

Representative Reactivities Table

Optitrol HEPR-1

Positive Control

Version: 1

Date: Dec 1st, 2020

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	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

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.