

Representative Reactivities Table

Optitrol HEPR-1

Positive Control

Version: 2

Date: 14.11.2022



| Analyte | Manufacturer | Assay Name | Method | Unit | Mean | SD | Samples | Labs | Representative Reactivity |
|--------------|--------------|-------------------------|--------|--------|-------|------|---------|------|---------------------------|
| Anti-HAV IgG | DiaSorin | LIAISON XL Anti-HAV | CLIA | Index | 0.72 | 0.03 | 10 | 2 | positive |
| Anti-HBs IgG | DiaSorin | LIAISON Anti-HBs II | CLIA | mIU/mL | 31.89 | 1.70 | 10 | 2 | positive |
| Anti-HBe IgG | DiaSorin | LIAISON XL Anti-HBe | CLIA | Index | 0.44 | 0.03 | 10 | 2 | positive |
| Anti-HEV IgG | DiaSorin | LIAISON XL Anti-HEV IgG | CLIA | IU/mL | 0,92 | 0,03 | 10 | 2 | positive |
| | Wantai | WANTAI HEV-IgG ELISA | ELISA | S/CO | 2.66 | 0.73 | 10 | 1 | positive |

The stated mean values were obtained by testing one product batch. They show possible representative values but no target values.
Test results may vary among used instruments, assays, reagent lots, and different laboratory protocols.

Representative Reactivities Table

Optitrol HEPR-2

Positive Control

Version: 2

Date: May 28, 2021



| Analyte | Manufacturer | Assay Name | Method | Unit | Mean | SD | Samples | Labs | Representative Reactivity |
|---------------------|--------------|-------------------------|--------|--------|-------|------|---------|------|---------------------------|
| Anti-HAV IgG | Abbott | Architect HAVAb IgG | CMIA | S/CO | 3.57 | 0.27 | 10 | 1 | positive |
| | Abbott | Alinity i HAVAb IgG | CMIA | S/CO | 4.70 | 1.00 | 10 | 1 | positive |
| | Roche | Elecsys Anti-HAV | ECLIA | COI | 0.24 | 0.02 | 10 | 2 | positive |
| | Siemens | ADVIA Centaur HAV Total | ChLIA | Index | 87.24 | 1.30 | 10 | 1 | positive |
| | Siemens | Atellica IM HAV Total | ChLIA | mIU/mL | 88.84 | 0.49 | 10 | 1 | positive |
| Anti-HBs IgG | Abbott | Architect Anti-HBs | CMIA | mIU/mL | 30.49 | 2.10 | 10 | 2 | positive |
| | Abbott | Alinity i Anti-HBs | CMIA | mIU/mL | 28.06 | 0.97 | 10 | 1 | positive |
| | Roche | Elecsys Anti-HBs | ECLIA | IU/L | 42.78 | 1.41 | 10 | 2 | positive |
| | Siemens | ADVIA Centaur Anti-HBs | ChLIA | Index | 35.78 | 0.61 | 10 | 1 | positive |
| | Siemens | Atellica IM Anti-HBs | ChLIA | mIU/mL | 32.26 | 0.72 | 10 | 1 | positive |
| Anti-HBe IgG | Abbott | Architect Anti-HBe | CMIA | S/CO | 0.63 | 0.02 | 10 | 2 | positive |
| | Abbott | Alinity i Anti-HBe | CMIA | S/CO | 0.61 | 0.02 | 10 | 1 | positive |
| | Roche | Elecsys Anti-HBe | ECLIA | COI | 0.68 | 0.04 | 10 | 2 | positive |
| | Siemens | Atellica IM Anti-HBe | ChLIA | Index | 2.77 | 0.02 | 10 | 1 | positive |
| Anti-HEV IgG | Mikrogen | recomWell HEV-IgG | ELISA | S/CO | 2.78 | 0.13 | 10 | 1 | positive |

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