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Certificate 2024
Inter-laboratory comparison

Spec. IgG in-vitro diagnostics with **RIDASCREEN® Spec. IgG Foodscreen**
carried out by R-Biopharm AG

This is to certify that:

Instytut Mikroekologii
ul. Sieska 10
60-129 Poznan
Poland

took part in the QC-assessment for food hypersensitivity in-vitro diagnostics
by using RIDASCREEN® Spec. IgG Foodscreen. In total 30 international laboratories participated.

This inter-laboratory comparison took place between **November 2024 – June 2025**.

We hereby certify, that

Instytut Mikroekologii

successfully participated in the **Inter-laboratory comparison 2024** using RIDASCREEN® Spec. IgG Foodscreen.

Dr. Andreas Schlereth
Deputy Vice President Nutrition Care

Nicole Schüller
Head of Allergy Diagnostics

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Inter-laboratory comparison 2024 - RIDASCREEN® Spec. IgG Foodscreen

1. Purpose

The test was performed to confirm assay reproducibility and to establish robustness in use.

2. Method

Each participant of the Inter-laboratory comparison (IC) received five serum samples as well as RIDASCREEN® Spec. IgG Fooodscreen plates (A8121-15) and reagents (A8020) for testing. The plates A8101, A8221-15, A8321-15, A8621-15, A8829-15 and A8921 are variations of the plate A8121-15 and thus these results are representative for all the products above. The participants have sent the raw data files to R-Biopharm for evaluation. All results were compared to the average result from all participants.

Your Lab, Instytut Mikroekologii, has the participant number #8.

3. Specifications

- All criteria stated in the IFU must be valid
- The control measurements must be within the expect range
- Overall qualitative agreement of the samples must be ≥ 70 %
- Reproducibility of the duplicated sample must be ≥ 75 %

4. Scores

A total of 100 points can be achieved. Only if the above criteria are fulfilled SCORE points will be noted for the criteria. 50% of the available SCORE points will be calculated based on the individual result relative to the average result from all participants. The following SCORES can be achieved:

Standards and control:	15
Overall agreement:	60 (12% per Serum)
Double detection:	25

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5. Overview

Lab.	control	comparability	reproducibility	SCORE
1	passed	5 of 5	passed	88,0
2	passed	5 of 5	passed	93,4
3	passed	5 of 5	passed	90,4
4	passed	5 of 5	passed	84,6
5	passed	5 of 5	passed	87,8
6	passed	5 of 5	passed	80,5
7	passed	4 of 5	not passed	54,4
8	passed	5 of 5	passed	93,3
9	passed	5 of 5	passed	91,7
10	passed	4 of 5	not passed	56,2
11	passed	5 of 5	passed	85,1
12	passed	3 of 5	passed	63,7
13	passed	5 of 5	passed	82,6
14	passed	4 of 5	not passed	57,3
15	passed	5 of 5	passed	86,3
16	not passed	5 of 5	passed	69,5
17	passed	5 of 5	passed	78,7
18	passed	5 of 5	passed	86,4
19	passed	5 of 5	passed	88,0
20	passed	4 of 5	passed	69,0
21	passed	5 of 5	passed	82,5
22	passed	2 of 5	passed	50,8
23	passed	5 of 5	passed	85,4
24	passed	5 of 5	passed	92,0
25	passed	5 of 5	not passed	64,4
26	not passed	4 of 5	not passed	37,6
27	passed	2 of 5	passed	51,8
28	passed	2 of 5	not passed	32,2
29	passed	2 of 5	passed	51,0

	from	till
poor	0	50
adequate	50	75
good	75	90
excelent	90	100

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6. Data

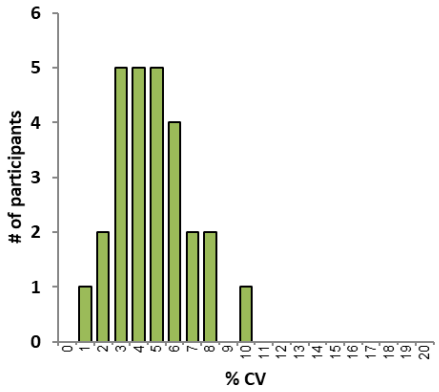

Figure 1 Distribution of the CV values for the control measurements.

