

CERTIFICATE

Survey of 25 October 2024

You have fulfilled the requirements of the External Quality Assessment with the following analysis

Allergy Diagnostic (720):

Validity 12 months:

Common wasp (Allergen-cl.) - i03 (R: B2)

Common wasp (quant) - i03

Honey bee (Allergen-cl.) - i01 (R: B2)

Honey bee (quant) - i01

IGE

(R) analysis is subject to the RiliBÄK

Customer:

10066716

Szpital Uniwersytecki nr 2 im. dr. Jana Biziela

Pracownia Immunologiczno-Alergologiczna

ul. Ujejskiego 75

85-168 Bydgoszcz

Düsseldorf, 29 November 2024



Prof. Dr. med. Michael Spannagl
(Head of Reference Institution)



Prof. Dr. rer. nat. Ingo Schellenberg
(Adviser)

CERTIFICATE OF PARTICIPATION

Survey of 25 October 2024

You have participated in the External Quality Assessment with the following analysis

Allergy Diagnostic (720):

Aspergillus fumigatus (Allergen-cl.) - m03 (R: B2)
Aspergillus fumigatus (quant) - m03
Celery (Allergen-cl.) - f85 (R: B2)
Celery (quant) - f85
Common wasp (Allergen-cl.) - i03 (R: B2)
Common wasp (quant) - i03
Hazel nut (Allergen-cl.) - f17 (R: B2)
Hazel nut (quant) - f17
Honey bee (Allergen-cl.) - i01 (R: B2)
Honey bee (quant) - i01
Horse epithelia (Allergen-cl.) - e03 (R: B2)
Horse epithelia (quant) - e03
IGE

(R) analysis is subject to the RiliBÄK

Customer:
10066716
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(Adviser)

Listing and evaluation of the results

10066716: Szpital Uniwersytecki nr 2 im. dr. Jana Biziela
Pracownia Immunologiczno-Alergologiczna

Survey of 25 October 2024

Adviser:

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720

Allergy Diagnostic

Analyte	Sample	Unit	Your value	Target value	TV-Type	Lower limit	Upper limit	Deviation	Z-Score	Meets criteria	
Horse epithelia (quant) - e03	61	kU/l		14.9	SV	5.96	23.8	61.1%	0,892	-	
	62			0.224	ET	0.000	0.560		0	-	
Hazel nut (quant) - f17	(1) 61	kU/l		30.7	SV	12.3	49.1	-42.9%	0		
	(1) 62		0.270	0.473	ET	0.350	0.757		-1,07		
Celery (quant) - f85	61	kU/l		9.99	SV	4.00	16.0	-15.3%	0	-	
	62		0.150	0.177	ET	0.000	0.560		-0,218	+	
Aspergillus fumigatus (quant) - m03	(1) 61	kU/l		2.97	SV	1.19	4.75	-22.6%	-0,948	+	
	(1) 62		2.30	0.130	ET	0.000	0.560		0	+	
Honey bee (quant) - i01	61	kU/l		4.87	SV	1.95	7.79	2.9%	0,275	+	
	62		5.01	0.116	ET	0.000	0.560		-5.2%	-0,375	
Common wasp (quant) - i03	61	kU/l		4.11	SV	1.64	6.58	-3.2%	-0,306	+	
	62		3.98	0.106	ET	0.000	0.560		3.8%	0,16	
IGE	61	IU/ml	134	129	SV	90.3	168	3.9%	0,442	+	

Analyte	Sample	Your unit	Stated value	Conversion factor	Method	Manufacturer	Device	Lot number	Standard
Horse epithelia (quant) - e03	61		24.0		64	PC		Q18X158	
	62								
Hazel nut (quant) - f17	61				64	PC		Q10X1046	
	62		0.270						
Celery (quant) - f85	61				64	PC			
	62		0.150						
Aspergillus fumigatus (quant) - m03	61		2.30		64	PC		Q18X158	
	62								
Honey bee (quant) - i01	61		5.01		64	TFS		389C2	
	62		0.110						
Common wasp (quant) - i03	61		3.98		64	TFS		CVAB2	
	62		0.110						
IGE	61		134	1.00	64	TFS			

