

Concordance of the Analytical Performance of Autoimmune Antibodies on the HOB BioCLIA® 6500 Automated Immunoassay Analyzer to the Phadia® 250 System

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Abstract

The difficulty in diagnosis, the generated autoantibodies are often not specific for a single disease. In fact, there is a need to increase the clinical efficiency in the autoimmune field. Therefore, we evaluated the CLIA-test-based HOB BioCLIA® 6500 in both, handling and performance in comparison to the FEIA-based Phadia® 250 system. We compared 23 autoimmune parameters and altogether 6640 measurements were done in our high-throughput lab. To judge the performance despite the lack of clinical data, the non-compliance and the κ -values were calculated to describe the effect of discrepant results between the Phadia® 250 and HOB BioCLIA® 6500 systems. For 16 of 21 compared parameters a good compliance is found. Notwithstanding for some of the parameters, e.g. celiac and rheumatoid parameters, a discrepancy is observed. In an additional "celiac project" we bought characterized sera from in.vent Diagnostica GmbH and repeated the measurement and did IFT. For anti-h-tTG-A, anti-DGP-A and anti-h-tTG-G a very good compliance can be stated.

Facts

This study was conducted in the serological department at the LADR GmbH MVZ Nord-West in Schüttert, Germany, a private lab for laboratory medicine. A comparative study of the HOB BioCLIA® 6500 (HOB Biotech Group, China) and the established Phadia® 250 system (ThermoFisher Scientific, Sweden) was performed.

Lapse of time: November 2018 to April 2019

Systems: BioCLIA® 6500 (new) and Phadia® 250 (established)

Measurements: over 6640 patient sera

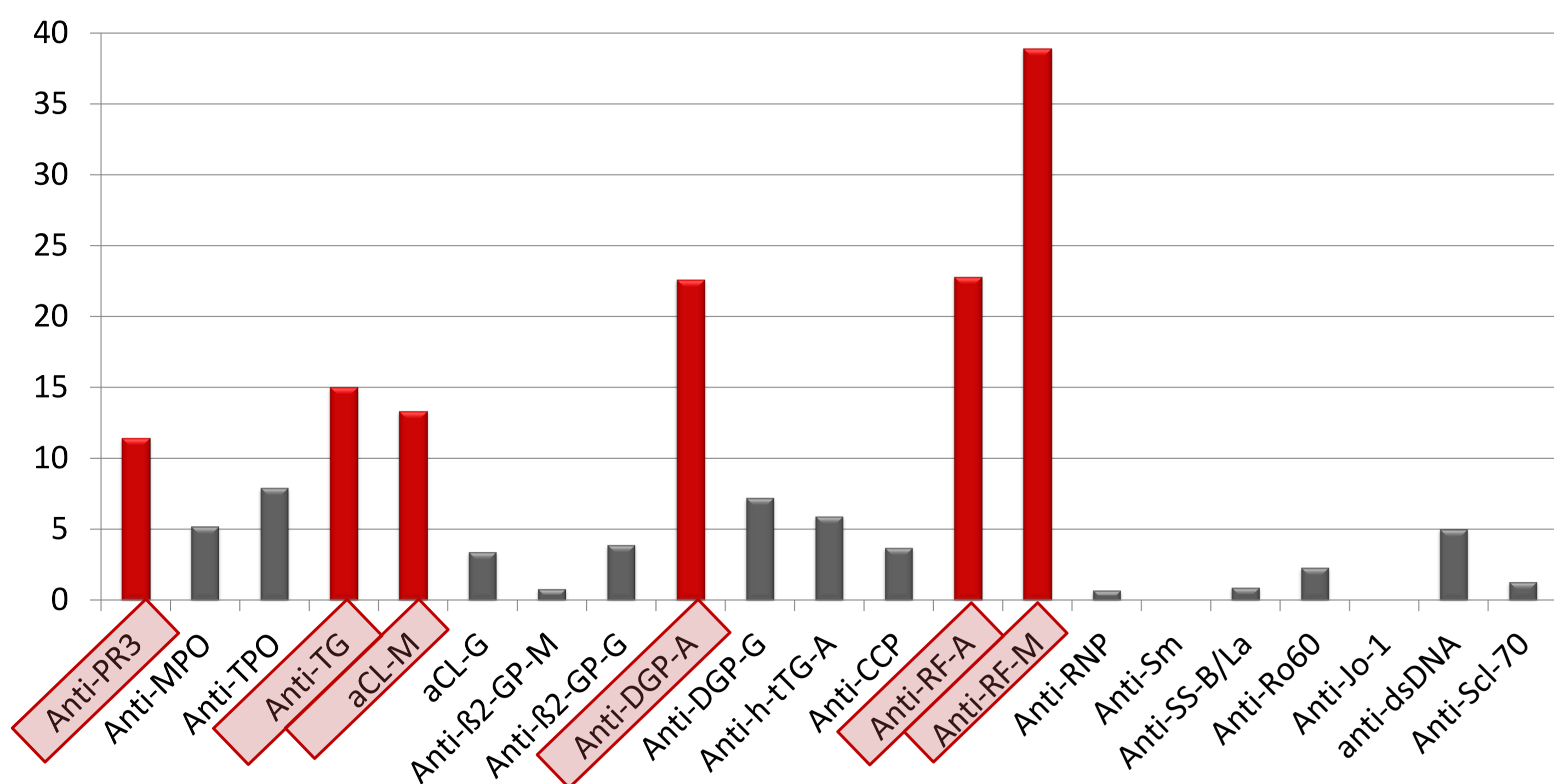
Age (groups): a view weeks (0) to 93 years (main proportion 51-65, followed by 36-50 years)



