

Opportunities for and barriers to omics-based biomarker discovery in steatotic liver diseases

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Table of contents

<i>nordicPRO-C3™</i>	2
Regulatory milestone.....	2
References	2
Enhanced Liver Fibrosis (ELF) test.....	3
Regulatory milestones.....	3
References	3
FibroScan	5
Regulatory milestones.....	5
References	5

nordicPRO-C3™

Regulatory milestone

Year	Description
2019	A letter of intent accepted by the FDA for <i>nordicPRO-C3™</i> as a diagnostic marker

References

Year	Context of use	Aetiology	Reference
2013	Diagnostic	ALD	Leeming et al. Alimentary Pharmacology & Therapeutics DOI: 10.1111/apt.12484
2014	Diagnostic	HCV/HIV co-infection	Jansen et al. PLoS One DOI: 10.1371/journal.pone.0108544
2015	Diagnostic/Prognostic	HCV	Nielsen et al. Liver Int. DOI: 10.1111/liv.12700
2018	Prognostic	PSC	Nielsen et al. Alimentary Pharmacology & Therapeutics DOI: 10.1111/apt.14806
2019	Diagnostic	T2D	F. Bril et al. Diabetes Care DOI: 10.2337/dc18-2578
2019	Secondary endpoint	MASH	S.A. Harrison et al. Lancet DOI: 10.1016/S0140-6736(19)32517-6
2019	Diagnostic	MASLD	S. J. Daniels et al. Hepatology DOI: 10.1002/oby.22344
2019	Diagnostic	MASLD	M. Boyle et al JHEP Reports DOI: 10.1016/j.jhepr.2019.06.004
2021	Diagnostic	ALD	B. S. Madsen et al. AP&T DOI: 10.1111/apt.16513
2021	Diagnostic	MASLD/MASH	P.B. Lassen et al. J of Clinical Endocrinology & Metabolism DOI: 10.1210/clinem/dgab897
2021	Diagnosis (systemic review)	MASLD	Mak et al. Biomedicines DOI: 10.3390/biomedicines9121920
2021	Trial inclusion (diagnostic)	MASH	M.J. Nielsen et al. Journal of Hepatology DOI: 10.1016/j.jhep.2021.08.016
2022	Diagnostic	MASLD	L Tang et al. Hepatology International DOI: 10.1007/s12072-022-10420-w
2022	Diagnostic	MASLD	L Tang et al. Metabolism Clinical and Experimental DOI: 10.1016/j.metabol.2021.154958.
2023	Screening (diagnostic)	NAFLD/NASH	Y. Vali et al. (LITMUS) Lancet Gastro Hep DOI: 10.1016/S2468-1253(23)00017-1

2023	Prognostic	ALD	S. Johansen et al. Liver International DOI: 10.1111/liv.15595
2023	Diagnostic and monitoring	MASLD	A. Armandi et al. J of Clinical Medicine DOI: 10.3390/jcm12020650
2023	Prognostic	HCV and a mixed cohort	M. J. Nielsen et al. JHEP reports DOI: 10.1016/j.jhepr.2023.100743

Enhanced Liver Fibrosis (ELF) test

Regulatory milestones

Year	Description
2004	Publication in Gastro with ELF measured on Immuno 1 platform
2011	CE mark. The first time ELF was commercially available for sale as an in vitro diagnostic device
2021	Approved by the FDA as a prognostic marker

References

Year	Context of use	Aetiology	Reference
2004	Diagnostic	Mixed	Rosenberg et al. Gastroenterology DOI: 10.1053/j.gastro.2004.08.052
2008	Diagnostic	MASLD	Guha et al. Hepatology DOI: 10.1002/hep.21984
2008	Prognostic	PBC	Mayo et al. Hepatology DOI: 10.1002/hep.22517
2009	Diagnostic	MASLD	Nobili et al. Gastroenterology DOI: 10.1053/j.gastro.2008.09.013
2010	Diagnostic	Mixed	Friedrich-Rust et al. BMC Gastroenterol DOI: 10.1186/1471-230X-10-103
2010	Prognostic	Mixed	Parkes et al. Gut DOI: 10.1136/gut.2009.203166
2011	Diagnostic	HCV	Parkes et al. J Viral Hepat DOI: 10.1111/j.1365-2893.2009.01263.x
2012	Diagnostic	HBV	Kim et al. PLoS One DOI: 10.1371/journal.pone.0041964
2013	Diagnostic / Normal Range	HCV	Lichtinghagen et al. J Hepatol DOI: 10.1016/j.jhep.2013.03.016
2013	Normal Range	---	Yoo et al. Liver Int. DOI: 10.1111/liv.12136
2014	Prognostic	HBV	Kim et al. Hepatology