Analyte	Sample	Method	Manufacturer	Device	Your specification(s)	Correct specification(s)	TV-Type	Meets criteria
Horse epithelia (Allergen-cl.) - e03	61	64	PC		4	3, 4	M	+
	62					0, 1	M	-
Hazel nut (Allergen-cl.) - f17	61	64	PC			4	M	-
	62				0	0, 1	M	+
Celery (Allergen-cl.) - f85	61	64	PC			2, 3	M	-
	62				0	0, 1	M	+
Aspergillus fumigatus (Allergen-cl.) - m03	61	64	PC		2	2, 3	M	+
	62					0	M	-
Honey bee (Allergen-cl.) - i01	61	64	TFS		3	2, 3	M	+
	62				0	0, 1	M	+
Common wasp (Allergen-cl.) - i03	61	64	TFS		3	2, 3	M	+
	62				0	0, 1	M	+

(1) In individual cases is a statistically valid valuation with consensus value not given, because size of the collective < 8 values.

Additional information on the evaluation is available for download in the RV-Online system in the column "Report".

Individual summary of results

10066716: Szpital Uniwersytecki nr 2 im. dr. Jana Biziela
Pracownia Immunologiczno-Alergologiczna

Survey of 25 October 2024

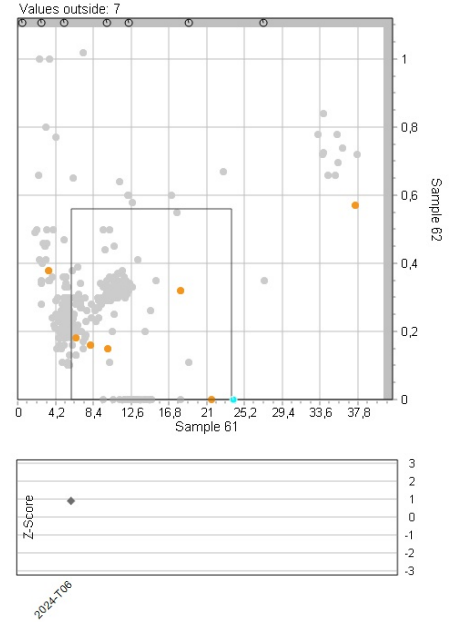
720

Allergy Diagnostic

Horse epithelia (quant) - e03 (kU/l, N = 419)										
Collective	Sample	Target value	Target range	Participants collective			Rate (%)			
				AVG	CV	Num.	Sam.	total		
Gold Standard Diagnostics CD Kassel	61	3.23	1.29 - 5.17	3.23	33.4	45	82.2	71.1		
	62	0.407	0.000 - 0.560	0.407	48.6	45	80.0			
BDL - Labordiagnostik Muenster	61	13.3	5.32 - 21.3	13.3	10.8	27	100	92.6		
	62	0.000	0.000 - 0.560	0.000		27	92.6			
Siemens Healthineers	61	34.7	13.9 - 55.5	34.7	4.24	11	90.9	90.9		
	62	0.730	0.350 - 1.17	0.730	7.95	11	90.9			
Euroimmun	61	18.5	7.40 - 29.6	18.5	53.9	10	90.0	80.0		
	62	0.233	0.000 - 0.560	0.233	0.000	10	90.0			
Fooke	61	5.57	2.23 - 8.91	5.57	11.3	222	97.7	95.9		
	62	0.233	0.093 - 0.373	0.233	19.3	222	96.4			
Hycor (1)	61	7.13	2.85 - 11.4	7.13	8.40	6				
	62	0.162	0.000 - 0.560	0.162	19.8	6				
Thermo Fisher Scientific (Phadia)	61	10.5	4.20 - 16.8	10.5	11.0	85	97.6	97.6		
	62	0.314	0.000 - 0.560	0.314	11.1	85	98.8			
Radim (1)	61	12.8	5.12 - 20.5	12.8	28.1	4				
	62	0.600	0.240 - 0.960	0.600	0.000	4				
other provider	61	14.9	5.96 - 23.8	14.9	68.5	9	66.7	66.7		
	62	0.224	0.000 - 0.560	0.224	83.0	9	77.8			

(1) In individual cases is a statistically valid valuation with consensus value not given, because size of the collective < 8 values.

