

# CMV AccuVert™

## Seroconversion Panel

0615-0039 / Batch #10142618

### OVERVIEW

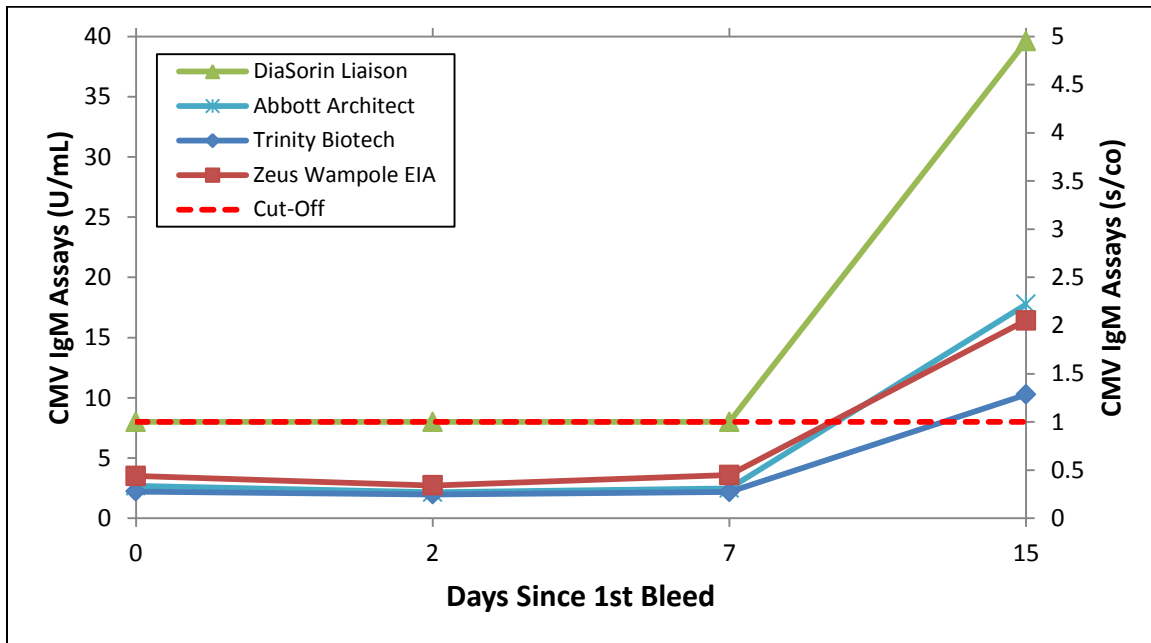
Cytomegalovirus (CMV) AccuVert™ Seroconversion Panel (0615-0039) is a 4-member panel of undiluted, naturally occurring plasma samples (1 vial per member, 1.2mL per vial). Panel members represent serial bleeds collected from a single patient over the course of 15 days during the development of a CMV infection and subsequent response. Each sample represents a single collection event. No preservatives were added.

Test results from commercially-available CMV DNA and antibody assays are included for the characterization of each panel member. This panel of human plasma samples demonstrates a change in expression from negative to positive for CMV antibodies during the development and progression of a CMV infection.

For Research Use Only. Not for use in diagnostic procedures. Data are provided for informational purposes. SeraCare Life Sciences does not claim that others can duplicate test results exactly.

CAUTION: Potentially infectious materials. Follow Universal Precautions. The units that make up this panel were tested and found negative for anti-HIV 1/2, HBsAg and HCV. This does not ensure the absence of these or other human pathogens.

Evolution of Early CMV IgM response on multiple assays



This graph demonstrates CMV IgM antibody reactivity amongst panel members from the Abbott ARCHITECT, Trinity Biotech EIA, and Zeus Wampole EIA expressed in s/co and the DiaSorin LIAISON expressed in U/mL.

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## Panel Member Information

| Panel Member | SeraCare Batch # | SeraCare Donor ID # | Bleed Date | Days Since 1st Bleed |
|--------------|------------------|---------------------|------------|----------------------|
| 01           | 9169453          | BD110962            | 22Apr2004  | 0                    |
| 02           | 9169467          | BD110962            | 24Apr2004  | 2                    |
| 03           | 9169510          | BD110962            | 29Apr2004  | 7                    |
| 04           | 9169564          | BD110962            | 07May2004  | 15                   |

CMV DNA<sup>1</sup>

| Panel Member          | Roche COBAS TaqMan<br>(c/mL) <sup>2,3</sup> | Qiagen Rotor-Gene PCR<br>(c/mL) |
|-----------------------|---|---------------------------------|
| 01                    | TND   | TND                             |
| 02                    | TND   | TND                             |
| 03                    | TND   | TND                             |
| 04                    | <b>*1.37 x 10<sup>2</sup></b>               | TND                             |
| Test Date             | 10Nov2015                                   | 04Nov2015                       |
| Test Site             | Reference Lab                               | Reference Lab                   |
| Kit Part Code         | Unavailable                                 | 4503245                         |
| Kit Lot No.           | W044770000                                  | 151035224                       |
| Kit Exp. Date         | 31Jul2016                                   | 30Sep2016                       |
| Kit Regulatory Status | IVD/CE                                      | RUO                             |

<sup>1</sup> Results are reported as a mean result of duplicate testing.<sup>2</sup> Results in bold red are considered positive/reactive. \* Test result reported for only single replicate, second replicate tested TND.<sup>3</sup> Results are reported in CMV genomic copies per mL (c/mL).

