Safety Assessment

according to Regulation (EC) No. 1907/2006 (REACH)

for the products listed in the product list (page 2 ff.)

General Intended Use

Test sera for the detection of blood group antigens using the techniques described in the package insert. For IN-VITRO DIAGNOSTIC use only by qualified and trained personnel.

Exceptions:

Product name	Ref.	Justification
Control solution for monoclonal reagents	05.147-10 05.147-10.V 05.147-10.X 05.147-1K	see intended purpose in the package insert
AHG serum blend	03.140-10 03.140-10.X	see intended purpose in the package insert

Technical Information Contact

Mon-Thu: 7:30-16:15
Fri: 7:30-15:00

Phone +49(0) 6223 / 8661 0
Fax +49(0) 6223 / 8661 13
E-Mail qara@antitoxin-gmbh.de

Classification of the Mixtures

The products have been evaluated in accordance with Regulation (EC) No. 1272/2008 and classified as non-hazardous. Please observe the warnings and precautions in the instructions for use.

Preparation of a Safety Data Sheet in accordance with Article 31 of Regulation (EC) No. 1907/2006 (REACH)

A safety data sheet is not required for these products, as they are neither classified as hazardous nor contain hazardous components or substances with Community (EC) occupational exposure limits or substances of very high concern (SVHC) above their respective legal thresholds. Consequently, in accordance with Regulation (EC) No. 1907/2006 (REACH), a safety data sheet is not necessary and is not available in this case.

Product list

Product name	Ref.	size
Anti-A monoclonal, IgM clone: Birma-1	01.001-10	10ml
	01.001-10.V	5 x 10ml
	01.001-10.X	10 x 10ml
Anti-B monoclonal, IgM clone: LB-2	01.003-10	10ml
	01.003-10.V	5 x 10ml
	01.003-10.X	10 x 10ml
Anti-AB monoclonal, IgM clones: ES-15, ES-4	01.005-10	10ml
	01.005-10.V	5 x 10ml
	01.005-10.X	10 x 10ml
Anti-H monoclonal, mouse clone: 10934C11	01.009-02	2ml
	01.009-03	3ml
	01.009-05	5ml
Anti-D monoclonal, human IgM clone: RUM-1	01.011-10	10ml
	01.011-10.V	5 x 10ml
	01.011-10.X	10 x 10ml
Anti-C monoclonal, human IgM clones: MS-24, P3X25513G8	01.018-05	5ml
	01.018-05.V	5 x 5ml
	01.018-05.X	10 x 5ml
	01.018-10	10ml
	01.018-10.V	5 x 10ml
	01.018-10.X	10 x 10ml
Anti-C monoclonal, human IgM clone: MS-273	01.021-05	5ml
	01.021-05.V	5 x 5ml
	01.021-05.X	10 x 5ml
	01.021-10	10ml
	01.021-10.V	5 x 10ml
	01.021-10.X	10 x 10ml
Anti-Cw monoclonal, human IgM clone: MS-110	01.022-02	2ml
	01.022-03	3ml
	01.022-05	5ml
Anti-c monoclonal, human IgM clone: MS-33	01.025-05	5ml
	01.025-05.V	5 x 5ml
	01.025-05.X	10 x 5ml
	01.025-10	10ml
	01.025-10.V	5 x 10ml
	01.025-10.X	10 x 10ml
Anti-c monoclonal, human IgM clone: MS-35	01.028-05	5ml
	01.028-05.V	5 x 5ml
	01.028-05.X	10 x 5ml
	01.028-10	10ml
	01.028-10.V	5 x 10ml
	01.028-10.X	10 x 10ml
Anti-E monoclonal, human IgM clones: MS-258, 906	01.029-05	5ml
	01.029-05.V	5 x 5ml
	01.029-05.X	10 x 5ml
	01.029-10	10ml
	01.029-10.V	5 x 10ml
	01.029-10.X	10 x 10ml
Anti-E monoclonal, human IgM clones: MS-12, MS-260	01.032-05	5ml
	01.032-05.V	5 x 5ml
	01.032-05.X	10 x 5ml
	01.032-10	10ml
	01.032-10.V	5 x 10ml
	01.032-10.X	10 x 10ml
Anti-e monoclonal, human IgM clones: MS-16, MS-21, MS-63	01.033-05	5ml
	01.033-05.V	5 x 5ml
	01.033-05.X	10 x 5ml
	01.033-10	10ml
	01.033-10.V	5 x 10ml
	01.033-10.X	10 x 10ml
Anti-e monoclonal, human IgM clones: MS-62, MS-69	01.036-05	5ml
	01.036-05.V	5 x 5ml
	01.036-05.X	10 x 5ml
	01.036-10	10ml
	01.036-10.V	5 x 10ml
	01.036-10.X	10 x 10ml
Anti-N monoclonal, mouse clones: 20H12, MN879	01.040-02	2ml
	01.040-05	5ml
Anti-K (KEL1) monoclonal, human IgM clone: MS-56	01.047-05	5ml
	01.047-05.V	5 x 5ml
	01.047-05.X	10 x 5ml
	01.047-10	10ml
	01.047-10.V	5 x 10ml
	01.047-10.X	10 x 10ml
Anti-Leb monoclonal, human clone: P3F234MD4	01.049-02	2ml
	01.049-03	3ml
	01.049-05	5ml

