Neo Scientific Peer Reviewed Journal
Volume 11, June, 2023 ISSN (E): 2949-7752
www.neojournals.com

STAGES OF DEVELOPMENT OF THE INTERNATIONAL STANDARD SERUM AGAINST BRUCIOLLEZ AND STANDARD EXAMPLE OF THE INDUSTRY

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Abstract:

In different states, antigens are prepared differently and an aglutination reaction is recorded. Therefore, it was decided by the FAO/WHO committee of experts on brucellosis that the amount of Agglutinins in 1 ml of blood serum should be given in the international unit (IU/ml). Weybridge laboratory has twice prepared and fully used an international standard serum against brucellosis. For the agglutination reaction, a candidate was prepared for a standard sample of the field, which allows you to determine the activity and specificity of the diagnosis of brucellosis.

Keywords

brucellosis, hyperimmunization, standard serum, industry-specific standard sample, international unit.

Introduction

The FAO / WHO committee on brucellosis (1971) recommended that the results of the serum agglutination reaction (ar) in the test tube be expressed in international units (IU). For this purpose, Anti Brucella abortus standard serum (ISAbS) was prepared at Weybridge Central Laboratory. In the first international unit of brucellosis serum prepared in the Weybridge laboratory, it is necessary that 1 ml of serum contains a preservative dry substance equal to 0.091 mg.

Based on the assignment of the FAO/WHO Expert Committee on brucellosis, the serum prepared in this laboratory was adopted as the standard serum at the second meeting of the FAO/WHO Expert Committee on brucellosis in Florence in October 1952 (official report 1953) [10,11].

At the 1963 General Meeting of the FAO/WHO committee of experts on brucellosis, it was decided that the amount of Agglutinins in 1 ml of blood serum should be given in an international unit (IU/ml). Dry, standard, international first brucellosis serum contains 91 mg of dry matter in 1 ml. So, the international unit is 1000 times less than usual, without which dry whey contains the dry substance of the standard (first) whey of 0.091 mg.

Thus, the First Standard serum is 1000 international units; one tenth of the standard is equal to 100 IU, etc.

However, in different states, antigen is prepared differently and AR is recorded. Therefore, due to this system, it provides comparative results as a test, but of secondary importance, since AR is used not to compare the results, but for the diagnosis of brucellosis.

Therefore, a "unity system" was proposed globally (FAO/WHO) in 1957. At the base of this system lies the agglutination titer of antigen (of this state) with the international standard serum.

Examples of such criteria include the following.

For example, in any laboratory, the titre of standard serum with a local antigen is 1:500, in which they store 1000 IU when tested with this antigen under international criteria.

If the serum titer is 1:400 with local antigen, 1:500 with standard serum, then the serum titer under investigation is 1:800 according to international criteria, etc.k.

Here the following formula of calculation is used:

$$\frac{a*b}{c}$$ in this,

a-constant magnitude-1000 IU;

b-serum titer obtained with local antigen (in our example 1: 400);

c-is the titer of whey obtained with local antigen and standard serum (in our example 1:500).

In this case, the titer of the antigen in the agglutination reaction

$$\frac{(1000*400)}{500} = 800 \text{ IU.}$$

The result is positive if the serum agglutination titer is equal to 100 IU in 1 ml.

In 1965, the First Standard serum containing 91 mg of dry matter in 1 ml was prepared and fully used in 1000 ampoules at Weybridge laboratory.

Therefore, in 1968, the FAO/WHO committee of experts on biological standardization commissioned this laboratory to prepare a new (second) standard serum. 1 ml of whey contains an average of 95.52 mg of dry matter, while the international unit is a thousand times less, that is, 0.0955 mg of dry matter. All the calculations indicated for the First Standard serum were saved.

The new standard serum (the second international standard serum against brucellosis) was adopted as the second international standard after extensive discussion in various laboratories [4,7,8].

In the development of immunobiological drug preparations, including series of polyvalent brucellosis diagnostic serums designed to correctly assess the results, and the brucellosis diagnostics for the agglutination reaction (AR), it is important to use standard samples (SS) to ensure the same demand for their quality [2,3,6]. Currently, experimental series of non-state-registered serums are used for the diagnosis of brucellosis [1]. Therefore, it is relevant to conduct research on obtaining polyvalent, brusellosis diagnostic serum for the

agglutination reaction, developing laboratory methods for controlling its quality and determining its effectiveness.

In addition, at present, in the absence of stable provision of the national biopharmaceutical industry with international SS, it is necessary to have domestic pharmacopoeia SS and/or SS enterprises that allow assessing the quality of newly produced series of biotechnological drugs in terms of the diagnosis of brucellosis.