			DOI: 10.1002/hep.27389
2015	Diagnostic	Mixed	Fagan et al. Liver Int. DOI: 10.1111/liv.12760
2015	Prognostic	PSC	Vesterhus et al. Hepatology DOI: 10.1002/hep.27825
2016	Prognostic	Mixed	Irvine et al. Liver Int. DOI: 10.1111/liv.12896
2016	Diagnostic	MASLD	NICE guideline NG49 https://www.nice.org.uk/guidance/ng49
2016	Prognostic	HIV/HCV	Peters et al. AIDS DOI: 10.1097/QAD.0000000000000975
2016	Prognostic	HCV	Puigvehí et al. PLoS One DOI: 10.1371/journal.pone.0164883
2017	Prognostic	PSC	de Vries et al. Liver Int. DOI: 10.1111/liv.13402
2017	Diagnostic	MASLD	Miele et al. Int J Biol Markers DOI: 10.5301/ijbm.5000292
2018	Prognostic	Mixed	Loo et al. Clin Chem DOI: 10.1373/clinchem.2018.289108
2018	Diagnostic	ALD	Thiele et al. Gastroenterology DOI: 10.1053/j.gastro.2018.01.005
2019	Diagnostic	MASLD	Anstee et al. Hepatology DOI: 10.1002/hep.30842
2019	Diagnostic/Prognostic	Mixed	Day et al. J Appl Lab Med DOI: 10.1373/jalm.2018.027359
2019	Prognostic	HBV	Liang et al. Aliment Pharmacol Ther. DOI: 10.1111/apt.15269
2019	Prognostic	PSC	Muir et al. Hepatology DOI: 10.1002/hep.30237
2019	Prognostic	MASLD	Sanyal et al. Hepatology DOI: 10.1002/hep.30664
2019	Diagnostic	MASLD	Srivastava et al. J Hepatol. DOI: 10.1016/j.jhep.2019.03033
2019	Prognostic	MASLD	Younossi et al. Clin Gastroenterol Hepatol. DOI: 10.1016/j.cgh.2019.02.024
2020	Prognostic	Mixed	Trembling et al. BMC Gastroenterol. DOI: 10.1186/s12876-020-01251-w
2021	Prognostic	MASLD	Are et al. Clin Gastroenterol Hepatol. DOI: 10.1016/j.cgh.2020.06.070

2021	Diagnostic/Prognostic	ALD	Connoley et al. BMC Gastroenterol. DOI: 10.1186/s12876-021-01795-5
2021	Prognostic	ALD	Rasmussen et al. J Hepatol. DOI: 10.1016/j.jhep.2021.05.037
2021	Screening	ALD	Rhodes et al. BMC Gastroenterol. DOI: 10.1186/s12876-021-01728-2
2021	Monitoring	PSC	Trivedi et al. Clin Gastroenterol Hepatol. DOI: 10.1016/j.cgh.2020.07.032
2021	Prognostic	MASLD	Younossi et al. Gastroenterology. DOI: 10.1053/j.gastro.2020.12.003
2022	Screening	Mixed	Åberg et al. United European Gastroenterol J. DOI: 10.1002/ueg2.12323
2022	Prognostic	MASLD	Johnson et al. Hepatol Commun. DOI: 10.1002/hep4.1852
2022	Monitoring	MASLD	Rinella et al. J Hepatol. DOI: 10.1016/j.jhep.2021.10.029
2022	Prognostic/Monitoring	MASLD	Sanyal et al. Hepatology. DOI: 10.1002/hep.32204
2022	Diagnostic	MASLD	Younossi et al. Aliment Pharmacol Ther. DOI: 10.1111/apt.17346
2023	Normal Range (Diagnostic)	---	Palladino et al. Clin Chim Acta. DOI: 10.1016/j.cca.2023.117461
2023	Prognostic	Mixed	Saarinén et al. JHEP Rep. DOI: 10.1016/j.jhepr.2023.100765
2023	Diagnostic	MASLD	Sanyal et al. Nat Med. DOI: 10.1038/s41591-023-02539-6
2024	Diagnostic/Prognostic	MASLD	Rinella et al. Hepatology DOI: 10.1097/HEP.0000000000000323