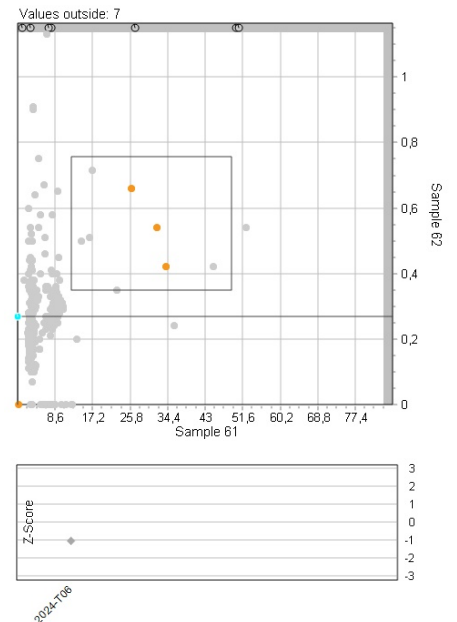
Rate of success: 92,4%



Hazel nut (quant) - f17 (kU/l, N = 443)										
Collective	Sample	Target value	Target range	Participants collective			Rate (%)			
				AVG	CV	Num.	Sam.	total		
Gold Standard Diagnostics CD Kassel	61	6.30	2.52 - 10.1	6.30	37.0	52	88.5	73.1		
	62	0.357	0.000 - 0.560	0.357	49.3	52	80.8			
BDL - Labordiagnostik Muenster	61	7.27	2.91 - 11.6	7.27	20.4	24	91.7	91.7		
	62	0.000	0.000 - 56.0	0.000		24	100			
Biocheck (Polycheck) (1)	61	30.7	12.3 - 49.1	30.7	15.4	4				
	62	0.473	0.350 - 0.757	0.473	40.0	4				
Siemens (DPC)	61	3.80	1.52 - 6.08	3.80	8.53	14	92.9	92.9		
	62	0.119	0.000 - 0.560	0.119	36.1	14	100			
Euroimmun	61	10.0	4.00 - 16.0	10.0	88.9	9	55.6	55.6		
	62	0.233	0.000 - 0.560	0.233	0.000	9	100			
Fooke 4-class system (1)	61	4.77	1.91 - 7.63	4.77	55.8	5				
	62	0.248	0.000 - 0.560	0.248	22.2	5				
Fooke 6-class system	61	3.10	1.24 - 4.96	3.10	10.8	217	99.5	97.2		
	62	0.239	0.000 - 0.560	0.239	30.1	217	97.7			
Hycor (1)	61	6.79	2.72 - 10.9	6.79	32.3	7				
	62	0.251	0.000 - 0.560	0.251	31.5	7				
Phadia, Thermo Scientific	61	8.60	3.44 - 13.8	8.60	10.1	94	96.8	96.8		
	62	0.285	0.000 - 0.560	0.285	11.9	94	98.9			
Radim (1)	61	2.21	0.884 - 3.54	2.21	22.4	6				
	62	0.240	0.000 - 0.560	0.240	0.000	6				
R-Biopharm (1)	61	17.3	6.92 - 27.7	17.3	119	6				
	62	0.145	0.000 - 0.560	0.145	137	6				
other provider (1)	61	26.7	10.7 - 42.7	26.7	97.8	5				
	62	0.624	0.350 - 0.998	0.624	89.9	5				

(1) In individual cases is a statistically valid valuation with consensus value not given, because size of the collective < 8 values.

