

AccuSet™ HEV Performance Panel

0820-0503 / Batch #10640609

OVERVIEW

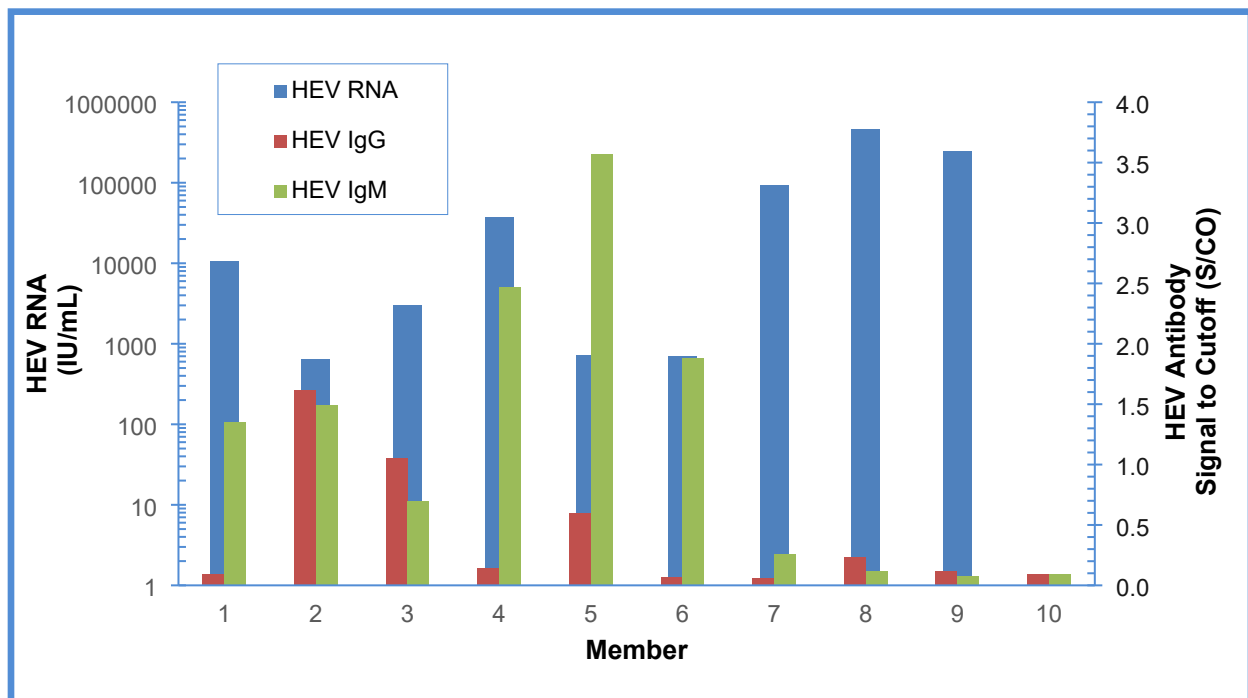
AccuSet™ Hepatitis E Virus Performance Panel 0820-0503 / Batch #10640609 is a 10-member validation panel of undiluted, naturally occurring plasma samples (1 vial per member, 1.0 mL per vial). Panel members represent bleeds from multiple individuals positive for Hepatitis E. Each sample represents a single collection event. No preservatives were added.

Test results from commercially-available HEV assays are included for characterization of the panel members. This panel of human plasma samples demonstrates a range of reactivity for various HEV test methods. One sample is included as a non-reactive sample and is negative for all HEV test methods performed.

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

CAUTION: Potentially infectious materials. Follow Universal Precautions. Some panel members were found positive for HEV; all were found negative for anti-HIV-1/2, anti-HCV, and HBsAg. This does not ensure the absence of these or other human pathogens.

AccuSet™ HEV Performance Panel



This graph represents panel member reactivity to the Altona Diagnostics RealStar® HEV RT-PCR Kit 2.0 (HEV RNA), DIA.PRO HEV IgG ELISA, and DIA.PRO HEV IgM ELISA test methods.