Product name	Ref.	size
Anti-Jka monoclonal, human IgM clone: MS-15	01.059-02	2ml
	01.059-05	5ml
Anti-Jkb monoclonal, human IgM clone: MS-8	01.060-02	2ml
	01.060-05	5ml
Anti-Lea monoclonal, mouse clone: LEA2	01.070-02	2ml
	01.070-03	3ml
	01.070-05	5ml
Anti-Leb monoclonal, mouse clone: LEB2	01.073-02	2ml
	01.073-03	3ml
	01.073-05	5ml
Anti-M monoclonal, mouse clone: LM110/140	01.088-02	2ml
	01.088-05	5ml
Anti-Lea monoclonal, mouse clone: GA2	01.089-02	2ml
	01.089-03	3ml
	01.089-05	5ml
Anti-P1 monoclonal, mouse clone: 650	01.118-02	2ml
	01.118-03	3ml
	01.118-05	5ml
Anti-S monoclonal, human IgM clone: MS-94	01.124-02	2ml
	01.124-05	5ml
Anti-s monoclonal, human IgM clone: P3BER	01.130-02	2ml
	01.130-05	5ml
Anti-D blend, monoclonal, human IgG +IgM clone: MS-26, TH-28	01.141-10	10ml
	01.141-10.V	5 x 10ml
	01.141-10.X	10 x 10ml
Anti-D monoclonal, human IgM clone: P3x61	01.167-10	10ml
	01.167-10.V	5 x 10ml
	01.167-10.X	10 x 10ml
Anti-K (KEL1) monoclonal, human IgM clone: AEK-4	01.169-05	5ml
	01.169-05.V	5 x 5ml
	01.169-05.X	10 x 5ml
	01.169-10	10ml
	01.169-10.V	5 x 10ml
	01.169-10-X	10 x 10ml
Anti-Cw for card method, monoclonal, human IgM clone: MS-110	01.177-03	3ml
	01.177-05	5ml
Anti-M for card method, monoclonal, mouse clone: LM110/140	01.179-05	5ml
Anti-N for card method, monoclonal, mouse clones: 20H12, MN879	01.180-03	3ml
	01.180-05	5ml
Anti-H for card method, monoclonal, mouse clone: 10934C11	01.198-03	3ml
	01.198-05	5ml
Anti-s for card method, monoclonal, human IgM clone: P3BER	01.199-03	3ml
	01.199-05	5ml
Anti-Lea for card method, monoclonal, mouse clone: GA2	01.200-05	5ml
Anti-Leb for card method, monoclonal, mouse clone: LEB1	01.210-05	5ml
Anti-Jka for card method, monoclonal, human IgM clone: MS-15	01.212-03	3ml
	01.212-05	5ml
Anti-Jkb for card method, monoclonal, human IgM clone: MS-8	01.213-03	3ml
	01.213-05	5ml
Anti-S for card method, monoclonal, human IgM clone: MS-94	01.216-03	3ml
	01.216-05	5ml
Anti-CDE monoclonal, human IgM + IgG clones: MS-24, MS-201, MS-80, MS-26	01.219-10	10ml
Anti-Cellano for card method, monoclonal, human IgG clone: P3A1180L67	01.233-03	3ml
	01.234-03	3ml
	01.236-03	3ml
Anti-M monoclonal, mouse clone: 11H2	01.240-02	2ml
	01.240-03	3ml
	01.240-05	5ml
Anti-Le(b) for card method, monoclonal, human clone: P3F234MD4	01.242-03	3ml
Anti-P1 for card method, monoclonal, human IgM clone: P3NIL100	01.243-03	3ml
Anti-Js(b) for card method, monoclonal, IgG clone: PRIM-1	01.244-02	2ml
Anti-Wr(a) monoclonal IgG	01.255-02	2ml
ABO-trol forte II	01.900-50 d-d-e	
	01.900-50-2	
ABO-trol forte plus	01.901-30 d-d-e	
	01.901-30-2	
Anti-S Coombs-reactive, polyclonal, human	02.041-02	2ml
	02.041-03	3ml
	02.041-05	5ml
	02.043-02	2ml
	02.043-03	3ml
	02.043-05	5ml
Anti-K (KEL1) Coombs-reactive, polyclonal, human	02.048-05	5ml
Anti-Cellano Coombs-reactive, polyclonal, human	02.050-02	2ml
	02.050-03	3ml
	02.050-05	5ml
Anti-Fya Coombs-reactive, polyclonal, human	02.053-02	2ml

