

EVALUATION OF THE ANALYTICAL PERFORMANCE OF THE AUTOIMMUNITY PROCESS LINES OF THE NEW AUTOMATED SYSTEM PHADIA®5000

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INTRODUCTION

Several Phadia® Laboratory Systems are often required for Allergy and Autoimmunity testing. All assays can now be performed on only one system, the new high capacity automated system Phadia®5000. The configuration chosen by CERBA Laboratory is the first worldwide.



First configuration worldwide: 2 process lines for Allergy and 2 process lines for Autoimmunity.

OBJECTIVE

To evaluate the Phadia®5000 analytical performance for autoimmunity testing.



Rack Input/Output module (160 racks) Loading area for samples, IQC, ImmunoCAP/EIA wells, Calibrators/CC.

METHODS

Repeatability and reproducibility are performed on 30 values for 21 autoantibodies (anti-SSA/Ro, SSB/La, Sm, U1RNP, Scl70, Jo1, centromere, ENA screening, dsDNA, CCP2, MPO, PR3, GBM, cardiolipin IgG and IgM, beta 2 glycoprotein 1 (B2GP1) IgG and IgM, deaminated gliadin peptide (DGP) IgG and IgA, transglutaminase (tTG) IgG and IgA). 30 samples selected on the entire measuring range are tested for the comparison study with Phadia®250 for 15 autoantibodies and 40 samples for the comparison study with ELISA for 6 autoantibodies.

RESULTS

Analytical performance of the Phadia®5000

Analytical performance of the Phadia®5000 versus Phadia®250

Antibodies	Characteristic Method		Comparison study between Phadia®250 and Phadia®5000	Precision
	Repeatability (CV%)	Reproducibility (CV%)	Kappa statistic of agreement	External Quality Control Results
	N=30 positive IQC values	N=30 positive IQC values	N=30 all over measuring range	EQC international programs
ENA screening	11.6	11.7	0.79*	Good response
SSA (Ro 60 + 52 kDa)	4.5	8.5	1	Good response
SSB	6.8	9.3	1	Good response
Sm (SmD3)	5.1	9.5	1	Good response
U1RNP	7.4	8.6	1	Good response
Scl70	4.5	5.0	1	Good response
Jo1	4.4	9.0	1	Good response
Centromere	5.7	7.4	1	Good response
CCP2	4.5	8.8	1	Good response
dsDNA	6.1	8.4	1	Good response
DGP IgA	6.7	8.7	1	Good response
DGP IgG	3.9	6.1	1	Good response
tTG IgA	5.2	6.6	1	Good response
tTG IgG	3.1 (N=16)	4.2	1	Good response
GBM	6.5	11.3	1	Good response

* Kappa of agreement ≠ 1 can be explained by the equivocal range given for the method.

EIA reagents are exactly the same between the Phadia®250 and the Phadia®5000 and there is no discrepancy for the interpretation of the 15 autoantibodies between the two systems.

Quality of results is maintained between Phadia®250 and Phadia®5000.

Analytical performance of the Phadia®5000 versus ELISA

Antibodies	Characteristic Method		Comparison study between ELISA and Phadia®5000	Precision
	Repeatability (CV%)	Reproducibility (CV%)	Kappa statistic of agreement	External Quality Control Results
	N=30 positive IQC values	N=30 positive IQC values	N=40 all over measuring range	EQC international programs
MPO	3.4	6.9	1	Good response
PR3	3.6	6.5	0.62	Good response
B2GP1 IgG	2.7	6.2	0.60	Good response
B2GP1 IgM	3.6	6.3	0.86	Good response
Cardiolipin IgG	2.4	4.6	0.26	Good response
Cardiolipin IgM	3.8	4.5	0.70	Good response

Analytical performance are in accordance with the expected requirements.

The Phadia®5000's high capacity allowed the automation of 6 parameters which were still done by ELISA before.

Automation on Phadia®5000 system versus ELISA allows :

- Emergency management for anti-MPO and PR3 antibodies (daily occurrence)
 - Faster results for APS investigation
 - No need to make several samples for the same patients because all the antibodies are done on the same system.
- It makes the pre-analysis faster and secure the results using only primary samples.**

Productivity improvement for the Autoimmunity platform before and after the Phadia®5000



Phadia® 5000 within the technical platform of CERBA laboratory

5 Phadia®250 were needed to permit all the Autoimmunity activity (4 dedicated to each antibodies family and 1 in mirror for all analysis) and ELISA technics were still performed for 6 antibodies.

Qualitative advantages:

- More than 2 hours per day won for technicians so they can be focused on the results and technical validation.
- Only one machine to load and collect samples, at the same place, and not 5 different places = better ergonomomy.
- The tube feeder (rack Input/Output module) is a great improvement for quality, rapidity and ergonomomy.

	Phadia®250	Phadia®5000	
Number of machines	5	1	
Tested antibodies	15	21	Automation of 6 new parameters
Tests/day	1200	2000	
Work time for technicians (loading - preparation...)	2h30/day	20min/day	Automatic WASH preparation Waste automatic discharge Automatic loading of distilled water Reagents volumes adapted to the Phadia®5000 capacity, so less bottle to load
Number of IQC bottle/day	13 positive control bottles 13 negative control bottles	9 positive control bottles 9 negative control bottles	Less bottle used because only one machine for all the analysis and no mirror

CONCLUSION

The high productivity thanks to this unique system configuration allows valuing the technician work in his technical competency and the result validation. The high throughput permits the automation of new parameters and consequently to secure the pre-analytics. The Phadia®5000 uses the same reagents than the Phadia®250 so that allows continuity in the quality of returned results. The Phadia®5000 answers to all the quality and automation requirements of the laboratory.