TND = Target not detected; IVD = In Vitro Diagnostic; CE = Conformité Européenne or CE Marking; RUO = Research Use Only

CMV IgM<sup>1</sup>

| Panel Member          | Trinity Biotech CMV<br>IgM<br>(s/co) <sup>4</sup> | Zeus Wampole CMV<br>IgM EIA (s/co) <sup>4</sup> | bioMerieux VIDAS<br>CMV IgM | DiaSorin LIAISON<br>CMV IgM<br>(U/mL) <sup>5</sup> | Abbott ARCHITECT<br>CMV IgM<br>(s/co) <sup>4</sup> |
|-----------------------|---|---|-----------------------------|--|--|
| 01                    | 0.3   | 0.4   | NEG                         | BLD  | 0.3  |
| 02                    | 0.2   | 0.3   | NEG                         | BLD  | 0.3  |
| 03                    | 0.3   | 0.4   | NEG                         | BLD  | 0.3  |
| 04                    | <b>1.3</b>  | <b>2.1</b>                                      | GRAY                        | <b>39.6</b>  | <b>2.2</b>   |
| Test Date             | 03Nov2015   | 12Nov2015                                       | 04Nov2015                   | 05Nov2015  | 17Nov2015  |
| Test Site             | SeraCare  | SeraCare  | Reference Lab               | Reference Lab                                      | Reference Lab                                      |
| Kit Part Code         | 2325260   | 9Z9501M   | Unavailable                 | Unavailable  | Unavailable  |
| Kit Lot No.           | 2325260-055                                       | 15050017  | 160507-0                    | 012033X  | 55792LF00  |
| Kit Exp. Date         | 31May2016   | 31Oct2016                                       | Unavailable                 | 15Dec2015  | 09Jul2016  |
| Kit Regulatory Status | IVD/CE  | IVD/CE  | Unavailable                 | Unavailable  | Unavailable  |

<sup>1</sup> Results are reported as a mean result of duplicate testing.<sup>4</sup> Results are reported as a signal to cut-off value (s/co). Positive/reactive results are noted in bold red with a signal to cut-off value greater than 1.0.<sup>5</sup> Results are reported as units per volume (U/mL). Positive/reactive results are noted in bold red with a unit per volume greater than the LOD at <8.0.

BLD = Below Limit of Detection; LOD = Limit of detection; IVD = In Vitro Diagnostic; CE = Conformité Européenne or CE Marking; RUO = Research Use Only

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CMV IgG<sup>1</sup>

| Panel Member   | Trinity Biotech CMV IgG (s/co) <sup>4</sup> | Zeus Wampole CMV IgG EIA (s/co) <sup>4</sup> | bioMerieux VIDAS CMV IgG | DiaSorin LIAISON CMV (U/mL) <sup>6</sup> | Abbott ARCHITECT CMV (AU/mL) <sup>7</sup> |
|----------------|---|--|--------------------------|--|---|
| 01             | 0.2   | 0.3  | NEG                      | BLD                                      | 0.6                                       |
| 02             | 0.2   | 0.3  | NEG                      | BLD                                      | 0.9                                       |
| 03             | 0.3   | 0.4  | NEG                      | BLD                                      | 1.4                                       |
| 04             | <b>1.0</b>                                  | <b>1.5</b>                                   | <b>POS</b>               | <b>1.80</b>                              | <b>21.6</b>                               |
| Test Date      | 04Nov2015                                   | 18Nov2015                                    | 04Nov2015                | 04Nov2015                                | 17Nov2015                                 |
| Test Site      | SeraCare                                    | SeraCare                                     | Reference Lab            | Reference Lab                            | Reference Lab                             |
| Kit Part Code  | 2325200                                     | 9Z9501G                                      | Unavailable              | Unavailable                              | Unavailable                               |
| Kit Lot No.    | 2325200-568                                 | 15070012                                     | 166331-0                 | 11037                                    | 54167LH00                                 |
| Kit Exp. Date  | 31May2016                                   | 31Dec2016                                    | Unavailable              | 02Feb2016                                | 25Jun2016                                 |
| Kit Regulatory | IVD/CE                                      | IVD/CE                                       | Unavailable              | Unavailable                              | Unavailable                               |

<sup>1</sup> Results are reported as a mean result of duplicate testing.<sup>2</sup> Results are reported as a signal to cut-off value (s/co). Positive/reactive results are noted in bold red with a signal to cut-off value greater than 1.0.<sup>6</sup> Results are reported as units per milliliter (u/mL). Positive/reactive results are noted in bold red with a unit per volume greater than the LOD at <0.20.<sup>7</sup> Results are reported as arbitrary units per milliliter (AU/mL). Positive/reactive results are noted in bold red with a unit of measure greater than 8.0.

BLD = Below Limit of Detection; IVD = In Vitro Diagnostic; CE = Conformité Européenne or CE Marking

CMV IgM/IgG Agglutination Assay<sup>1</sup>

| Panel Member          | Beckman Coulter PK7200-PA |
|-----------------------|---------------------------|
| 01                    | Non-reactive              |
| 02                    | Non-reactive              |
| 03                    | Non-reactive              |
| 04                    | <b>Positive</b>           |
| Test Date             | 05Nov2015                 |
| Test Site             | Reference Lab             |
| Kit Part Code         | Unavailable               |
| Kit Lot No.           | VR00025                   |
| Kit Exp. Date         | Oct2016                   |
| Kit Regulatory Status | Unavailable               |

<sup>1</sup> Results are reported as a mean result of duplicate testing.

The package insert for this panel can be found at [www.seracare.com](http://www.seracare.com)

A printed copy of the package insert or data sheet may be requested by email at [info@seracare.com](mailto:info@seracare.com), or by phone at 508.244.6400

### ASK ABOUT RELATED SERACARE PRODUCTS

- AccuSet™ Performance Panels
- CMV Disease State Biological Materials
- ACCURUN® Independent Quality Controls
- SeraCon™ and Basematrix Processed Plasma