AccuSet™ Autoimmune Performance Panel

0840-0001 / Batch # 10312059

OVERVIEW

AccuSet™ Autoimmune Performance Panel (0840-0001) is a 20-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 or negative for analytes known to cause autoimmune related diseases. Each sample represents a single collection event. No preservatives were added.

Test results from commercially-available autoimmune assays are included for characterization of the panel members. This panel of human plasma samples demonstrates a range of reactivity for analytes that indicate autoimmune disease. This panel can also be used to evaluate analyte-dependent immunoassay interferences. One sample is included as a non-reactive sample and is negative for RF, HAMA, CCP, and ANA.

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.

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

AccuSet™ Autoimmune Performance Panel

	Connective Tissue Disease Cascade														
				Cascade 1	Cascade 2					Cascade 3				Cascade 4	
Member	RF	HAMA	CCP	ANA	dsDNA	SM/RNP	SM	RNP	Chromatin	SSA	SSB	Scl-70	Jo-1	Ribo P	Centromere B
01	+	•	+	•											
02	•	+	•	•											
03	+	•	+	•											
04	•	+	•	•											
05	+	•	+	+	•	•	•	•	•	•	•	•	•	•	•
06	+	•	+	•											
07	+	•	+	•											
08	+	+	+	+	•	•	•	•	•	•	•	•	•	•	•
09	+	•	•	•											
10	+	•	+	+	•	•	•	•	•	•	•	•	•	•	•
11	•	•	•	+	•	•	•	•	•	•	•	•	+		
12	•	•	•	+	+	+	+	+	+						
13	+	•	•	+	•	•	•	•	•	•	•	•	•	•	•
14	•	•	•	+	•	+	•	+	+						
15	•	•	•	+	•	•	•	•	•	+	•	•	•		
16	•	•	•	+	+ / •	•	•	•	•	+	•	•	•		
17	+	•	•	+	+	•	•	+	+						
18	•	•	•	+	+	+	+	+	+						
19	•	•	•	+	•	•	•	•	+						
20	•	•	•	•											

This table demonstrates reactivity of panel members for various analytes related to autoimmune infections. Panel members were characterized via a connective tissue disease cascade performed at a regional reference laboratory. Positive members are denoted by a red plus symbol, negative members are denoted by a black circle, and indeterminate results are denoted with the red plus symbol and black circle.

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Panel Member Information

Panel Member	SeraCare Batch #	SeraCare Donor ID #	Bleed Date	Clinical Diagnosis	Medication / Dosage (if available)
01	9233353	BD106446	13-Aug-2008	NA	NA
02	10293194	BD340563	15-May-2015	NA	NA
03	9233346	BD106446	30-Jul-2008	NA	NA
04	10302615	BD343241	02-Oct-2013	NA	NA
05	10070840	BD111317	03-Aug-2014	NA	NA
06	10265755	BD307192	04-Apr-2017	NA	NA
07	10048509	BD111344	10-Mar-2014	NA	NA
08	10290938	BD339195	13-Jul-2017	Rheumatoid Arthritis	ENBREL: 50mg LEVOTHYROXINE: 250mg PREDNISONE: 5mg
09	10290939	BD306913	17-Aug-2017	NA	METOPROLOL: 25mg XARELTO: 20mg LOSARTAN: 50mg SYNTHROID: 25mcg METFORMIN: 500mg IRON: 325mg LASIX: 20mg ASPIRIN: 81mg
10	10290941	BD339196	17-Aug-2017	Rheumatoid Arthritis	ENBREL: 50mg MOBIC: 15mg
11	9219810	BD105145	02-Nov-2007	NA	NA
12	9256959	BD111160	26-Feb-2012	NA	NA
13	9256965	BD111215	29-Jan-2012	NA	NA
14	9260851	BD111380	12-Aug-2012	NA	NA
15	9238521	BD107385	10-Feb-2009	NA	NA
16	10295097	BD340651	25-Apr-2013	Lupus	PREDNISONE LYRICA
17	10295098	BD340652	04-Oct-2013	Lupus	BENLYSTA IRON XANAX OXYCODONE
18	10295099	BD340653	16-May-2017	Lupus	COUMADIN ASPIRIN VITAMIN C PLAQUENIL
19	10295100	BD340654	24-Aug-2017	Lupus	PREDNISONE METOPROLOL LYRICA
20	10116615	BD244037	29-Sep-2014	NA	NA