ANTITOXIN GmbH | Industriestraße 88 | 69245 Bammental | Germany

T: +49(0) 6223 / 8661 0 | F +49(0) 6223 / 8661 13 | qara@antitoxin-gmbh.de | www.antitoxin.de

Product name	Ref.	size
	02.053-05	5ml
Anti-Fyb Coombs-reactive, polyclonal, human	02.054-02	2ml
	02.054-05	5ml
Anti-Jka Coombs-reactive, polyclonal, human	02.057-02	2ml
	02.057-05	5ml
Anti-Xga Coombs-reactive, polyclonal, human	02.063-02	2ml
	02.063-03	3ml
	02.063-05	5ml
Anti-Kpa Coombs-reactive, polyclonal, human	02.065-02	2ml
	02.065-03	3ml
	02.065-05	5ml
Anti-Kpb Coombs-reactive, polyclonal, human	02.066-02	2ml
	02.066-03	3ml
	02.066-05	5ml
Anti-Vw Coombs-reactive, polyclonal, human	02.146-02	2ml
	02.146-03	3ml
	02.146-05	5ml
Anti-Wra Coombs-reactive, polyclonal, human	02.164-02	2ml
	02.164-03	3ml
	02.164-05	5ml
Anti-Cellano for card method, Coombs-reactive, polyclonal, human	02.178-03	3ml
	02.178-05	5ml
Anti-Fya for card method, Coombs-reactive, polyclonal, human	02.182-03	3ml
	02.182-05	5ml
Anti-Fyb for card method, Coombs-reactive, polyclonal, human	02.183-03	3ml
	02.183-05	5ml
Anti-Jka for card method, Coombs-reactive, polyclonal, human	02.184-02	2ml
	02.184-03	3ml
	02.184-05	5ml
Anti-S for card method, Coombs-reactive, polyclonal, human	02.188-03	3ml
	02.188-05	5ml
	02.189-03	3ml
	02.189-05	5ml
Anti-Lua for card method, Coombs-reactive, polyclonal, human	02.192-03	3ml
	02.192-05	5ml
Anti-Lub for card method, Coombs-reactive, polyclonal, human	02.193-03	3ml
	02.193-05	5ml
Anti-Kpa for card method, Coombs-reactive, polyclonal, human	02.194-02	2ml
	02.194-03	3ml
	02.194-05	5ml
Anti-Kpb for card method, Coombs-reactive, polyclonal, human	02.195-02	2ml
	02.195-03	3ml
	02.195-05	5ml
Anti-Cob for card method, Coombs-reactive, polyclonal, human	02.227-03	3ml
	02.227-05	5ml
Anti-Wra for card method, Coombs-reactive, polyclonal, human	02.228-03	3ml
	02.228-05	5ml
Anti-Dia for card method, Coombs-reactive, polyclonal, human	02.229-03	3ml
	02.229-05	5ml
Anti-Coa for card method, Coombs-reactive, polyclonal, human	02.230-03	3ml
	02.230-05	5ml
Anti-Cw for card method, Coombs-reactive, polyclonal, human	02.232-03	3ml
	02.232-05	5ml
Anti-Cw incomplete, polyclonal, human	02.251-02	2ml
	02.251-03	3ml
	02.251-05	5ml
AHG serum blend	03.140-10	10ml
	03.140-10.X	10 x 10ml
Anti-A1 Lectin (Dolichos biflorus)	04.007-02	2ml
	04.007-03	3ml
	04.007-05	5ml
	04.007-10	10ml
Anti-AHP Lectin (Helix pomatia)	04.008-02	2ml
	04.008-03	3ml
	04.008-05	5ml
Anti-H Lectin (Laburnum alpinum)	04.161-02	2ml
	04.161-03	3ml
	04.161-05	5ml
Anti-A1 for card method, Lectin (Dolichos biflorus)	04.235-03	3ml
Control solution for monoclonal reagents	05.147-10	10ml
	05.147-10.V	5 x 10ml
	05.147-10.X	10 x 10ml
	05.147-1K	1000ml
Medtrokarte NK-4	NK4	20 Stk.

ANTITOXIN GmbH | Industriestraße 88 | 69245 Bammental | Germany

T: +49(0) 6223 / 8661 0 | F +49(0) 6223 / 8661 13 | qara@antitoxin-gmbh.de | www.antitoxin.de