FibroScan

Regulatory milestones

Year	Description
2003	CE mark as a class IIa medical device
2013	First 510(k) FDA clearance for FibroScan medical device

References

Year	Context of use	Aetiology	Reference
2003	Diagnostic	HCV	Sandrin et al. Ultrasound in Medicine & Biology

			DOI: 10.1016/j.ultrasmedbio.2003.07.001
2006	Diagnostic	Mixed	Foucher et al. Gut DOI: 10.1136/gut.2005.069153
2007	Diagnostic	Mixed	Talwalkar et al. Clin Gastroenterol Hepatol DOI: 10.1016/j.cgh.2007.07.020
2008	Diagnostic	Mixed	Friedrich-Rust et al. Gastroenterology DOI: 10.1053/j.gastro.2008.01.034
2009	Monitoring	HCV	Vergniol et al. J Viral Hepat DOI: 10.1111/j.1365-2893.2008.01055.x
2010	Diagnostic	MASLD	Wong et al. Hepatology DOI: 10.1002/hep.23312
2011	Prognostic	HCV	Vergniol et al. Gastroenterology DOI: 10.1053/j.gastro.2011.02.058
2013	Prognostic	HBV	Ledinghen et al. Aliment Pharmacol Ther DOI: 10.1111/apt.12307
2014	Monitoring	HCV	Vergniol et al. Hepatology DOI: 10.1002/hep.27069
2014	Monitoring	HBV	Jang et al. Clin Res Hepatol Gastroenterol DOI: 10.1016/j.clinre.2013.10.003
2016	Prognostic	MASLD	Boursier et al. Journal of Hepatology DOI: 10.1016/j.jhep.2016.04.023
2018	Monitoring	HBV	Wu et al. Liver International DOI: 10.1111/liv.13623
2018	Monitoring	HBV	Liang et al. J Viral Hepat DOI: 10.1111/jvh.12814
2018	Monitoring	HBV	Li et al. Clinical and Experimental Medicine DOI: 10.1007/s10238-018-0486-5
2018	Diagnostic	ALD	Nguyen-Khac et al. Lancet Gastroenterol & Hepatol DOI: 10.1016/S2468-1253(18)30124-9
2019	Diagnostic	MASLD	Siddiqui et al. Clin Gastroenterol Hepatol DOI: 10.1016/j.cgh.2018.04.043
2019	Diagnostic	MASLD	Eddowes et al. Gastroenterology DOI: 10.1053/j.gastro.2019.01.042
2020	Diagnostic	Mixed	Papatheodoridi et al. Journal of Hepatology DOI: 10.1016/j.jhep.2020.11.050
2020	Prognostic	MASLD	Petta et al. Clin Gastroenterol Hepatol DOI: 10.1016/j.cgh.2020.06.045
2020	Monitoring	MASH	Harrison et al. Journal of Hepatology

			DOI: 10.1016/j.jhep.2020.02.027
2020	Monitoring	MASH	Newsome et al. New England Journal of Medicine DOI: 10.1056/NEJMoa2028395
2021	Monitoring	MASH	Rinella et al. Journal of Hepatology DOI: 10.1016/j.jhep.2021.10.029
2021	Prognostic	MASH	Sanyal et al. Hepatology DOI: 10.1002/hep.32204
2021	Diagnostic	MASLD	Mòzes et al. Gut DOI: 10.1136/gutjnl-2021-324243
2022	Diagnostic	MASLD	Sanyal et al. Journal of Hepatology DOI: 10.1016/j.jhep.2022.10.034
2022	Prognostic	MASH	Loomba et al. Gut DOI: 10.1136/gutjnl-2022-327777
2022	Monitoring	MASH	Alkhouri et al. Journal of Hepatology DOI: 10.1016/j.jhep.2022.04.003
2023	Monitoring	MASH	Sanyal et al. Journal of Hepatology DOI: 10.1016/j.jhep.2023.07.014
2023	Prognostic	MASLD	Mòzes et al. Lancet Gastroenterol & Hepatol DOI: 10.1016/S2468-1253(23)00141-3
2023	Diagnostic	MASLD	Vali et al. Lancet Gastroenterol & Hepatol DOI: 10.1016/S2468-1253(23)00017-1