NA = Not Available

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RF, HAMA, CCP

Panel Member	Beckman Coulter IMMAGE® Rheumatoid Factor (RF) (IU/mL)[1]	Zeus Scientific HAMA IgG ELISA (ng/mL)[2]	Inova Diagnostics CCP IgG ELISA (Units)[3]
01	**POS; 384.0**	NEG; 3.2	**POS; >250**
02	NEG; 0.0	**POS; 387.4**	NEG; <16
03	**POS; 486.0**	NEG; 12.7	**POS; >250**
04	NEG; 0.0	**POS; 297.2**	NEG; <16
05	**POS; 2505.0**	NEG; 69.8	**POS; >250**
06	**POS; 1930.0**	NEG; 9.1	**POS; >250**
07	**POS; 3375.0**	NEG; 2.1	**POS; >250**
08	**POS; 1995.0**	**POS; 82.3**	**POS; >250**
09	**POS; 671.0**	NEG; 0.0	NEG; <16
10	**POS; 1570.0**	NEG; 0.0	**POS; >250**
11	NEG; 0.0	NEG; 0.0	NEG; <16
12	NEG; 0.0	NEG; 0.0	NEG; <16
13	**POS; 428.5**	NEG; 0.0	NEG; <16
14	NEG; 0.0	NEG; 0.0	NEG; <16
15	NEG; 0.0	NEG; 0.0	NEG; <16
16	NEG; 0.0	NEG; 0.0	NEG; <16
17	**POS; 21.5**	NEG; 0.0	NEG; <16
18	NEG; 0.0	NEG; 0.0	NEG; <16
19	NEG; 0.0	NEG; 0.0	NEG; <16
20	NEG; 0.0	NEG; 0.0	NEG; <16
Test Date	25-Jan-2018	16-Jan-2018	17-Jan-2018
Test Site	RL	SC	RL
Kit Part Code	NA	6401	NA
Kit Lot No.	NA	17100021	NA
Kit Exp. Date	NA	31-July-2018	NA
Kit Regulatory Status	IVD/CE	IVD/CE	IVD/CE

[1]Test results are means of duplicates expressed as international units per milliliter (IU/mL). Positive results are noted in bold red.
[2]Test results are means of duplicates expressed as nanogram per milliliter (ng/mL). Positive results are noted in bold red.
[3]Test results are means of duplicates expressed in Units. Positive results are noted in bold red.
POS = Positive; NEG = Negative
RL = Reference Lab; SC = SeraCare; NA = Not Available
IVD = In-vitro diagnostic; CE = Conformité Européenne or CE Marking

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ANA (Connective Tissue Disease - Cascade 1)[1]

Panel Member	Bio-Rad BioPlex 2200 ANA (IFA)	Bio-Rad BioPlex 2200 ANA Pattern
01	NEG	NEG
02	NEG	NEG
03	NEG	NEG
04	NEG	NEG
05	**POS; 1:40**	**Homogeneous**
06	NEG	NEG
07	NEG	NEG
08	**POS; 1:40**	**Homogeneous**
09	NEG	NEG
10	**POS; 1:40**	**Homogeneous**
11	**POS; 1:160**	**Centromere**
12	**POS; 1:320**	**Homogeneous**
13	**POS; ≥ 1:1280**	**Nucleolar**
14	**POS; 1:320**	**Speckled**
15	**POS; 1:160**	**Speckled**
16	**POS; 1:320**	**Homogeneous**
17	**POS; 1:1280**	**Homogeneous**
18	**POS; 1:80**	**Homogeneous**
19	**POS; 1:1280**	**Homogeneous**
20	NEG	NEG
Test Date	16-Jan-2018	
Test Site	RL	
Kit Part Code	NA	
Kit Lot No.	NA	
Kit Exp. Date	NA	
Kit Regulatory Status	IVD	

[1]Test results are reported as a single run expressed as reactivity to immunofluorescent assay (IFA). Positive results are noted in bold red.
POS = Positive; NEG = Negative
RL = Reference Lab; NA = Not Available
IVD = In-vitro diagnostic

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dsDNA, SM/RNP, SM, RNP, Chromatin (Connective Tissue Disease - Cascade 2)[1]

