AccuSet™ Babesia Performance Panel

0845-0185 / Batch #10408670

OVERVIEW

AccuSet™ Babesia Performance Panel 0845-0185 / Batch #10408670 is a 15-member validation panel of undiluted, naturally occurring plasma samples (1 vial per member, 1.0 mL per vial). Panel members represent bleeds from individuals positive for antibodies to Babesia microti. Each sample represents a single collection event. No preservatives were added.

Members included in this panel were selected following a whole blood collection event that demonstrated a reactive result for Babesia NAT screening and were excluded for general use. Test results from commercially available babesia antibody assays are included for characterization of the panel members. This panel of human plasma samples demonstrates a range of antibody reactivities for Babesia IgM and Babesia IgG. One sample is included as a non-reactive sample and is negative for all babesia test methods performed.

For Research Use Only. Not for use in diagnostic procedures. Data are offered 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 anti-HCV. This does not ensure the absence of these or other human pathogens.

Panel Member Information

Panel Member	SeraCare Batch #	Bleed Date	Anticoagulant
01	10375325	31-Jul-2018	CP2D
02	10375330	14-Aug-2018	CP2D
03	10387241	05-Nov-2018	CP2D
04	10375326	28-Jul-2018	CP2D
05	10383314	23-Oct-2018	CP2D
06	10375332	31-Aug-2018	CP2D
07	10383313	23-Oct-2018	CP2D
08	10387236	08-Nov-2018	CP2D
09	10387243	26-Oct-2018	CP2D
10	10387244	18-Nov-2018	CP2D
11	10383316	23-Oct-2018	CP2D
12	10387237	08-Nov-2018	CP2D
13	10387240	20-Nov-2018	CP2D
14	10383318	03-Oct-2018	CP2D
15	10395743	14-Jan-2019	CP2D

CP2D = Citrate Phosphate Double Dextrose

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Babesia IgM[1,2]

Panel Member	Babesia IgM Immunofluorescence Assay by ARUP Laboratories	Babesia IgM Immunofluorescence Assay by Quest Diagnostics	Babesia IgM Western Blot Result
01	**1:320**, **1:320**	**1:320**, **1:320**	**POS**, **POS**
02	**1:320**, **1:320**	**1:320**, **1:320**	**POS**, **POS**
03	**1:40**, **1:160**	**1:80**, **1:160**	NEG, NEG
04	**1:320**, **1:320**	**1:160**, **1:160**	NEG, NEG
05	**1:40**, 1:20	**1:80**, **1:20**	NEG, NEG
06	**1:320**, **1:320**	**1:320**, **1:320**	**POS**, **POS**
07	**1:160**, **1:160**	**1:40**, **1:20**	NEG, **POS**
08	**1:80**, **1:40**	**1:40**, **1:40**	**POS**, **POS**
09	**1:320**, **1:320**	**1:320**, **1:320**	**POS**, **POS**
10	**1:320**, **1:320**	**1:160**, **1:160**	**POS**, **POS**
11	**1:40**, **1:80**	**1:40**, <1:20	NEG, NEG
12	<1:20, <1:20	<1:20, <1:20	NEG, NEG
13	<1:20, <1:20	<1:20, <1:20	NEG, NEG
14	<1:20, <1:20	<1:20, <1:20	NEG, NEG
15	<1:20, <1:20	<1:20, <1:20	NEG, NEG
Test Date	21-Apr-2019	22-Apr-2019	23-Apr-2019
Test Site	RL	RL	RL
Kit Part Code	NA	NA	NA
Kit Lot No.	NA	NA	NA
Kit Exp. Date	NA	NA	NA

[1]Positive/reactive results are noted in bold red.
[2]Results are reported individually from duplicate testing.
POS = Positive; NEG = Negative
RL = Reference Lab
NA = Not Available
LDT = Laboratory Developed Test

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Babesia IgG[1,2]

Panel Member	Babesia IgG Immunofluorescence Assay by ARUP Laboratories	Babesia IgG Immunofluorescence Assay by Quest Diagnostics	Babesia IgG Immunofluorescence Assay by IMUGEN	Babesia IgG Western Blot Result
01	**1:128, 1:64**	**1:64**, <1:64	**1:512, 1:512**	NEG, NEG
02	**1:256, 1:256**	**1:1024, 1:1024**	**>1:1024, >1:1024**	**POS, POS**
03	**1:256, 1:256**	**1:512, 1:512**	**1:256, 1:512**	**POS, POS**
04	**1:256, 1:256**	**1:512, 1:1024**	**1:256, 1:512**	**POS, POS**
05	**1:256, 1:128**	**1:128, 1:512**	**1:256, 1:256**	**POS, POS**
06	**1:256, 1:256**	**1:1024, 1:1024**	**>1:1024, >1:1024**	**POS, POS**
07	**1:256, 1:256**	**1:512, 1:1024**	**1:512, 1:512**	**POS, POS**
08	**1:256, 1:256**	**1:1024, 1:512**	**1:512, 1:512**	**POS, POS**
09	**1:256, 1:256**	**1:512, 1:512**	**1:512, 1:512**	**POS, POS**
10	**1:128, 1:128**	**1:512, 1:512**	**1:256, 1:256**	**POS, POS**
11	**1:128, 1:128**	**1:512, 1:512**	**1:256, 1:256**	**POS, POS**
12	**1:256, 1:256**	**1:1024, 1:1024**	**>1:1024, 1:512**	**POS, POS**
13	**1:256, 1:256**	**1:1024, 1:1024**	**>1:1024, >1:1024**	**POS, POS**
14	**1:256, 1:128**	**1:1024, 1:512**	**1:256, 1:512**	**POS, POS**
15	<1:16, <1:16	<1:64, <1:64	<1:32, <1:32	NEG, NEG
Test Date	22-Apr-2019	22-Apr-2019	23-Apr-2019	23-Apr-2019
Test Site	RL	RL	RL	RL
Kit Part Code	NA	NA	NA	NA
Kit Lot No.	NA	NA	NA	NA
Kit Exp. Date	NA	NA	NA	NA

[1]Positive/reactive results are noted in bold red.
[2]Results are reported individually from duplicate testing.
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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 info@seracare.com or by phone at 508.244.6400.