Picture: <https://www.bioclia.de/>

	Phadia® 250	HOB BioCLIA® 6500
Sensitivity	> 10 ⁻¹⁵ mol/L	10 ⁻¹⁸ mol/L
Dynamic range	< 10 ⁵	10 ⁷
Method	FEIA	CLIA
Through put	60 T/h	100-218 T/h
Sample loading	Random access	Random access
Flexibility	Flexible selection (51)	Flexible selection (47)
Reagents	Stored on board	Stored on board

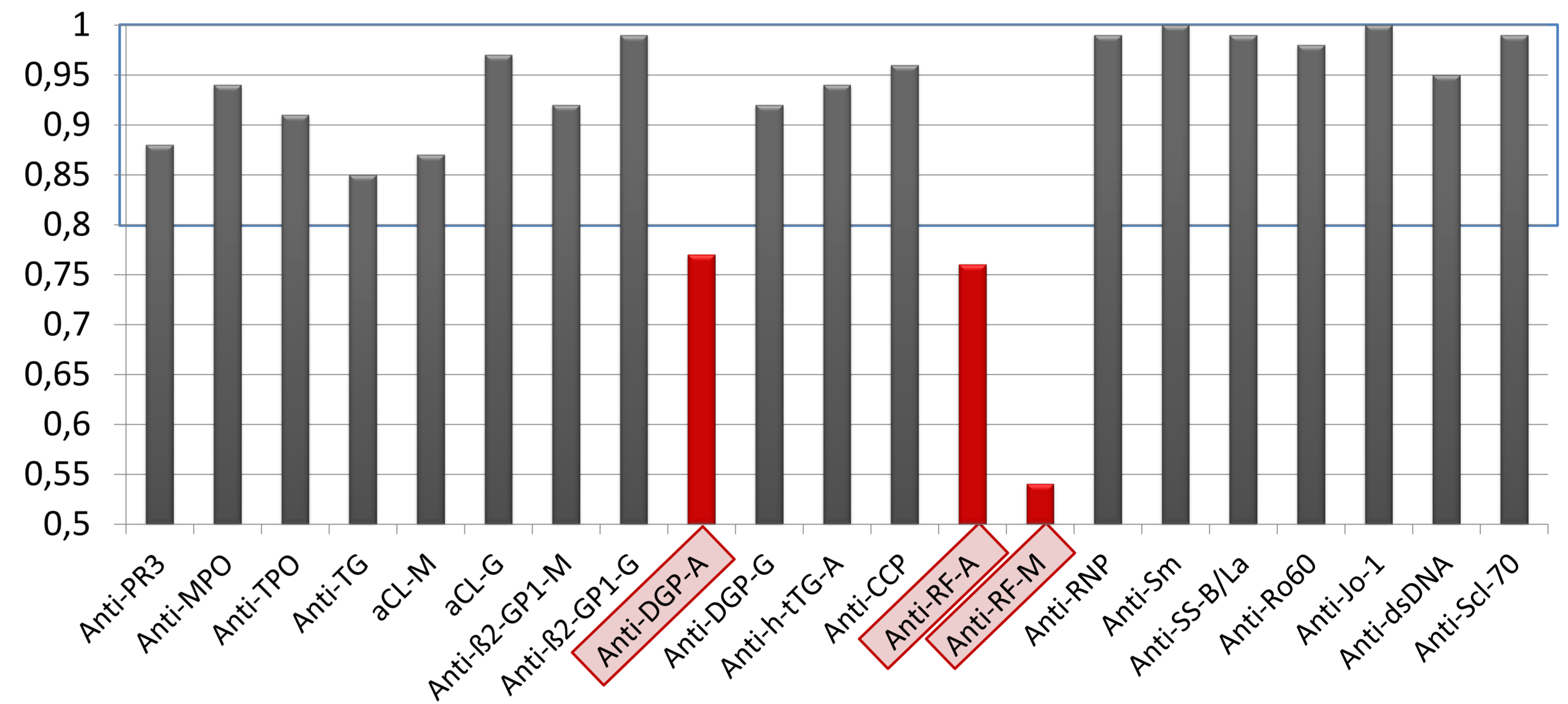
Non-Compliance [%]