Panel Member	Bio-Rad BioPlex 2200 dsDNA (AI)	Bio-Rad BioPlex 2200 SM/RNP (AI)	Bio-Rad BioPlex 2200 SM (AI)	Bio-Rad BioPlex 2200 RNP (AI)	Bio-Rad BioPlex 2200 Chromatin (AI)
01	NT	NT	NT	NT	NT
02	NT	NT	NT	NT	NT
03	NT	NT	NT	NT	NT
04	NT	NT	NT	NT	NT
05	NEG; 1.0	NEG; <1.0	NEG; <1.0	NEG; <1.0	NEG; <1.0
06	NT	NT	NT	NT	NT
07	NT	NT	NT	NT	NT
08	NEG; <1.0	NEG; <1.0	NEG; <1.0	NEG; <1.0	NEG; <1.0
09	NT	NT	NT	NT	NT
10	NEG; 1.0	NEG; <1.0	NEG; <1.0	NEG; <1.0	NEG; <1.0
11	NEG; <1.0	NEG; <1.0	NEG; <1.0	NEG; <1.0	NEG; <1.0
12	**POS; 43**	**POS; 2.3**	**POS; 2.7**	**POS; 5.7**	**POS; 3.6**
13	NEG; <1.0	NEG; <1.0	NEG; <1.0	NEG; <1.0	NEG; <1.0
14	NEG; <1.0	**POS; >8.0**	NEG; <1.0	**POS; >8.0**	**POS; 5.0**
15	NEG; <1.0	NEG; <1.0	NEG; <1.0	NEG; <1.0	NEG; <1.0
16	IND; 6	NEG; <1.0	NEG; <1.0	NEG; <1.0	NEG; <1.0
17	**POS; 99**	NEG; <1.0	NEG; <1.0	**POS; 1.0**	**POS; >8.0**
18	**POS; 46**	**POS; >8.0**	**POS; 3.0**	**POS; 6.2**	**POS; 7.6**
19	NEG; 3	NEG; <1.0	NEG; <1.0	NEG; <1.0	**POS; >8.0**
20	NT	NT	NT	NT	NT
Test Date	17-Jan-2018	17-Jan-2018	17-Jan-2018	17-Jan-2018	17-Jan-2018
Test Site	RL	RL	RL	RL	RL
Kit Part Code	NA	NA	NA	NA	NA
Kit Lot No.	NA	NA	NA	NA	NA
Kit Exp. Date	NA	NA	NA	NA	NA
Kit Regulatory Status	IVD	IVD	IVD	IVD	IVD

[1]Test results are reported as a single run expressed as antibody index units (AI). Positive results are noted in bold red.
NT = Not Tested; POS = Positive; NEG = Negative; IND = Indeterminate
RL = Reference Lab; NA = Not Available
IVD = In-vitro diagnostic

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SSA, SSB, Scl-70, Jo-1 (Connective Tissue Disease - Cascade 3)[1]

Panel Member	Bio-Rad BioPlex 2200 SSA (AI)	Bio-Rad BioPlex 2200 SSB (AI)	Bio-Rad BioPlex 2200 Scl-70 (AI)	Bio-Rad BioPlex 2200 Jo-1 (AI)
01	NT	NT	NT	NT
02	NT	NT	NT	NT
03	NT	NT	NT	NT
04	NT	NT	NT	NT
05	NEG; <1.0	NEG; <1.0	NEG; <1.0	NEG; <1.0
06	NT	NT	NT	NT
07	NT	NT	NT	NT
08	NEG; <1.0	NEG; <1.0	NEG; <1.0	NEG; <1.0
09	NT	NT	NT	NT
10	NEG; <1.0	NEG; <1.0	NEG; <1.0	NEG; <1.0
11	NEG; <1.0	NEG; <1.0	NEG; <1.0	**POS; 3.8**
12	NT	NT	NT	NT
13	NEG; <1.0	NEG; <1.0	NEG; <1.0	NEG; <1.0
14	NT	NT	NT	NT
15	**POS; >8.0**	NEG; <1.0	NEG; <1.0	NEG; <1.0
16	**POS; >8.0**	NEG; <1.0	NEG; <1.0	NEG; <1.0
17	NT	NT	NT	NT
18	NT	NT	NT	NT
19	NT	NT	NT	NT
20	NT	NT	NT	NT
Test Date	17-Jan-2018	17-Jan-2018	17-Jan-2018	17-Jan-2018
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
Kit Regulatory Status	IVD	IVD	IVD	IVD

[1]Test results are reported as a single run expressed as antibody index units (AI). Positive results are noted in bold red.
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Ribosomal P, Centromere B (Connective Tissue Disease - Cascade 4)[1]

Panel Member	Bio-Rad BioPlex 2200 Ribosomal P (AI)	Bio-Rad BioPlex 2200 Centromere B (AI)
01	NT	NT
02	NT	NT
03	NT	NT
04	NT	NT
05	NEG; <1.0	NEG; <1.0
06	NT	NT
07	NT	NT
08	NEG; <1.0	NEG; <1.0
09	NT	NT
10	NEG; <1.0	NEG; <1.0
11	NT	NT
12	NT	NT
13	NEG; <1.0	NEG; <1.0
14	NT	NT
15	NT	NT
16	NT	NT
17	NT	NT
18	NT	NT
19	NT	NT
20	NT	NT
Test Date	17-Jan-2018	17-Jan-2018
Test Site	RL	RL
Kit Part Code	NA	NA
Kit Lot No.	NA	NA
Kit Exp. Date	NA	NA
Kit Regulatory Status	IVD	IVD

[1]Test results are reported as a single run expressed as antibody index units (AI). Positive results are noted in bold red.
NT = Not Tested; NEG = Negative
RL = Reference Lab; NA = Not Available
IVD = In-vitro diagnostic

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.