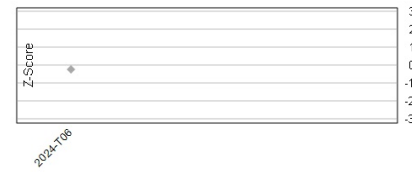
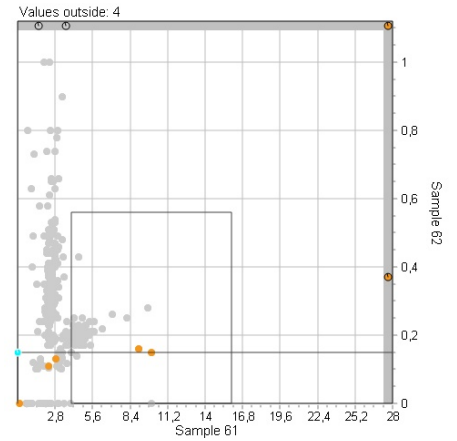
Rate of success: 90,7%



Celery (quant) - f85 (kU/l, N = 398)										
Collective	Sample	Target value	Target range	Participants collective			Rate (%)			
				AVG	CV	Num.	Sam.	total		
Gold Standard Diagnostics CD Kassel	61	1.56	0.624 - 2.50	1.56	44.8	22	90.9	72.7		
	62	0.398	0.159 - 0.637	0.398	53.0	22	77.3			
BDL - Labordiagnostik Muenster	61	1.76	0.704 - 2.82	1.76	39.2	27	81.5	81.5		
	62	0.000	0.000 - 0.560	0.000		27	100			
Siemens Healthineers	61	3.16	1.26 - 5.06	3.16	9.78	12	91.7	91.7		
	62	0.117	0.000 - 0.560	0.117	19.7	12	100			
Euroimmun	61	5.66	2.26 - 9.06	5.66	69.4	8	37.5	37.5		
	62	0.233	0.000 - 0.560	0.233	0.000	8	100			
Fooke 4-class system (1)	61	3.35	1.34 - 5.36	3.35	30.1	4				
	62	0.360	0.000 - 0.560	0.360	35.8	4				
Fooke 6-class system	61	2.50	1.00 - 4.00	2.50	8.96	218	100	93.6		
	62	0.335	0.000 - 0.560	0.335	26.0	218	93.6			
Hycor	61	1.59	0.636 - 2.54	1.59	12.0	8	100	100		
	62	0.111	0.000 - 0.560	0.111	9.01	8	100			
Thermo Fisher Scientific (Phadia)	61	4.55	1.82 - 7.28	4.55	12.5	85	97.6	97.6		
	62	0.202	0.000 - 0.560	0.202	11.9	85	100			
Radim (1)	61	1.82	0.728 - 2.91	1.82	15.1	5				
	62	0.240	0.000 - 0.560	0.240	0.000	5				
other provider	61	9.99	4.00 - 16.0	9.99	108	9	22.2	22.2		
	62	0.177	0.000 - 0.560	0.177	70.1	9	88.9			

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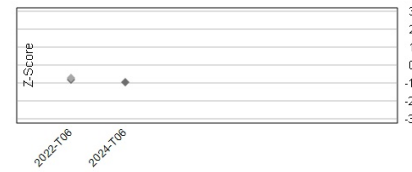
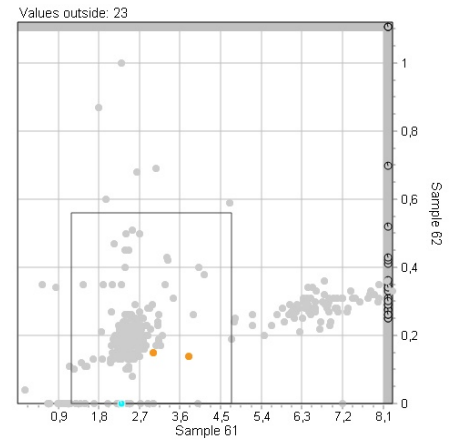
Rate of success: 89,9%