Graph 1: Bars over 10% (red coloured parameters) show an increased non-compliance in comparison to the Phadia® 250 system. (Clinical data missing)

Results

κ -values HOB BioCLIA® 6500



Graph 2: Calculated Cohen's kappa (κ -values). Strength of agreement: 1.00-0.81: almost perfect (blue box); 0.80-0.61: substantial; 0.60-0.41: moderate; 0.40-0.21: fair; 0.20-0.00: slight; <0.00 poor.

Table 1: Re-testing rheumatoid factors with routine samples.

Total RF (Roche)		RF-M Roche/Phadia® / BioCLIA®	RF-A Roche/Phadia® / BioCLIA®	Comparison of the compliance:
57 pos.	ppp	32	14	1. Roche vs. Phadia vs. BioCLIA RF-M 44/75 (58%) RF-A 31/75 (41%)
	pnp	15	15	
	ppn	6	1	2. Roche vs. Phadia RF-M 53/75 (71%) RF-A 43/75 (57%)
	pnn	4	27	
18 neg.	npp	0	0	3. Roche vs. BioCLIA RF-M 62/75 (83%) RF-A 46/75 (61%)
	nnp	3	1	
	npn	3	0	4. Phadia vs. BioCLIA RF-M 48/75 (64%) RF-A 58/75 (77%)
	nnn	12	17	

Legend: ppp= pos./pos./pos.; pnp= pos./neg./pos.;; in the order Roche®/Phadia®/BioCLIA®.

Table 2: Re-testing celiac parameters. Comparison of 17 defined sera (in.vent) from 6 patients on the BioCLIA® 6500, Phadia® 250 and in the IFT.

Pat.-ID	Probe	BioCLIA® 6500 [RU/ml]				Phadia 250 [U/ml]				IFT
		h-tTG-A	DGP-A	DGP-G	h-tTG-G	h-tTG-A	DGP-A	DGP-G	h-tTG-G	
1	1	pos.	pos.	pos.	pos.	pos.	pos.	pos.	pos.	pos./pos.
	2	pos.	pos.	pos.	pos.	pos.	pos.	pos.	pos.	-
	3	pos.	pos.	pos.	pos.	pos.	pos.	pos.	pos.	-
	4	pos.	pos.	pos.	pos.	pos.	pos.	pos.	pos.	-
	5	pos.	pos.	pos.	pos.	pos.	pos.	pos.	pos.	pos.
	6	pos.	pos.	pos.	pos.	pos.	pos.	pos.	pos.	-
	7	pos.	pos.	pos.	pos.	pos.	pos.	pos.	pos.	-
2	1	pos.	pos.	pos.	pos.	pos.	pos.	pos.	pos.	pos.
	3	pos.	pos.	pos.	pos.	pos.	pos.	pos.	pos.	pos.
3	1	pos.	pos.	pos.	pos.	pos.	pos.	pos.	pos.	pos.
	4	pos.	pos.	pos.	pos.	pos.	pos.	pos.	pos.	neg./neg.
5	1	pos.	pos.	pos.	pos.	pos.	pos.	pos.	pos.	pos./pos.
	2	pos.	pos.	pos.	pos.	pos.	pos.	pos.	pos.	-
	3	pos.	pos.	pos.	pos.	pos.	pos.	pos.	pos.	-
	4	pos.	pos.	pos.	pos.	pos.	pos.	pos.	pos.	-
6	1	pos.	pos.	pos.	pos.	pos.	pos.	pos.	pos.	pos./pos.

Conclusion

Between the two used systems, for 16 of 21 compared parameters we found a good compliance. Notwithstanding for some of the parameters, e.g. celiac parameters and the rheumatoid factors, a discrepancy to the Phadia® 250 system is shown. In the additional project with the in.vent-sera, we found a very good compliance for anti-h-tTG-A, anti-DGP-A and anti-h-tTG-G. The anti-DGP-G and IFT (Endomysium G) were discrepant, a reason could be the occurrence of much IgG in the tissue and therefore a bad sensitivity in the IFT. The HOB BioCLIA® 6500 is a fast processing instrument with sliding sample racks and additional priority lanes for emergency samples.

Take Home Message

- High throughput autoimmune analyzer; modern CLIA technology
- Good to handle; intuitive
- It is possible to reload samples/reagents during the run
- Short time to result
- Low-maintenance
- Overall, good concordance to the Phadia® 250 system
- Good concordance of rheumatoid factors to Roche (RF-M) and ThermoFisher (RF-A)
- Celiac: Perfect IFT confirmation