



# *Certificate 2023*

## *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 Mikrobiologii**  
**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 26 international laboratories participated.

This inter-laboratory comparison took place between **November 2023 – March 2024**.

We hereby certify, that

**Instytut Mikrobiologii**

**successfully participated in the Inter-laboratory comparison 2023**  
using RIDASCREEN® Spec. IgG Foodscreen.

Dr. Andreas Schlereth  
Deputy Vice President Nutrition Care

Nicole Schüller  
Head of Allergy Diagnostics



## Inter-laboratory comparison 2023 - 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 Foodscreen 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 Mikrobiologii, has the participant number #13.**

### 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  $\geq 80\%$
- Reproducibility of the duplicated sample must be  $\geq 85\%$

### 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:	70 (14% per Serum)
Double detection:	15



## Inter-laboratory comparison 2023 - RIDASCREEN® Spec. IgG Foodscreen

### 5. Overview

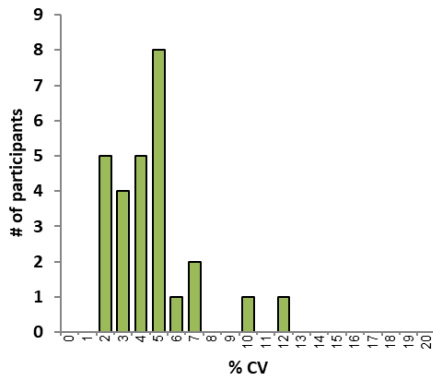
Lab.	control	comparability	reproducibility	SCORE
1	passed	5 of 5	passed	77.8
2	passed	3 of 5	not passed	47.0
3	passed	4 of 5	not passed	53.7
4	passed	4 of 5	passed	67.8
5	passed	5 of 5	passed	78.3
6	passed	5 of 5	passed	81.0
7	passed	5 of 5	passed	66.1
8	passed	4 of 5	passed	68.3
9	passed	4 of 5	passed	75.6
10	passed	5 of 5	passed	77.9
11	passed	5 of 5	passed	89.8
12	passed	5 of 5	not passed	54.0
13	passed	5 of 5	passed	90.2
14	passed	4 of 5	passed	72.2
15	passed	5 of 5	passed	72.4
16	passed	4 of 5	passed	64.2
17	passed	5 of 5	passed	82.3
18	passed	5 of 5	passed	87.5
19	passed	5 of 5	passed	79.9
20	passed	5 of 5	passed	79.4
21	passed	4 of 5	passed	57.3
22	passed	5 of 5	passed	83.4
23	passed	4 of 5	passed	73.6
24	passed	5 of 5	passed	84.7
25	passed	5 of 5	passed	69.1
26	passed	5 of 5	passed	85.9

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



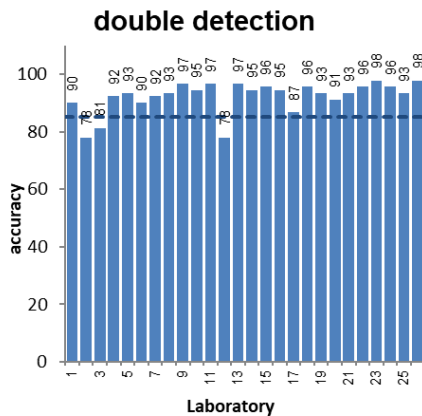
**Inter-laboratory comparison 2023 - RIDASCREEN® Spec. IgG Foodscreen**

**6. Data**



**The CV of the control measurements in your laboratory (#13) is: 1,8 %**

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

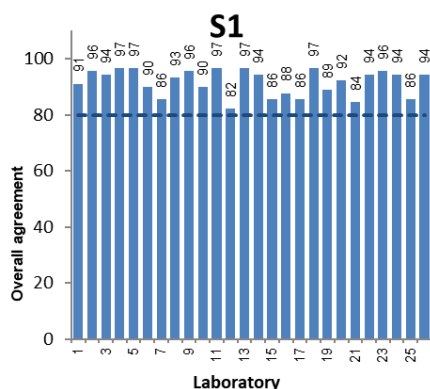


**The repeatability of the double sample in your laboratory (#13) is: 96,7 %**

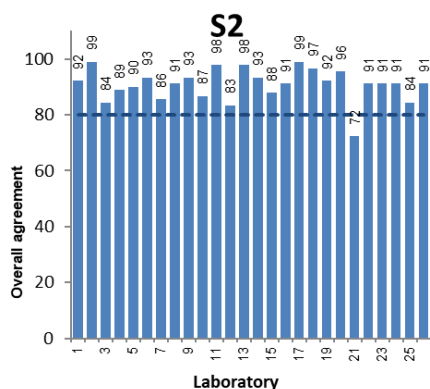
**Figure 2** Repeatability of the double probe. The repeatability of the samples two and four (double probe) was determined. Blue bar, relative repeatability of the results obtained from two samples of the same serum within the same lab. blue line, min. value (85%) for the repeatability.



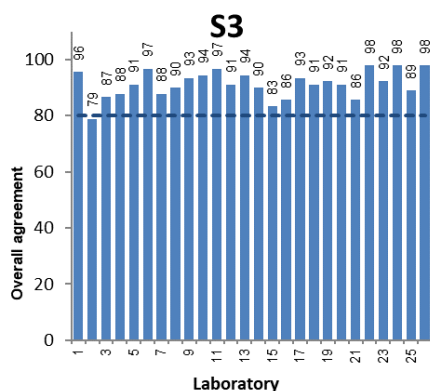
## Inter-laboratory comparison 2023 - RIDASCREEN® Spec. IgG Foodscreen



The overall agreement of sample no. 1  
in your laboratory (#13) is: 96,7 %



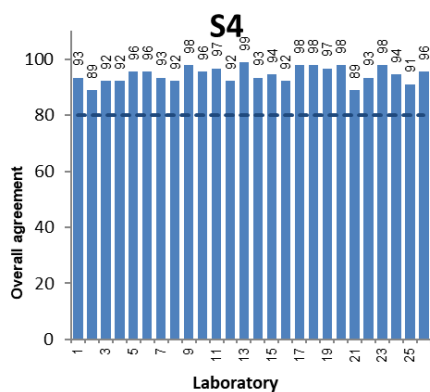
The overall agreement of sample no. 2  
in your laboratory (#13) is: 97,8 %



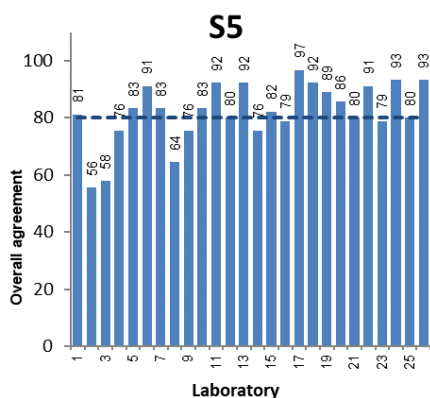
The overall agreement of sample no. 3  
in your laboratory (#13) is: 94,4 %



## Inter-laboratory comparison 2023 - RIDASCREEN® Spec. IgG Foodscreen



The overall agreement of sample no. 4  
in your laboratory (#13) is: 98,9 %



The overall agreement of sample no. 5  
in your laboratory (#13) is: 92,2 %

**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 (80%) for the agreement.



## 7. Comments

Best result in the IC!