Aspergillus fumigatus (quant) - m03 (kU/l, N = 428)										
Collective	Sample	Target value	Target range	Participants collective			Rate (%)			
				AVG	CV	Num.	Sam.	total		
Immunolab Clinical	61	2.24	0.896 - 3.58	2.24	37.4	48	83.3	70.8		
	62	0.324	0.000 - 0.560	0.324	43.8	48	83.3			
BDL - Labordiagnostik Muenster	61	1.25	0.500 - 2.00	1.25	38.8	26	84.6	84.6		
	62	0.000	0.000 - 0.560	0.000		26	100			
Biocheck (Polycheck) (1)	61	2.97	1.19 - 4.75	2.97	23.8	4				
	62	0.130	0.000 - 0.560	0.130	23.1	4				
Siemens (DPC)	61	10.6	4.24 - 17.0	10.6	17.6	13	92.3	92.3		
	62	0.298	0.000 - 0.560	0.298	16.8	13	100			
Euroimmun	61	35.7	14.3 - 57.1	35.7	67.2	10	60.0	40.0		
	62	0.391	0.000 - 0.560	0.391	44.0	10	70.0			
Fooke 4-Klassen System (1)	61	3.02	1.21 - 4.83	3.02	28.8	4				
	62	0.263	0.000 - 0.560	0.263	41.8	4				
Fooke 6-Klassen System	61	2.51	1.00 - 4.02	2.51	8.61	217	99.5	99.5		
	62	0.194	0.000 - 56.0	0.194	18.6	217	100			
Hycor	61	1.36	0.544 - 2.18	1.36	17.7	8	100	100		
	62	0.110	0.000 - 0.560	0.110	12.7	8	100			
Phadia, Thermo Scientific	61	6.70	2.68 - 10.7	6.70	11.7	86	100	100		
	62	0.281	0.000 - 0.560	0.281	13.5	86	100			
Radim (1)	61	4.26	1.70 - 6.82	4.26	10.5	5				
	62	0.240	0.000 - 0.560	0.240	0.000	5				
andere Hersteller (1)	61	1.49	0.596 - 2.38	1.49	89.9	7				
	62	0.060	0.000 - 0.560	0.060	137	7				

(1) In individual cases is a statistically valid valuation with consensus value not given, because size of the collective < 8 values.

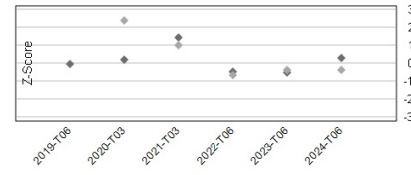
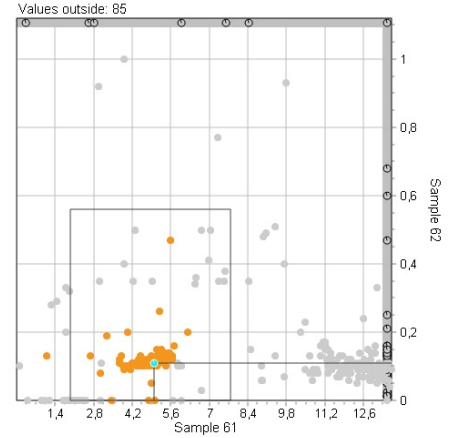
Rate of success: 93%



