



IMMUNOLAB

Research & Development Department
Of Salmonella Center Ltd.

www.immunolab.com.pl

info@immunolab.com.pl

phone/fax: +48 58 781 44 91

ul. Kładki 24

80-822 Gdańsk

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DECLARATION OF CONFORMITY

Manufacturer: Research & Development Department of Salmonella Center Ltd.
IMMUNOLAB Sp. z o.o.

Product for *in vitro* diagnostic: **Sera for slide agglutination of *Salmonella*** –
list of versions in the attachment

Qualification: For *in vitro* diagnostic use, other than listed A and B and other than
product used for the working evaluation

We declare that product: sera for slide agglutination of *Salmonella* is agreed with the Act on Medical Devices of 20 May, 2010 and the Directive 98/79/EC of the European Parliament and of the Council on *in vitro* diagnostic medical devices and fulfilled the essential requirements defined in the Annex 1 to the Regulation of the Minister of Health on essential requirements and procedures for assessing the conformity of *in vitro* diagnostic medical devices. conformity assessment of medical devices.

Sera for slide agglutination of *Salmonella* have been marked with the sign:

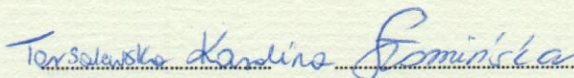


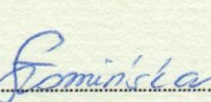
Technical documentation in accordance with Annex 3 to the above-mentioned Regulation is located at the manufacturer's headquarters and is available on request within 5 years of the end of production.

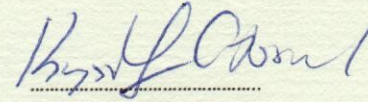
On the basis of this certificate, the products covered by it may be implemented into use and made available on the market - in accordance with Art. 110 of Regulation (EU) 2017/746 of the European Parliament and of the Council on *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU by 27 May 2025.

Gdańsk 30.08.2022r.

.....
(place, date)


.....
Coordinator of the Quality
Management System


.....
Production Manager


.....
Chairman of the Board



The attachment to the Declaration of Conformity:

List of sera for slide agglutination of *Salmonella* – versions for 1 ml, 3 ml, 5 ml:

Antiserum OA (factor 2) ready-to-use rabbit serum, preserved with thiomersal
Antiserum OB (factors 4,5) ready-to-use rabbit serum, preserved with thiomersal
Antiserum OC (factors 6,7,8,20) ready-to-use rabbit serum, preserved with thiomersal
Antiserum OD (factors 9,46) ready-to-use rabbit serum, preserved with thiomersal
Antiserum OE (factors 3,10,15) ready-to-use rabbit serum, preserved with thiomersal
Antiserum OE₄ (factors 1,3,19) ready-to-use rabbit serum, preserved with thiomersal
Antiserum O G (factors 13,22,23) ready-to-use rabbit serum, preserved with thiomersal
Antiserum O 2 (OA groups) ready-to-use rabbit serum, preserved with thiomersal
Antiserum O 3 (OE,OE₄ groups) ready-to-use rabbit serum, preserved with thiomersal
Antiserum O 3,10 ready-to-use rabbit serum, preserved with thiomersal
Antiserum O 4 ready-to-use rabbit serum, preserved with thiomersal
Antiserum O 6 ready-to-use rabbit serum, preserved with thiomersal
Antiserum O 6,7 ready-to-use rabbit serum, preserved with thiomersal
Antiserum O 7 ready-to-use rabbit serum, preserved with thiomersal
Antiserum O 8 ready-to-use rabbit serum, preserved with thiomersal
Antiserum O 8,20 ready-to-use rabbit serum, preserved with thiomersal
Antiserum O 9 ready-to-use rabbit serum, preserved with thiomersal
Antiserum O 10 ready-to-use rabbit serum, preserved with thiomersal
Antiserum O 11 ready-to-use rabbit serum, preserved with thiomersal
Antiserum O 12 ready-to-use rabbit serum, preserved with thiomersal



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Antiserum O 13 (OG group) ready-to-use rabbit serum, preserved with thiomersal
Antiserum O 13,22 ready-to-use rabbit serum, preserved with thiomersal
Antiserum O 13,23 ready-to-use rabbit serum, preserved with thiomersal
Antiserum O 14 (OH group) ready-to-use rabbit serum, preserved with thiomersal
Antiserum O 14,24 ready-to-use rabbit serum, preserved with thiomersal
Antiserum O 15 ready-to-use rabbit serum, preserved with thiomersal
Antiserum O 16 ready-to-use rabbit serum, preserved with thiomersal
Antiserum O 18 ready-to-use rabbit serum, preserved with thiomersal
Antiserum O 19 ready-to-use rabbit serum, preserved with thiomersal
Antiserum O 20 ready-to-use rabbit serum, preserved with thiomersal
Antiserum O 21 ready-to-use rabbit serum, preserved with thiomersal
Antiserum O 22 ready-to-use rabbit serum, preserved with thiomersal
Antiserum O 23 ready-to-use rabbit serum, preserved with thiomersal
Antiserum O 28 ready-to-use rabbit serum, preserved with thiomersal
Antiserum O 35 ready-to-use rabbit serum, preserved with thiomersal
Antiserum O 41 ready-to-use rabbit serum, preserved with thiomersal
Antiserum O 46 ready-to-use rabbit serum, preserved with thiomersal
Antiserum Vi ready-to-use rabbit serum, preserved with thiomersal
Polyvalent antiserum OMA (A, B, D₁, D₂, E₁, E₄ groups) ready-to-use rabbit serum, preserved with thiomersal
Polyvalent antiserum OMB (C₁, C₂, C₃, F, G, H groups) ready-to-use rabbit serum, preserved with thiomersal
Polyvalent antiserum OM ready-to-use rabbit serum, preserved with thiomersal
Polyvalent antiserum HM ready-to-use rabbit serum, preserved with thiomersal
Polyvalent antiserum HE (eh, enx, enz₁₅) ready-to-use rabbit serum, preserved with thiomersal
Polyvalent antiserum HG (fg, fgs, gm, gmq, gmt, gp, gpu, gt, gst, gq) ready-to-use rabbit serum, preserved with thiomersal

