

Performance of the kit *Echinococcus multilocularis* Bordier Affinity Products

Product name: Echinococcus multilocularis ELISA
Catalogue number: 9300
Manufacturer: Bordier Affinity Products SA

Purpose: In May 2016, a new Em2 antigen will replace the old Em2 antigen in the Em2-Em18 E. multilocularis ELISA kit. Preliminary tests were made to set the cut-off with this new antigen. This study was designed to compare the old kit and the new kit.

Cut-off value:

Cut-off OD value was intentionally decreased because the mean OD value of the negative and cross reaction samples has decreased as shown in the table below. It was designed in a study involving 310 serum samples.

	OD value Old kit	OD value New kit	Total samples
Negative samples mean OD value	0.327	0.110	228
Cross reaction samples mean OD value	0.556	0.243	43
Cross reaction E. granulosus samples mean OD value	0.655	0.271	16
E. multilocularis positive samples mean OD value	2.647	2.919	23
Total			310

Negative and positive control serum of the new kit were set to give the same OD values of the old kit control serum. We can see that the OD value of the cut-off has decreased in the table below.

	OD value Old kit	OD value New kit
Negative serum control (9300-06)	0.091	0.062
Cut-off serum control (9300-07)	0.838	0.547
Positive serum control (9300-08)	1.806	1.896

Analytical Performances:

The new version of the kit was tested in comparison to the old version using 531 serum samples.

Test group	Number tested	New kit positive	New kit negative
Old kit positive	144	133	11
Old kit negative	387	13	374

The **analytical sensitivity** of the new kit is **92.4%** compared to the old kit.
The **analytical specificity** of the new kit is **96.6%** compared to the old kit.

Repeatability:

Two human serum samples were tested 24 times on the same assay with the new kit.

	Sample 1	Sample 2
Average (OD value)	0.580	1.407
Standard deviation (OD value)	0.026	0.064
Variation coefficient (%)	4.5	4.6

Reproducibility:

The two human serum samples were tested 10 times on different days with the new kit.

	Sample 1	Sample 2
Average (OD value)	0.647	1.518
Standard deviation (OD value)	0.033	0.058
Variation coefficient (%)	5.1	3.8

Clinical Performance:

The new version of the kit was tested in comparison to the old version using 151 positive serum sample and 376 negative serum sample.

Test group	Number tested	Old kit		New kit	
		Positive	Negative	Positive	Negative
E. multilocularis positive case	151	123	28	125	26
Negative	267	6	261	6	261
Cross reaction	46	3	43	3	43
Cross reaction E. granulosus	63	10	53	10	53

Parameters	Old kit	New kit
Sensitivity (%)	81	83
Specificity (%) VS Negative	98	98
Specificity (%) VS cross reaction	93	93
Specificity (%) VS E. granulosus	84	84

Conclusion:

The new kit has close performance to the old kit and is acceptable for use.
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