Honey bee (quant) - i01 (kU/l, N = 461)										
Collective	Sample	Target value	Target range	Participants collective			Rate (%)			
				AVG	CV	Num.	Sam.	total		
Gold Standard Diagnostics CD Kassel	61	6.70	2.68 - 10.7	6.70	40.9	63	84.1	71.4		
	62	0.368	0.000 - 0.560	0.368	52.2	63	81.0			
BDL - Labordiagnostik Muenster	61	2.03	0.812 - 3.25	2.03	20.6	26	92.3	92.3		
	62	0.000	0.000 - 0.560	0.000		26	100			
Siemens Healthineers	61	5.69	2.28 - 9.10	5.69	14.9	17	100	100		
	62	0.079	0.000 - 0.560	0.079	35.4	17	100			
Euroimmun (1)	61	41.7	16.7 - 66.7	41.7	22.2	5				
	62	0.233	0.000 - 0.560	0.233	0.000	5				
Fooke 4-class system (1)	61	7.34	2.94 - 11.7	7.34	10.4	4				
	62	0.180	0.000 - 0.560	0.180	54.4	4				
Fooke 6-class system	61	13.0	5.20 - 20.8	13.0	10.7	218	98.6	98.6		
	62	0.097	0.000 - 0.560	0.097	29.9	218	100			
Hycor	61	1.01	0.404 - 1.62	1.01	18.9	9	88.9	88.9		
	62	0.067	0.000 - 0.560	0.067	0.000	9	100			
Thermo Fisher Scientific (Phadia)	61	4.87	1.95 - 7.79	4.87	10.5	101	98.0	98.0		
	62	0.116	0.000 - 0.560	0.116	13.8	101	100			
Radim	61	4.96	1.98 - 7.94	4.96	25.2	8	100	100		
	62	0.240	0.096 - 0.384	0.240	0.000	8	100			
other provider	61	11.3	4.52 - 18.1	11.3	10.7	10	30.0	30.0		
	62	0.133	0.000 - 0.560	0.133	10.2	10	80.0			

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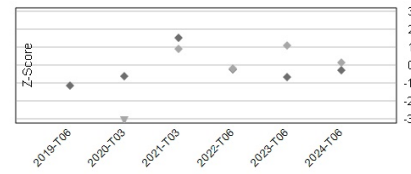
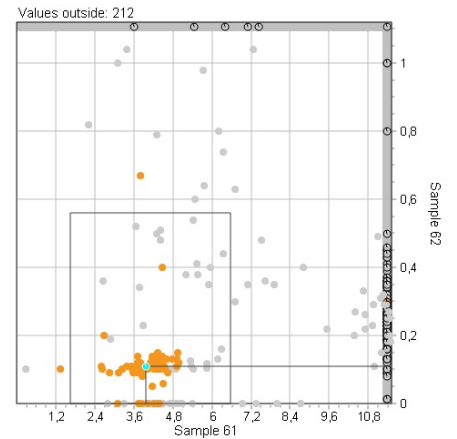
Rate of success: 92,2%



Common wasp (quant) - i03 (kU/l, N = 463)										
Collective	Sample	Target value	Target range	Participants collective			Rate (%)			
				AVG	CV	Num.	Sam.	total		
Gold Standard Diagnostics CD Kassel	61	5.39	2.16 - 8.62	5.39	33.4	64	85.9	62.5		
	62	0.431	0.000 - 0.560	0.431	65.4	64	71.9			
BDL - Labordiagnostik Muenster	61	4.49	1.80 - 7.18	4.49	19.2	26	92.3	92.3		
	62	0.000	0.000 - 0.560	0.000		26	100			
Siemens Healthineers	61	5.31	2.12 - 8.50	5.31	12.1	17	100	100		
	62	0.088	0.000 - 0.560	0.088	42.0	17	100			
Euroimmun (1)	61	18.7	7.48 - 29.9	18.7	63.6	5				
	62	0.233	0.000 - 0.560	0.233	0.000	5				
Fooke 4-class system (1)	61	9.40	3.76 - 15.0	9.40	73.0	4				
	62	0.433	0.000 - 0.560	0.433	67.7	4				
Fooke 6-class system	61	13.2	5.28 - 21.1	13.2	10.1	218	98.6	98.2		
	62	0.256	0.000 - 0.560	0.256	30.1	218	99.5			
Hycor	61	0.989	0.396 - 1.58	0.989	44.9	9	77.8	77.8		
	62	0.067	0.000 - 0.560	0.067	0.000	9	100			
Thermo Fisher Scientific (Phadia)	61	4.11	1.64 - 6.58	4.11	10.3	102	98.0	97.1		
	62	0.106	0.000 - 0.560	0.106	23.6	102	99.0			
Radim	61	2.56	1.02 - 4.10	2.56	15.4	8	100	100		
	62	0.240	0.000 - 0.560	0.240	0.000	8	100			
other provider	61	12.9	5.16 - 20.6	12.9	10.9	10	40.0	40.0		
	62	0.155	0.000 - 0.560	0.155	91.0	10	90.0			

