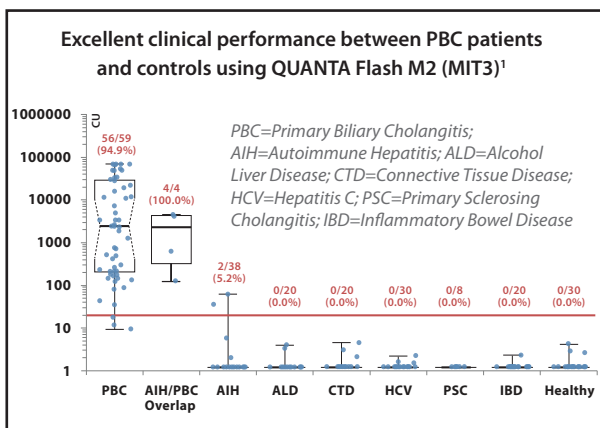




Differentiate

Excellent clinical performance when trying to differentiate autoimmune disease from other causes



- In the PBC patient population, QUANTA Flash M2 (MIT3) demonstrated excellent sensitivity and specificity with an odds ratio of 1530.7¹
- In the AIH-2 patient population, QUANTA Flash LKM-1 CIA displayed a specificity of 100% when HCV patients were excluded²
- QUANTA Flash liver assays show a high level of agreement between CIA and IIF AMA-M2 methods²

Excellent clinical performance with QUANTA Flash M2 (MIT3) in cohort of PBC patients and controls¹

- QUANTA Flash M2 (MIT3) uses a triple hybrid recombinant antigen that incorporates three immuno-dominant epitopes to PBC in one molecule³
- High level of agreement was found between CIA and IIF AMA-M2 methods¹

Clinical performance of QUANTA Flash M2 (MIT3)³

Clinical Analysis (N=407)		QUANTA Flash M2 (MIT3)			Analysis (95% confidence)
		Positive	Negative	Total	
Diagnosis	PBC	128	24	152	Sensitivity: 84.2% (77.6 - 89.2%)
	Controls	8	247	255	Specificity: 96.9% (93.9 - 98.4%)
	Total	136	271	407	

Increase diagnostic certainty in AIH by testing with QUANTA Flash LKM-1²

- In the AIH-2 patient population, QUANTA Flash LKM-1 CIA demonstrated a sensitivity of 50% combined with a specificity of 93% including HCV patients and specificity of 100% when HCV patients were excluded²
- Excellent agreement was found between CIA, IIF and immunoblot methods²

Clinical performance of QUANTA Flash LKM-1⁴

Clinical Analysis (N=334)		QUANTA Flash LKM-1			Analysis (95% confidence)
		Positive	Negative	Total	
Diagnosis	AIH-2	20	6	26	Sensitivity: 76.9% (56.4 - 91.0%)
	Controls [*]	8	300	308	Specificity: 97.4% (94.9 - 98.9%)
	Total	28	306	334	

*LKM-1 positivity has been described in patients with Hepatitis C virus infection (Hepatitis C virus N=20)

QUANTA Flash Liver Disease assays^{3,4}

Reference #	Test #	QUANTA Flash assay	Measuring range (CU)
701303	50 Test	QUANTA Flash M2 (MIT3)	1.2-3000
701298	50 Test	QUANTA Flash LKM-1	1.6-400

References

1. Garcia, M. et al. M2 (MIT3) Chemiluminescent immunoassay demonstrates reliable clinical performance in primary biliary cholangitis. 10th International Congress on Autoimmunity; 2016 Apr 6-10; Leipzig, Germany. 2. Garcia, M. et al. LKM-1 Chemiluminescent immunoassay demonstrates reliable clinical performance in autoimmune hepatitis. 10th International Congress on Autoimmunity; 2016 Apr 6-10; Leipzig, Germany. 3. QUANTA Flash M2 (MIT3) Direction Insert. 4. QUANTA Flash LKM-1 Direction Insert.

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