

Anti-HBc IgM Mixed Titer AccuSet™ Performance Panel Modified PHE203(M) (0805-0216)

A SERACARE PANEL PRODUCT

INTENDED USE

The Anti-HBc Mixed Titer AccuSet™ Performance Panel Modified PHE203(M) is intended for use by diagnostic manufacturers, researchers, and clinical laboratories to develop, evaluate, or troubleshoot anti-HBc IgM test methods. Characterized samples and comprehensive data are provided for comparative analysis. For research use only. Not for use in diagnostic procedures.

PRODUCT DESCRIPTION

This product is a modified 22-member panel originating from Anti-HBc Mixed Titer Performance Panel PHE203-1.0. Panel members 1, 2, and 24 from the original 25-member panel are no longer available. Panel members are undiluted, naturally occurring plasma samples with anti-HBc IgM reactivity ranging from negative to strong positive. No preservatives were added.

Cat. No. 0805-0216 1 vial per member
 22 members, 1.0 mL per vial

STORAGE

Panel members should be stored at -20°C or colder. SeraCare Life Sciences recommends that the panel members be divided into smaller aliquots to avoid multiple freeze-thaw cycles, if appropriate. If turbidity or particulate matter is observed, the samples should be centrifuged in accordance with each test kit manufacturer's instructions for sample preparation.

INTERPRETATION OF RESULTS

The Data Sheet for the Anti-HBc Mixed Titer AccuSet™ Performance Panel Modified is available at www.seracare.com. The Data Sheet lists results for panel members generated using commercially-available screening, monitoring, and confirmatory test methods.

Tests were performed at SeraCare or at recognized reference laboratories (RL) by individuals who routinely use these procedures. Information regarding specific test methods is available on the Data Sheet. Data Sheets are updated when new data are available.

LIMITATIONS

The Anti-HBc Mixed Titer AccuSet™ Performance Panel Modified is offered 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.

PRECAUTIONS

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

Do not pipette by mouth. Do not smoke, eat, or drink in areas where specimens are handled. These materials should be disposed of in a manner that will inactivate pathogenic agents.

REFERENCES

1. Siegel JD, Rhinehart E, Jackson M, Chiarello L, and the Healthcare Infection Control Practices Advisory Committee, 2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings.

For assistance, contact SeraCare Technical Support at 508.244.6400.

The Data Sheet and Package Insert for this panel in PDF form can be found at www.seracare.com

A printed copy of the Data Sheet may be requested by email at info@seracare.com, or by phone at 508.244.6400

ASK ABOUT RELATED SERACARE PRODUCTS

- ACCURUN® Quality Controls
- AccuType™ Viral Isolates
- SeraCon™ and Basematrix Processed Plasma



SeraCare Life Sciences
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Data Sheet

***** Anti-HBc IgM Assays¹ *****

Member I.D. #	Abbott Architect	Abbott AxSYM	Bayer ADVIA	Diasorin	DPC IMMULITE®	Ortho VITROS®
	Core-M	Core-M™ 2.0	Centaur® HBc IgM	ETI-CORE-IGMK (HBc IgM) Plus	Anti-HBc IgM	Anti-HBc IgM
	Assay RL53	Assay SeraCare	Assay RL46	Assay SeraCare	Assay SeraCare	Assay RL48
	s/co	s/co	s/co	s/co	PEI U/mL	s/co
PHE203-01 ²	0.0	0.1	0.1	0.1	<2.0	0.0
PHE203-02 ²	12.9	4.9	ALR*	10.9	>100.0	3.1
PHE203-03	22.6	5.4	ALR*	11.9	>100.0	3.3
PHE203-04	0.9	2.1	0.9	2.0	15.2	0.6
PHE203-05	6.0	3.7	ALR*	9.2	>100.0	2.6
PHE203-06	1.8	1.8	3.7	3.6	88.2	1.6
PHE203-07	20.3	5.6	ALR*	12.5	>100.0	3.3
PHE203-08	2.1	2.0	3.0	3.9	98.7	1.6
PHE203-09	19.0	5.6	ALR*	11.8	>100.0	3.3
PHE203-10	3.2	3.1	ALR*	5.9	>100.0	2.2
PHE203-11	6.6	4.3	ALR*	11.3	>100.0	2.8
PHE203-12	0.1	1.2	0.5	0.6	8.8	0.2
PHE203-13	2.8	3.4	8.7	6.2	>100.0	1.9
PHE203-14	18.2	5.2	ALR*	11.8	>100.0	3.2
PHE203-15	6.7	4.2	5.1	10.9	>100.0	2.8
PHE203-16	4.6	2.8	3.2	6.1	>100.0	2.3
PHE203-17	0.3	2.1	0.2	0.9	7.7	0.2
PHE203-18	1.5	2.7	1.8	2.6	37.9	1.0
PHE203-19	24.6	5.4	ALR*	12.7	>100.0	3.3
PHE203-20	1.4	0.8	0.7	0.7	57.7	0.6
PHE203-21	1.7	1.7	0.7	3.3	59.6	1.4
PHE203-22	1.2	1.5	0.9	2.0	32.0	1.1
PHE203-23	1.7	1.5	1.1	2.1	22.4	1.1
PHE203-24 ²	17.2	5.2	ALR*	12.9	>100.0	3.2
PHE203-25	8.0	3.0	7.5	7.0	>100.0	2.5