(1) In individual cases is a statistically valid valuation with consensus value not given, because size of the collective < 8 values.

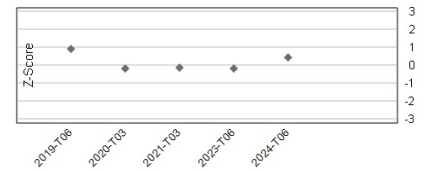
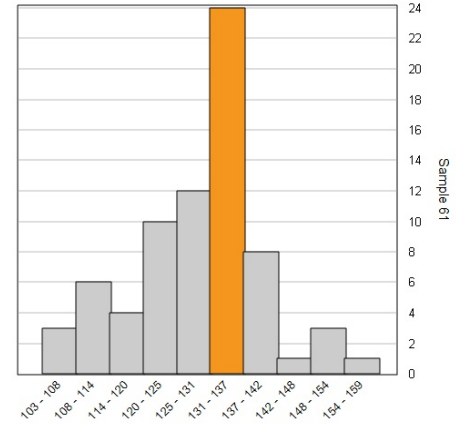
Rate of success: 90,3%



IGE (IU/ml, N = 478)										
Collective	Sample	Target value	Target range			Participants collective			Rate (%)	
						AVG	CV	Num.	Sam.	total
Gold Standard Diagnostics CD Kassel I	61	91.5	64.1	-	119	91.5	11.8	76	94.7	94.7
BDL - Labordiagnostik Muenster	61	126	88.2	-	164	126	12.1	25	100	100
Siemens Healthineers	61	120	84.0	-	156	120	12.9	20	95.0	95.0
Fooke	61	67.2	47.0	-	87.4	67.2	19.5	216	84.3	84.3
Hycor (1)	61	101	70.7	-	131	101	17.4	7		
Thermo Fisher Scientific (Phadia)	61	129	90.3	-	168	129	8.76	80	92.5	92.5
Radim	61	131	91.7	-	170	131	14.9	10	100	100
Roche	61	126	88.2	-	164	126	4.79	25	100	100
other provider	61	105	73.5	-	137	105	13.9	19	89.5	89.5

(1) In individual cases is a statistically valid valuation with consensus value not given, because size of the collective < 8 values.

Rate of success: 90,2%



720

Allergy Diagnostic

Horse epithelia (Allergen-cl.) - e03 (N = 422, Rate of success: 96,7%)

Collective	Sample	Allergen-class							
		0	1	2	3	4	5	6	
Gold Standard Diagnostics CD Kassel	61	1		7	39	1			
	62	26	16	5	1				
BDL - Labordiagnostik Muenster	61				2	25			
	62	25		2					
Siemens Healthineers	61				1	8			
	62		3	5					
Euroimmun	61			1	11	4			
	62	16							
Fooke	61				220	2			
	62	30	191						
Hycor	61				6				
	62	6							
Thermo Fisher Scientific (Phadia)	61				79	2			
	62	70	11						
Radim	61				4				
	62		4						
other provider	61			1	4	3	1		
	62	5	2	1					

Hazel nut (Allergen-cl.) - f17 (N = 446, Rate of success: 95,5%)