AccuSet™ HEV Performance Panel

0820-0503 / Batch #10640609

Panel Member Information

| Panel Member | SeraCare Batch Number | Bleed Date |
|--------------|-----------------------|-------------|
| 01 | 10624521 | 26-Dec-2019 |
| 02 | 10624523 | 07-Jan-2019 |
| 03 | 10624524 | 14-Jun-2019 |
| 04 | 10624526 | 30-Oct-2019 |
| 05 | 10624527 | 18-May-2020 |
| 06 | 10624528 | 28-Oct-2020 |
| 07 | 10624529 | 12-Apr-2013 |
| 08 | 10624530 | 18-Apr-2017 |
| 09 | 10624531 | 04-Apr-2017 |
| 10 | 10127358 | 11-Jun-2015 |

HEV RNA

| Panel Member | Altona Diagnostics RealStar® HEV RT-PCR Kit 2.0 (IU/mL) ¹ |
|---------------|--|
| | 01 |
| 02 | 6.37 x 10² |
| 03 | 3.01 x 10³ |
| 04 | 3.76 x 10⁴ |
| 05 | 7.31 x 10² |
| 06 | 7.10 x 10² |
| 07 | 9.25 x 10⁴ |
| 08 | 4.61 x 10⁵ |
| 09 | 2.47 x 10⁵ |
| 10 | TND |
| Test Date | 17-Oct-2022 |
| Test Site | RL |
| Kit Part Code | NA |
| Kit Lot No. | 036392 |
| Kit Exp. Date | 09-Apr-2023 |

¹Results are reported as the mean result of duplicate testing; positive/reactive results are noted in bold red.

RL = Reference Lab; NA = Not Available

TND=Target Not Detected

AccuSet™ HEV Performance Panel

0820-0503 / Batch #10640609

HEV IgG and IgM Antibody

| Panel Member | DIA.PRO HEV IgG ELISA (S/CO) ^{1,2} | DIA.PRO HEV IgM ELISA (S/CO) ¹ | Mikrogen Diagnostik recomWell HEV IgG (U/mL) ¹ | Mikrogen Diagnostik recomWell HEV IgM (U/mL) ^{1,3} |
|---------------|---|---|---|---|
| 01 | 0.09 | 1.35 | 6.48 | 35.49 |
| 02 | 1.62 | 1.49 | 160.00 | 46.35 |
| 03 | 1.19 , 0.91* | 0.70 | 33.75 | 7.73 |
| 04 | 0.14 | 2.47 | 7.47 | 30.92 |
| 05 | 0.60 | 3.57 | 90.81 | 41.68 |
| 06 | 0.07 | 1.88 | 5.33 | 23.84, 26.92* |
| 07 | 0.06 | 0.26 | 1.43 | 7.92 |
| 08 | 0.23 | 0.12 | 1.61 | 2.81 |
| 09 | 0.12 | 0.08 | 1.93 | 1.54 |
| 10 | 0.09 | 0.09 | 2.39 | 1.46 |
| Test Date | 06-Oct-2022 | 07-Oct-2022 | 07-Oct-2022 | 07-Oct-2022 |
| Test Site | SC | SC | SC | SC |
| Kit Part Code | EVG.CE | EVM.CE | 5004 | 5005 |
| Kit Lot No. | 0622 | 0222 | EHE072202 | EHE072201 |
| Kit Exp. Date | 30-Sep-2023 | 31-May-2023 | 31-Dec-2023 | 31-Dec-2023 |

¹Results are reported as the mean result of duplicate testing; positive/reactive results are noted in bold red.

²Values between 0.90 – 1.10 S/CO are considered equivocal.

³Values between 20.00 – 24.00 U/mL are considered borderline.

*Interpretation variability; individual replicates reported.

SC = SeraCare

The package insert for this panel can be found at
www.seracare.com.

A printed copy of the package insert or data sheet may be requested by email at CDx-Info@LGCGroup.com or by phone at 508.244.6400.