (NCA separately).

After 1-hour incubation and washing, the wells are treated with a WNRA-specific antibody labeled with the enzyme horseradish peroxidase (HRP).

After a second incubation and washing step, the wells are incubated with the tetramethylbenzidine (TMB) substrate. An acidic stopping solution is then added and the degree of enzymatic turnover of the substrate is determined by absorbance measurement at 450 nanometers.

Above a certain threshold, the ratio of the absorbance of the WNRA and the Control wells accurately determines whether antibodies to WNV are present. A set of positive and negative samples is provided as internal controls in order to monitor the integrity of the kit components.

Features and Benefits
• U.S. FDA Cleared
• ☻ Marked for the European community
• High sensitivity and specificity >95%
• Excellent reproducibility
• Easy-to-use protocol
• Fast turn around time for assay results – 4 hours or less
• Excellent correlation with CDC ELISA
• Contains all necessary reagents and controls to complete test
• 96 well plate (breakaway strips)
• Excellent technical support provided
• Competitive pricing
• Made in the USA
• ISO compliant

Contact us:
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Catalog No. WNMS-1

Ordering Information:
To place an order, contact your local distributor or InBios directly.
SITE 1:
These samples include 50 clinically and laboratory confirmed cases of WNV (n=50) or undetermined flavivirus (positive for both WNV and SLE; n=2). In addition, 125 sequential endemic samples were tested, of which 2 were confirmed with undetermined flavivirus or WNV by PRNT.

<table>
<thead>
<tr>
<th>Clinical Category</th>
<th>Pos.</th>
<th>Neg.</th>
<th>Equivocal</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>PRNT Positive</td>
<td>50</td>
<td>2</td>
<td>0</td>
<td>52</td>
</tr>
<tr>
<td>Negative</td>
<td>1</td>
<td>121</td>
<td>1</td>
<td>123</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>51</strong></td>
<td><strong>123</strong></td>
<td><strong>1</strong></td>
<td><strong>175</strong></td>
</tr>
</tbody>
</table>

**WN Virus Positive:**
Sensitivity = 50/52 = 96.2%
Confidence Interval: 87.0 – 98.9%

**WN Virus Negative:**
Specificity = 121/123 = 98.4%
Confidence Interval: 94.3 - 99.6%

SITE 2:
These samples include 88 clinically and laboratory confirmed cases of WNV and/or SLE. In addition, 130 endemic samples were tested, of which 14 were confirmed with SLE and/or WNV by PRNT.

<table>
<thead>
<tr>
<th>Clinical Category</th>
<th>Pos.</th>
<th>Neg.</th>
<th>Equivocal</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>PRNT Positive</td>
<td>99</td>
<td>2</td>
<td>1</td>
<td>102</td>
</tr>
<tr>
<td>Negative</td>
<td>1</td>
<td>115</td>
<td>0</td>
<td>116</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>100</strong></td>
<td><strong>117</strong></td>
<td><strong>1</strong></td>
<td><strong>218</strong></td>
</tr>
</tbody>
</table>

**WN Virus Positive:**
Sensitivity = 99/102 = 97.1%
Confidence Interval: 91.7 – 99.0%

**WN Virus Negative:**
Specificity = 115/116 = 99.1%
Confidence Interval: 95.3 - 99.9%

SITE 3:
These samples include 150 clinically and laboratory confirmed cases of WNV. In addition, 150 endemic samples were tested, of which 23 were confirmed with SLE and/or WNV by CDC ELISA.

<table>
<thead>
<tr>
<th>Clinical Category</th>
<th>Pos.</th>
<th>Neg.</th>
<th>Equivocal</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>PRNT Positive</td>
<td>172</td>
<td>1</td>
<td>0</td>
<td>173</td>
</tr>
<tr>
<td>Negative</td>
<td>0</td>
<td>127</td>
<td>0</td>
<td>127</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>172</strong></td>
<td><strong>128</strong></td>
<td><strong>0</strong></td>
<td><strong>300</strong></td>
</tr>
</tbody>
</table>

**WN Virus Positive:**
Sensitivity = 172/173 = 99.4%
Confidence Interval: 96.8 – 99.9%

**WN Virus Negative:**
Specificity = 127/127 = 100.0%
Confidence Interval: 97.1 - 100%

SITE 4:
These samples include 210 endemic samples, none of which were confirmed with (or tested for) SLE or WNV by CDC MAC.

<table>
<thead>
<tr>
<th>Clinical Category</th>
<th>Pos.</th>
<th>Neg.</th>
<th>Equivocal</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>CDC MAC Positive</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Negative</td>
<td>0</td>
<td>210</td>
<td>0</td>
<td>210</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>0</strong></td>
<td><strong>210</strong></td>
<td><strong>0</strong></td>
<td><strong>210</strong></td>
</tr>
</tbody>
</table>

**WN Virus Negative:**
Specificity = 210/210 = 100.0%
Confidence Interval: 98.2 – 100.0%