For the first time, the industry candidate for standard serum (CSS) 42-28- 6-83P of brucellosis polyvalent serum was manufactured in 1983 (GISK named after L.A. Tarasevich, NIIEM named after N.F. Gamalei and the Odessa Enterprise for the Production of bakpreparations) from the blood of cattle, hyperimmunized by inactivated heating at a temperature of 100^0C cultures of virulent strains of *Brucella abortus, B. melitensis and B. suis* in S-form.

The previous series of CSS 42-28-6-01P brucellosis serum was prepared and studied in 2001 at the L.A. Tarasevich GISK and N.F. Gamalei NIIEM. The specific activity of the CSS persisted for 10 years (the period of observation), which was confirmed by the data of the quality assessment of the production series of the brucellosis liquid diagnosticum for RA.

Due to the need to prepare a standard sample and confirm it as a national standard sample, blood serum was taken from rabbits hyperimmunized with cultures of the RSSPMCEMIPD in *Brucella abortus 19* strain and a candidate for CSS of a polyvalent diagnostic serum for brucellosis in ar was prepared.

In order to create a technology for the production of serums, conduct medical and technical tests for the purpose of state registration of the drug, 72 laboratory series and 8 pilot production series were prepared..

The specific activity of the serum prescribed for CSS was evaluated in the reaction of agglutination with strains of brucellosis pathogens. The specificity of the serum was studied on strains of heterologous microorganisms and reference strains of brucellosis pathogens. The "four plus" system was used to record the results.

The positive result of the agglutination reaction with strains of various types of brucella in the form of serum titers was at least 3+ (coarse-grained agglutination, complete clarification of the liquid over the sediment or slight turbidity of the liquid), the highest dilution was taken. Candidates for CSS descriptions of polyvalent serum for the diagnosis of brucellosis were studied (Table).

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Candidate for the industry-specific standard sample-descriptions of polyvalent brucellosis diagnostic serum

Whey the number of	Common protein			albumin			globulin			IgA			IgM			IgG			Rait reaction	
	A	B	V	A	B	V	A	B	V	A	B	V	A	B	V	A	B	V	A	B
2.1	52,8	90,5	37,7	29,4	41,0	11,6	23,4	49,5	26,1	0,24	0,30	0,06	0,31	1,14	0,83	2,27	4,16	1,89	-	1:1600 ++++
2.2	69,4	104.3	34,9	35,7	49,2	13,5	33,7	55,1	21,4	0,25	0,20	-0,05	0,31	1,05	0,74	2,13	4,20	2,07	-	1:1600 ++
2.3	52,8	102,3	49,5	29,4	51,9	22,5	23,4	50,4	27	0,24	0,33	0,09	0,31	1,16	0,85	2,27	4,28	2,01	-	1:3200 ++
2.5	67,7	89,0	21,3	38,5	39,4	0,9	28,3	49,6	21,3	0,23	0,29	0,06	0,35	1,11	0,76	2,05	4,81	2,76	-	1:1600 +++
2.6	46,9	44,0	-2,9	26,4	24,2	-2,2	20,5	19,8	-0,7	0,24	0,28	0,04	0,39	1,09	0,7	1,97	4,89	2,92	-	1:1600 +++
3.3	52,8	161,4	108,6	29,4	70,7	41,3	23,4	90,7	67,3	0,24	0,18	-0,06	0,31	0,94	0,63	2,27	4,85	2,58	-	1:3200 ++++
3.4	63,9	140,8	76,9	39,1	67,4	28,3	24,8	73,4	48,6	0,24	0,21	-0,03	0,36	0,92	0,56	2,61	4,83	2,22	-	1:1600 +
3.5	67,7	148,2	80,5	38,5	74,0	35,5	28,3	74,2	45,9	0,23	0,29	0,06	0,35	0,68	0,33	2,05	5,56	3,51	-	1:1600 ++++
Candidate for standard sample	80,5			42,6			37,9 (A/Γ=1,12)			melted									1:1600 ++++	
										0,089			0,116			0,275				
										undissolved										
										1,80			2,31			4,67				

Note: A - pre - vaccination indicators; B-post-vaccination indicators; V-difference between pre-and post-vaccination indicators.

Conclusion

As a result of the preparation of a standard sample of the industry in order to control the detection of Brussels infection by serological method in our republic:

allows you to determine the activity and specificity of polyvalent brucellosis serum production series for agglutination reaction and brucellosis diagnostics for agglutination reaction;

it will be easier to assess the results obtained by serological method in the diagnosis of brucellosis disease;

it will be possible to compare the results obtained by various researchers on the Serological examination of brucellosis;

in the bacteriological diagnosis of brucellosis, it is used in the identification of the isolated culture of Brucella in the window of the object and in the extended agglutination reaction in the test tubes.

it is used in the correct diagnosis of brucellosis, identification of brusella strains, epidemiological monitoring of brucellosis.

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