# **Your Partners in Parasitology**

# and Mycology



# **LDBIO Diagnostics Western Blot**

## **Reference IMMUNOBLOTS**

for Serology Confirmation

# LDBIO Diagnostics ICT

## Lateral flow RAPID TESTS

for Serology Screening

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LDBIO Diagnostics meets the requirements of the new European regulation. All our products will be maintained and remain available.



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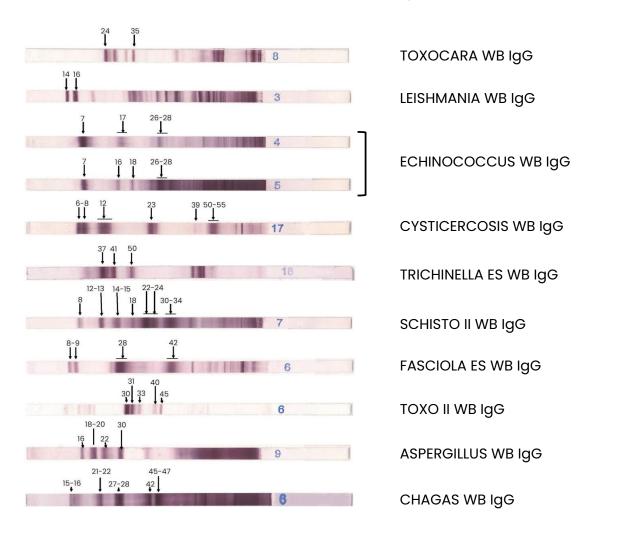




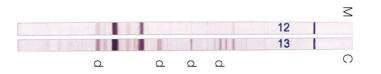
# **IMMUNOBLOTS**

COMMON REAGENTS • COMMON PROCEDURE READY FOR USE • AUTOMATABLE • RELIABLE

### IGG SEROLOGY CONFIRMATION



## **CONGENITAL TOXOPLASMOSIS DIAGNOSIS AT BIRTH**



CIP WB between Mother's (M) and Child's (C) serum. Additional bands (d) are present on the child's strip : the test is positive.

## **OCULAR TOXOPLASMOSIS DIAGNOSIS**



CIP WB between Serum (S) and Aqueous Humor (AH). Additional bands (d) are present on the AH strip : the test is positive.



# **RAPID TESTS**

### SIMPLE • ROBUST • NO WATER • NO ELECTRICITY



## Performances of ICT Toxoplasma IgG-IgM test in comparison with Vidas Toxo Competition to determine the immune status of patients against *Toxoplasma gondii*.

Sylvie Abraham<sup>1</sup>, Rima McLeod<sup>2</sup>, Nadhira Houhou-Fidouh<sup>3</sup>, Pascale Niçaise-Rolland<sup>4</sup>, Luce Landraud<sup>5</sup>, Sandrine Houze<sup>1</sup>

<sup>1</sup> Bichat-Claude Bernard Hospital, Laboratory of Parasitology, Paris, France; <sup>2</sup> The University of Chicago, AMB N310, Chicago, USA; <sup>3</sup> Bichat-Claude Bernard Hospital, Laboratory of Virology, Paris, France; <sup>4</sup> Bichat-Claude Bernard Hospital, Laboratory of Immunology, Paris, France; <sup>5</sup> Louis Mourier Hospital, Laboratory of Microbiology, Colombes, France

Keywords: Toxoplasmosis, immunochromatographic test, serology

Toxoplasmosis is a ubiquitous parasitosis caused by *Toxoplasma gondii* (Tg). In immunocompetent people, the infection is usually asymptomatic with the induction of a protective immune response. In immunocompromised patients or seronegative pregnant woman infected during pregnancy, the infection may be more severe.

The objective of the study was to evaluate the place of a new immunochromatographic test, Toxoplasma ICT IgG-IgM (LDBio Diagnostics), in the diagnostic strategy. This test allows the detection of anti-Tg immunoglobulins G (IgG) and M (IgM) simultaneously.

We included 1145 prospective sera and 380 samples selected for their specificity or sensitivity. Specificity study included sera with biological markers of other disease, and samples with false positive results with Architect IgG or IgM Tg technique. Sensitivity study included samples from immunocompromised patients, and sera from patients with an old or recent infection. The performance of the ICT was evaluated in comparison with Vidas Toxo Competition (Biomérieux) and Toxoscreen (Biomérieux). In case of discrepancy, the Vidas Toxo IgG and IgM II and Western Blot Toxo II IgG were performed to determine the immune status.