Run Date:	29-Jan-09/3-Feb-09	18-Dec-08/29-Dec-08/6-Mar-09	13-Mar-09	11-Dec-08/16-Dec-08/6-Mar-09	27-Jan-09	5-Feb-09/11-Mar-09
Kit Lot #:	67750HN00	65036M200	37559135	0270230B	517	6360
Exp. Date:	16-Sep-09	10-Oct-09	21-Apr-10	5-May-09	31-Dec-09	12-Oct-09
Product #:	6C33-20	8B89-20	00504619	P001928	LKMC1M	6801425

¹EIA results are means of duplicates expressed as specimen signal to cutoff ratios (s/co) or cutoff to signal ratios (co/s).

Ratios are considered reactive for results expressed as either s/co or co/s. Ratios > 10.0 are considered reactive for results expressed as PEI U/mL.

²Panel members 1, 2, and 24 are no longer available. Data are provided for informational purposes only.

*ALR = Above the Linear Range

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***** Other HBV Assays¹ *****

Member I.D. #	Genetic Systems™ HBsAg EIA 3.0 Assay SeraCare	Diasorin ETI-EBK (HBeAg) Plus Assay SeraCare	Diasorin ETI-AB-COREK (anti-HBc) Plus Assay SeraCare
	s/co	s/co	co/s
PHE203-01 ²	0.3	0.1	0.2
PHE203-02 ²	9.0	0.1	132.0
PHE203-03	>27.0	21.2	175.3
PHE203-04	>27.0	>46.6	164.4
PHE203-05	0.3	0.1	>263.0
PHE203-06	>27.0	>46.6	76.7
PHE203-07	>27.0	0.9	175.3
PHE203-08	>27.0	>46.6	197.3
PHE203-09	>27.0	>46.6	197.3
PHE203-10	0.3	0.1	197.3
PHE203-11	>27.0	0.1	197.3
PHE203-12	>27.0	0.2	197.3
PHE203-13	>27.0	>46.6	>263.0
PHE203-14	14.2	0.6	>263.0
PHE203-15	>27.0	0.3	>263.0
PHE203-16	>27.0	0.1	157.8
PHE203-17	>27.0	0.1	>263.0
PHE203-18	>27.0	0.1	197.3
PHE203-19	>27.0	>46.6	>263.0
PHE203-20	>27.0	11.7	43.8
PHE203-21	>27.0	3.3	>263.0
PHE203-22	>27.0	>46.6	4.5
PHE203-23	0.7	0.5	>263.0
PHE203-24 ²	>27.0	20.0	>263.0
PHE203-25	0.3	0.1	>263.0
Run Date:	11-Mar-09	30-Mar-09	6-Mar-09
Kit Lot #:	219CCC-05	0600290A/2	9910370A/1
Exp. Date:	18-Jun-09	13-May-09	16-Jun-09
Product #:	32591	P001930	P001927

¹EIA results are means of duplicates expressed as specimen signal to cutoff ratios (s/co) or cutoff to signal ratios (co/s).

Ratios are considered reactive for results expressed as either s/co or co/s. Ratios 10.0 are considered reactive for results expressed as PEI U/mL.

²Panel members 1, 2, and 24 are no longer available. Data are provided for informational purposes only.