Epitogen Lyme VIsE IgM Assay



Epitogen[®] Lyme VIsE IgM Assay: Redefining Lyme Disease Research

VISE is a surface lipoprotein in *Borrelia burgdorferi* that undergoes antigenic variation through segmental recombination with silent cassettes. This process allows the bacterium to evade immune detection and persist in the host, creating significant variability in VISE among different *Borrelia* species—posing a major challenge for research and diagnostics.

Using our proprietary Epitogen® technology, we successfully expressed **27 full-length VIsE variants** representing key pathogenic species: *B. burgdorferi* sensu stricto, *B. afzelii*, *B. garinii*, *B. mayonii*, *B. spielmanii*, *B. bissetiae*, *B. bavariensis*, and *B. valaisiana*.

This expansive VIsE antigen panel is designed to advance *Borrelia* research, improve strain-specific diagnostics, and support accurate epidemiological tracking. Powered by our unique Epitogen® scaffold, it ensures precise antigen orientation for reliable comparison and high assay performance.

Intended Use:

The assay is designed for use in two key scenarios:

a) Strain Identification in Confirmed Lyme Disease Cases:

It provides additional insight into the specific Borrelia strain responsible for infection in patients who have already tested positive for Lyme disease. This information can support epidemiological tracking, inform treatment decisions, and enhance our understanding of regional strain prevalence.

b) Re-evaluation of Serology-Negative but Clinically Suspected Lyme Cases:

In patients presenting with clinical symptoms consistent with Lyme disease but who test negative on standard serological assays, this test offers an additional diagnostic tool. It may detect immune responses to less commonly targeted Borrelia species or variants, potentially improving diagnostic sensitivity and supporting earlier intervention.

Complementary Use with the Lyme VIsE IgG Assay:

When used in combination with the Lyme VIsE IgG Assay, this test provides deeper insights into the infection stage and immune system profile—offering enhanced diagnostic clarity and greater confidence in clinical decision-making.

Antigen coating

1-27 VIsE Borrelia variants.

B Empty well.

Ρ

- N Scaffold control.
 - Lyme antigen.

Borrelia Hermssi antigens

Borrelia miyamotoi antigens

Test Sample (3 samples/plate) – apply Lyme positive sample. <u>Note</u>: VIsE identifiers and their corresponding species of origin will be provided in the technical manual.

| Differential VIsE Layout | | | | | | | | |
|--------------------------|----------|----------|--|--|--|--|--|--|
| Sample 1 | Sample 2 | Sample 3 | | | | | | |
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|---|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|
| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 |
| А | VisE 1 | VisE 2 | VIsE 3 | VisE 4 | VisE 1 | VIsE 2 | VlsE 3 | VisE 4 | VisE 1 | VlsE 2 | VIsE 3 | VlsE 4 |
| В | VisE 5 | VisE 6 | VIsE 7 | VIsE 8 | VisE 5 | VIsE 6 | VIsE 7 | VIsE 8 | VisE 5 | VlsE 6 | VIsE 7 | VIsE 8 |
| С | VIsE 9 | VisE 10 | VisE 11 | VIsE 12 | VisE 9 | VisE 10 | VisE 11 | VIsE 12 | VIsE 9 | VisE 10 | VisE 11 | VIsE 12 |
| D | VIsE 13 | VIsE 14 | VIsE 15 | VIsE 16 | VisE 13 | VisE 14 | VIsE 15 | VisE 16 | VIsE 13 | VisE 14 | VIsE 15 | VIsE 16 |
| Е | VIsE | VIsE 18 | VisE 19 | VIsE 20 | VisE 17 | VisE 18 | VisE 19 | VisE 20 | VisE 17 | VisE 18 | VisE 19 | VisE 20 |
| F | VIsE 21 | VIsE | VIsE 23 | VIsE | VisE 21 | VIsE | VIsE 23 | VisE 24 | VIsE 21 | VIsE 22 | VIsE 23 | VIsE |
| G | VIsE 25 | VisE 26 | VIsE | В | VisE 25 | VisE 26 | VIsE | В | VIsE 25 | VisE 26 | VIsE | в |
| Н | N | Р | | Miyamotoi | N | Р | | Miyamoto | N | Ρ | | Miyamotoi |
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