The CV of the control measurements in your laboratory (#8) is: 2,6 %

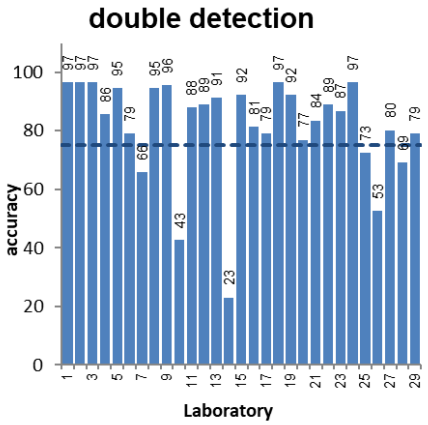

Figure 2 Repeatability of the double probe. The repeatability of the samples two and four (double probe) was determined. Blue bar, relative repeatability of the results obtained from two samples of the same serum within the same lab. blue line, min. value (75%) for the repeatability.

The repeatability of the double sample in your laboratory (#8) is: 94,5 %

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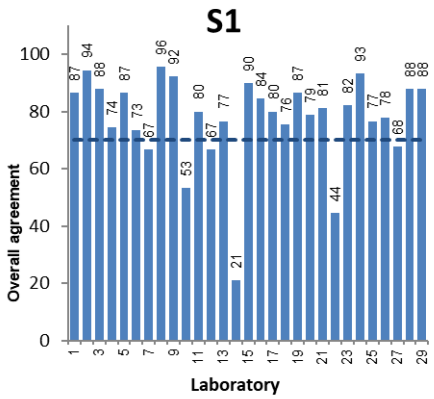
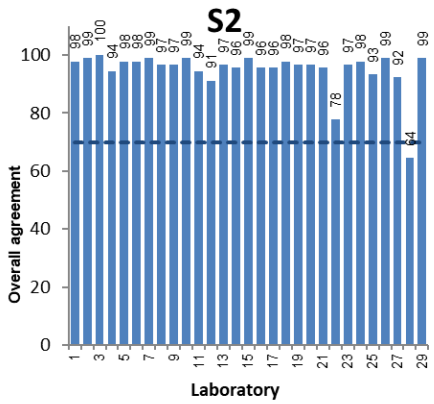
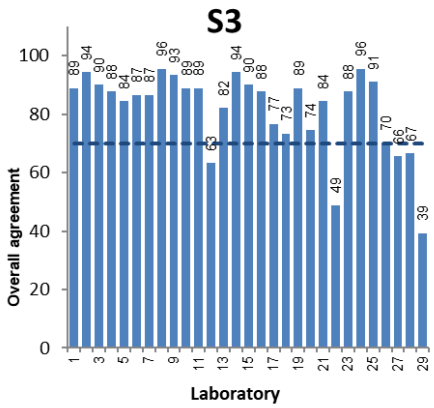


The overall agreement of sample no. 1 in your laboratory (#8) is: 95,6 %



The overall agreement of sample no. 2 in your laboratory (#8) is: 96,7 %



The overall agreement of sample no. 3 in your laboratory (#8) is: 95,6 %

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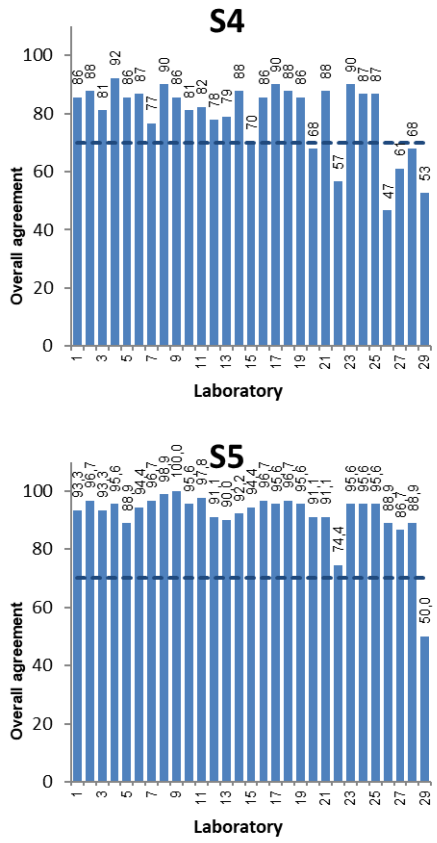

Figure 3 Overall agreement for the five samples. The overall agreement of each sample was calculated relative to the average results obtained from all participants. Blue bar, overall agreement; blue line, min. value (70%) for the agreement.

The overall agreement of sample no. 4 in your laboratory (#8) is: 90 %

The overall agreement of sample no. 5 in your laboratory (#8) is: 98,9 %

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