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Polyvalent antiserum HL (lv, lw, lz ₁₃ , lz ₂₈) ready-to-use rabbit serum, preserved with thiomersal
Polyvalent antiserum HZ₄ (Z ₄ Z ₂₃ , Z ₄ Z ₂₄) ready-to-use rabbit serum, preserved with thiomersal
Polyvalent antiserum H1 (factor 1,2,5,6,7) ready-to-use rabbit serum, preserved with thiomersal
Polyvalent antiserum Hq, s, t, p, u (factor 1,2,5,6,7) ready-to-use rabbit serum, preserved with thiomersal
Antiserum H a ready-to-use rabbit serum, preserved with thiomersal
Antiserum H b ready-to-use rabbit serum, preserved with thiomersal
Antiserum H c ready-to-use rabbit serum, preserved with thiomersal
Antiserum H d ready-to-use rabbit serum, preserved with thiomersal
Antiserum H i ready-to-use rabbit serum, preserved with thiomersal
Antiserum H i (stężona) ready-to-use rabbit serum, preserved with thiomersal
Antiserum H g ready-to-use rabbit serum, preserved with thiomersal
Antiserum H g,m ready-to-use rabbit serum, preserved with thiomersal
Antiserum H g,p ready-to-use rabbit serum, preserved with thiomersal
Antiserum H f,g ready-to-use rabbit serum, preserved with thiomersal
Antiserum H m ready-to-use rabbit serum, preserved with thiomersal
Antiserum H p ready-to-use rabbit serum, preserved with thiomersal
Antiserum H f ready-to-use rabbit serum, preserved with thiomersal
Antiserum H q ready-to-use rabbit serum, preserved with thiomersal
Antiserum H s ready-to-use rabbit serum, preserved with thiomersal
Antiserum H t ready-to-use rabbit serum, preserved with thiomersal
Antiserum H u ready-to-use rabbit serum, preserved with thiomersal
Antiserum H e,h ready-to-use rabbit serum, preserved with thiomersal
Antiserum H h ready-to-use rabbit serum, preserved with thiomersal
Antiserum H e,n,x ready-to-use rabbit serum, preserved with thiomersal

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Antiserum H n ready-to-use rabbit serum, preserved with thiomersal
Antiserum H x ready-to-use rabbit serum, preserved with thiomersal
Antiserum H k ready-to-use rabbit serum, preserved with thiomersal
Antiserum H l,v ready-to-use rabbit serum, preserved with thiomersal
Antiserum H v ready-to-use rabbit serum, preserved with thiomersal
Antiserum H l,w ready-to-use rabbit serum, preserved with thiomersal
Antiserum H w ready-to-use rabbit serum, preserved with thiomersal
Antiserum H r ready-to-use rabbit serum, preserved with thiomersal
Antiserum H r (concentrated) ready-to-use rabbit serum, preserved with thiomersal
Antiserum H y ready-to-use rabbit serum, preserved with thiomersal
Antiserum H 1,2,5 ready-to-use rabbit serum, preserved with thiomersal
Antiserum H 2 ready-to-use rabbit serum, preserved with thiomersal
Antiserum H 2 (concentrated) ready-to-use rabbit serum, preserved with thiomersal
Antiserum H 5 ready-to-use rabbit serum, preserved with thiomersal
Antiserum H 6 ready-to-use rabbit serum, preserved with thiomersal
Antiserum H 7 ready-to-use rabbit serum, preserved with thiomersal
Antiserum H z ready-to-use rabbit serum, preserved with thiomersal
Antiserum H z 6 ready-to-use rabbit serum, preserved with thiomersal
Antiserum H z 10 ready-to-use rabbit serum, preserved with thiomersal
Antiserum H z 13 ready-to-use rabbit serum, preserved with thiomersal
Antiserum H n,z 15 ready-to-use rabbit serum, preserved with thiomersal
Antiserum H z4 z23 ready-to-use rabbit serum, preserved with thiomersal
Antiserum H z 23 ready-to-use rabbit serum, preserved with thiomersal

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Antiserum anty H z 24 ready-to-use rabbit serum, preserved with thiomersal
Antiserum H z 28 ready-to-use rabbit serum, preserved with thiomersal
Antiserum H z 29 ready-to-use rabbit serum, preserved with thiomersal
Antiserum H z 35 ready-to-use rabbit serum, preserved with thiomersal
Antiserum H z 36 ready-to-use rabbit serum, preserved with thiomersal
Antiserum H z 38 ready-to-use rabbit serum, preserved with thiomersal
Antiserum H z 39 ready-to-use rabbit serum, preserved with thiomersal
Antiserum H z 42 ready-to-use rabbit serum, preserved with thiomersal
Antiserum H z 53 ready-to-use rabbit serum, preserved with thiomersal
Antiserum H z 57 ready-to-use rabbit serum, preserved with thiomersal