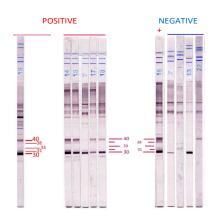
The sensitivity of Toxoplasma ICT was 99,3% with a specificity of 100%. In comparison, the sensitivity of Toxoscreen was 100% with a specificity of 99,8%. The sensitivity of Toxo Competition was 98,7% with a specificity of 99,1%. The performance of ICT was excellent even for low IgG titers, especially in immunocompromised patients, and for confirmation of the specificity of IgM against Tg in case of isolated IgM.

This ICT allows to obtain results easily and quickly. This test would permit screening of patients or confirm a serology result. Unfortunately, this technique does not allow the kinetics of antibody titers, nor to differentiate IgM from IgG. If the test is positive, additional tests could be necessary.

ECCMID congress. 2022.

#### WESTERN BLOT LDBIO TOXO II IgM®

Toxoplasma seroconversion / non-specific IgM differentiation



#### Interpretation

The presence on the strip of a minimum of 2 bands out of specific bands P30, P31, P33, P38 and P40, AND the inclusion of the band P30 kDa, allows the assay to be interpreted as positive and to conclude that anti-*T. gondii* IgM antibodies are present in the tested sample.

NEW

**P30 and P40** are the most frequent bands in case of mild positive IgM serology result.

#### Performances<sup>1</sup>

The leftover of laboratory samples stored after clinical diagnosis of 234 sera corresponding to 96 toxoplasmic seroconversions (2 to 3 sera/patient) and 169 sera corresponding to 69 patients with cross reactions and/or non-specific IgM (1 to 3 sera/patient) were retrospectively analysed. All the patients had a documented seroconversion with the last IgG /IgM negative to the first IgG /IgM positive or a false positive result without seroconversion as previously analysed in the different laboratories with panel of different serological techniques.

	Western Blot IgM	
	Positive	Négative
Seroconversions (N=96)	96	0
False positives IgM (N=69)	9	60

Performances in confirmation of seroconversion and IgM cross-reaction: Se = 100% (IC95 [96.2-100%])

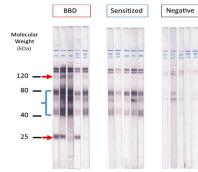
Sp = 86.7% (IC95 [76.7-93.9%])

<sup>1</sup> Diagnostic accuracy of Toxoplasma Western Blot test in suspected seroconversion in pregnancy: a multicentric study. Valeria Meroni, Alfonso Corcione, Luigia Scudeller, Marie-Pierre Brenier-Pinchart, Hélène Fricker-Hidalgo, Coralie L'Ollivier, Hervé Pelloux, Luc Paris. 6<sup>a</sup> Internal Congress of Congenital Toxoplasmosis. 2019.

#### **PEO WESTERN BLOT IgG®**



Bird Breeders' Lung Disease immunoblot diagnosis



#### Interpretation

 The simultaneous presence of the bands P40-80 and P25 or P120 is indicative of bird-breeder's lung disease.

• The simultaneous presence of the bands P40-80 is indicative of sensitization.

#### Performances<sup>3</sup>

The evaluation included two complementary cohorts of patients:

- A prospective cohort of 185 sera characterized by an automated screening technique in a specialized biology laboratory and whose positives were sent for confirmation to a bird-breeder's disease EAA diagnosis reference laboratory (16 BBD, 5 sensitized, 164 negative).
- A complementary cohort of characterized sera from the same reference laboratory of 63 sera (38 BBD, 10 sensitized, 15 negative).

Patients	Profiles of PEO WB IgG (N=248)		
	BBD	Sensitized	Negative
BBD (N=54)	45	7	2
Sensitized (N=15)	2	2	11
Negative (N=179)	15	23	141

The BBD profile allowed the correct identification of 45/54 BBD patients, while allowing the exclusion of 177/194 of the other samples. Its sensitivity was therefore 83.3% (CI95 [70.2-91.6%]) and its specificity 91.2% (CI95 [86.1-94.7%]).

<sup>3</sup> Evaluation of a rapid screening test (PEO ICT IgG IgM) and a confirmatory test (PEO WB IgG) for the serological diagnosis of bird breeders' lung disease. Serine Regult<sup>23</sup>, Raphael Parrows<sup>1</sup>, Lise Siard<sup>3</sup>, Antoine Huguenin<sup>45</sup>, Régine Geers<sup>45</sup>, Dominique Aubert<sup>45</sup>, Christine Bouz<sup>2</sup>, Denis Limonne<sup>1</sup>, Isabelle Villena<sup>45</sup>.