Collective	Sample	Allergen-class						
		0	1	2	3	4	5	6
Gold Standard Diagnostics CD Kassel	61	1			53	2	1	
	62	37	12	6	2			
BDL - Labordiagnostik Muenster	61				23	1		
	62	24						
Biocheck (Polycheck)	61					3		
	62	1	3					
Siemens (DPC)	61			1	10			
	62	10	1					
Euroimmun	61			2	9	4		
	62	11	4					
Fooke 4-class system	61			1	3	1		
	62	2	3					
Fooke 6-class system	61			8	208			
	62	45	169	1				
Hycor	61	1			6			
	62	7						
Phadia, Thermo Scientific	61				88			
	62	85	3					
Radim	61			7				
	62	7						
R-Biopharm	61				4	1	1	
	62	3	3					
other provider	61			1	3		2	
	62	2	1	3				

Celery (Allergen-cl.) - f85 (N = 399, Rate of success: 93,5%)

Collective	Sample	Allergen-class						
		0	1	2	3	4	5	6
Gold Standard Diagnostics CD Kassel	61		1	17	4			
	62	13	6	3	1			
BDL - Labordiagnostik Muenster	61			26	1			
	62	27						
Siemens Healthineers	61			9	1			
	62	10						
Euroimmun	61		1	7	5			
	62	13						
Fooke 4-class system	61			1	3			
	62	2	2					
Fooke 6-class system	61			20	194			
	62	12	188	15				
Hycor	61	1		7				
	62	8						
Thermo Fisher Scientific (Phadia)	61			3	79			
	62	82						
Radim	61			5				
	62	5						
other provider	61		1	3	4	1	1	1
	62	9	2	1				

Aspergillus fumigatus (Allergen-cl.) - m03 (N = 432, Rate of success: 95,6%)

Collective	Sample	Allergen-class						
		0	1	2	3	4	5	6
Immunolab Clinical	61			27	23	1		
	62	39	6	5				
BDL - Labordiagnostik Muenster	61		1	25				
	62	26						
Biocheck (Polycheck)	61			3	1			
	62	3						
Siemens (DPC)	61				11			
	62	8	3					
Euroimmun	61	1		3		9	3	
	62	7	6	3				
Fooke 4-Klassen System	61			1	3			
	62	2	2					
Fooke 6-Klassen System	61			19	197			
	62	57	157	1				
Hycor	61	1		7				
	62	8						
Phadia, Thermo Scientific	61				82			
	62	80	2					
Radim	61				5			
	62	5						
other provider	61	2		6	1			
	62	9						

Honey bee (Allergen-cl.) - i01 (N = 467, Rate of success: 95,5%)

Collective	Sample	Allergen-class						
		0	1	2	3	4	5	6
Gold Standard Diagnostics CD Kassel	61			5	63	3		
	62	50	11	6	3	1		
BDL - Labordiagnostik Muenster	61			24	2			
	62	25	1					
Siemens Healthineers	61				14			
	62	14						
Euroimmun	61				3	6	1	
	62	10						
Fooke 4-class system	61			2	1	1		
	62	3	1					
Fooke 6-class system	61			1	20	197		
	62	209	8					
Hycor	61		1	8				
	62	8						
Thermo Fisher Scientific (Phadia)	61			6	91			
	62	96	1					
Radim	61				8			
	62	8						
other provider	61	1		3	2	3		1
	62	8		1	1			



Common wasp (Allergen-cl.) - i03 (N = 468, Rate of success: 94,9%)

Collective	Sample	Allergen-class						
		0	1	2	3	4	5	6
Gold Standard Diagnostics CD Kassel	61			3	66	2		
	62	44	13	12	3			
BDL - Labordiagnostik Muenster	61				26			
	62	26						
Siemens Healthineers	61			1	13			
	62	13	1					
Euroimmun	61			1	5	4		
	62	10						
Fooke 4-class system	61				3	1		
	62	3		1				
Fooke 6-class system	61				17	201		
	62	46	172					
Hycor	61	1	1	7				
	62	8						
Thermo Fisher Scientific (Phadia)	61			10	87			
	62	96	1					
Radim	61			8				
	62	8						
other provider	61	1	1	1	3	3	1	
	62	8	1		1			