



# IMMUNOLAB

Research & Development Department  
Of Salmonella Center Ltd.

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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:

CE

Dokumentacja techniczna zgodna z Załącznikiem nr 3 do w/w Rozporządzenia znajduje się w siedzibie wytwórcy i jest dostępna na życzenie w ciągu 5 lat od zakończenia produkcji.

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.

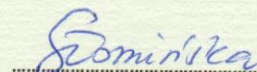
On the basis of this certificate, the products covered by it may be implemented into use and made available on the market - in accordance with Art. 110 of Regulation (EU) 2017/746 of the European Parliament and of the Council on *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and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

Gdańsk 25.05.2022r.


.....  
(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:

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



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<b>Antiserum O 13 (OG group)</b> ready-to-use rabbit serum, preserved with thiomersal
<b>Antiserum O 13,22</b> ready-to-use rabbit serum, preserved with thiomersal
<b>Antiserum O 13,23</b> ready-to-use rabbit serum, preserved with thiomersal
<b>Antiserum O 14 (OH group)</b> ready-to-use rabbit serum, preserved with thiomersal
<b>Antiserum O 14,24</b> ready-to-use rabbit serum, preserved with thiomersal
<b>Antiserum O 15</b> ready-to-use rabbit serum, preserved with thiomersal
<b>Antiserum O 16</b> ready-to-use rabbit serum, preserved with thiomersal
<b>Antiserum O 18</b> ready-to-use rabbit serum, preserved with thiomersal
<b>Antiserum O 19</b> ready-to-use rabbit serum, preserved with thiomersal
<b>Antiserum O 20</b> ready-to-use rabbit serum, preserved with thiomersal
<b>Antiserum O 21</b> ready-to-use rabbit serum, preserved with thiomersal
<b>Antiserum O 22</b> ready-to-use rabbit serum, preserved with thiomersal
<b>Antiserum O 23</b> ready-to-use rabbit serum, preserved with thiomersal
<b>Antiserum O 28</b> ready-to-use rabbit serum, preserved with thiomersal
<b>Antiserum O 35</b> ready-to-use rabbit serum, preserved with thiomersal
<b>Antiserum O 41</b> ready-to-use rabbit serum, preserved with thiomersal
<b>Antiserum O 46</b> ready-to-use rabbit serum, preserved with thiomersal
<b>Antiserum Vi</b> ready-to-use rabbit serum, preserved with thiomersal
<b>Polyvalent antiserum OMA (A, B, D<sub>1</sub>, D<sub>2</sub>, E<sub>1</sub>, E<sub>4</sub> groups)</b> ready-to-use rabbit serum, preserved with thiomersal
<b>Polyvalent antiserum OMB (C<sub>1</sub>, C<sub>2</sub>, C<sub>3</sub>, F, G, H groups)</b> ready-to-use rabbit serum, preserved with thiomersal
<b>Polyvalent antiserum OM</b> ready-to-use rabbit serum, preserved with thiomersal
<b>Polyvalent antiserum HM</b> ready-to-use rabbit serum, preserved with thiomersal
<b>Polyvalent antiserum HE (eh, enx, enz<sub>15</sub>)</b> ready-to-use rabbit serum, preserved with thiomersal
<b>Polyvalent antiserum HG (fg, fgs, gm, gmq, gmt, gp, gpu, gt, gst, gq)</b> ready-to-use rabbit serum, preserved with thiomersal

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

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

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