#### A. FUMIGATUS WESTERN BLOT IgE®

Aspergillus sensitization and ABPA immunoblot diagnosis

#### Interpretation

- The profile is split into :
- B16, B18-20, B22 and B30 = major bands.
  Other bands in the < 37 kDa area (B10, B17, B33, B34, B36, B37) = minor bands.</li>
- $\rightarrow$  The sensitisation profile is defined by the
- presence of at least 2 major bands.
- → The ABPA profile is defined by the presence of at least 2 major bands + at least 2 minor bands.

#### Performances<sup>2</sup>

A study was conducted in a laboratory with expertise in the diagnosis of ABPA. It included 229 sera positive for specific IgE anti-Aspergillus by CLIA technique. Of the samples, 23 were from patients with ABPA.

	Positive WB	Negative WB	Total
CLIA 0.35-2 UA/ml	62	79	141
CLIA >2 UA/ml	85	3	88
Total	147	82	229

The presence of at least two major bands, indicating WB positivity, was found in 147 samples (64%, 95CI [58-70%]) including all ABPA. The sensitivity of the test was 97% (85/88, 95CI [90-99%]) at 2 AU/mI threshold.

	ABPA profile	Sensitization profile	Negative	Total
ABPA	22	1	0	23
Sensitization	14	110	82	206
Total	36	111	82	229

For the differential diagnosis between ABPA and sensitization, the ABPA profile (presence of 2 major bands + 2 other bands of molecular weight < 37 kDa) was found in 22/23 ABPA and was absent in 192/206 sensitizations. The sensitivity and specificity of the profile were therefore 96% (95CI [76-99%]) and 93% (95CI [89-96%]), respectively.

<sup>2</sup> Interest of Aspergillus fumigatus Western Blot assay for differential diagnostic between IgE sensitization and Allergic Broncho Pulmonary Aspergillosis. Raphaël Piarroux, Jean-Christophe Dubus, Martine Reynaud-Gaubert, Marion Gouitaa, Stéphane Ranque, Joana Vitte. 9<sup>th</sup> Trends in Medical Mycology. 2019.

#### PEO ICT IgG-IgM®

Bird Breeders' Lung Disease rapid test screening



#### Interpretation

The reading must be done between 20 and 30 minutes after starting the timer.

- **Positive test**: 2 lines, a **black** "T" and a blue "C" appear in the corresponding areas.
- **Negative test**: No black line appears. Only the blue "C" line is visible.
  - Invalid test: The "C" line does not appear.

#### Perrormances

The evaluation included two complementary cohorts of patients:

- A prospective cohort of 185 sera characterized by an automated screening technique in a specialized biology laboratory and whose positives were sent for confirmation to a reference laboratory for Bird-Breeder's lung disease diagnosis (16 BBD, 5 sensitized, 164 negative).
- A complementary cohort of 63 characterized sera from the same reference laboratory (38 BBD, 10 sensitized, 15 negative).

	PEO ICT IgG-IgM		
Patients	(N=248)		
	Positive	Negative	
BBD (N=54)	48	6	
Sensitized (N=15)	6	9	
Negative (N=179)	26	153	

LDBIO PEO ICT IgG-IgM was positive in 54/69 samples, 48/54 of which were BBD, while being negative in 153/179 negative samples. Its sensitivity is therefore 78.3% (IC95 [66.4-86.9%]) for all positives and 88.9% (IC95 [76.7-95.4%]) for BBD patients. Its specificity is 85.5% (CI95 [79.2-90.1%]).

#### New LDBIO PEO tests global performances (ICT+WB):

**PEO ICT IgG IgM** and **PEO WB IgG** have a high level of performance and offer a new approach for the screening and confirmation of BBD and sensitized patients.

The combined use of these two techniques, screening by ICT and confirmation by WB, has a sensitivity of 87.5% and a specificity of 90.8% in the diagnosis of BBD.

<sup>3</sup> Evaluation of a rapid screening test (PEO ICT IgG IgM) and a confirmatory test (PEO WB IgG) for the serological diagnosis of bird breeders' lung disease. Serine Reguig<sup>1,2</sup>, Raphaël Piarroux<sup>1</sup>, Lise Slard<sup>3</sup>, Antoine Huguenin<sup>4,3</sup>, Rêgine Geers<sup>4,5</sup>, Dominique Aubert<sup>4,3</sup>, Christine Bouz<sup>3</sup>, Denis Limonne<sup>1</sup>, Isabelle Villena<sup>4,5</sup>. *SFP-SFMM congress.* 2022.

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T: 033 3321 2371 E: info@guadratech.co.uk





