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YEARS OF IMPACT

We're just
getting started.

Comparative evaluation of the diagnostic accuracy of point-of- care anti-HCV antibody tests for hepatitis C infection

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The Kirby Institute at UNSW Sydney is located on the Traditional Lands of the Bidjigal peoples.

We acknowledge the Traditional Owners of Country throughout Australia, and First Nations people's continuing connection to culture, land, sea, waters, and community.

We pay our respects to Elders, both past and present.

Disclosures

- The Kirby Institute is funded by the Australian Government Department of Health and Ageing. The views expressed in this publication do not necessarily represent the position of the Australian Government.
- MM is supported by an NHMRC Investigator Grant.
- ETHOS: NHMRC Partnership Grant
- SIMPLIFY: Gilead Sciences Inc – investigator-initiated research grant
- D3FEAT and TARGET3D: Abbvie – investigator initiated research grant

Background

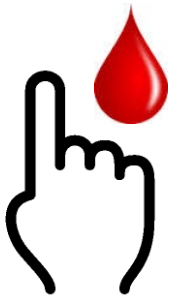


- Evaluation of point-of-care HCV antibody diagnostic accuracy is required in real-world settings and key populations.
- Diagnostic performance may be affected by individual characteristics (infection status, treatment history).

Clinician
feedback
**False
negative
tests?**

Aim: To compare the diagnostic performance of two fingerstick point-of-care HCV antibody assays (SD Bioline HCV, INSTI HCV Antibody Test) with standard of care (Abbott Alinity i)

Methods: Diagnostic performance



ETHOS II

Jun 2024 - Aug 2025



Apr 2016 - Dec 2020

Prospective real-world cohort of people who inject drugs
Paired fingerstick whole blood (point-of-care HCV Ab + RNA)
+
venepuncture plasma (lab HCV antibody + RNA)
N=398

Three clinical trials – acute and chronic HCV
Stored venepuncture plasma
prior and following DAA treatment
(point-of-care HCV Ab + lab HCV Ab + RNA)
N=159

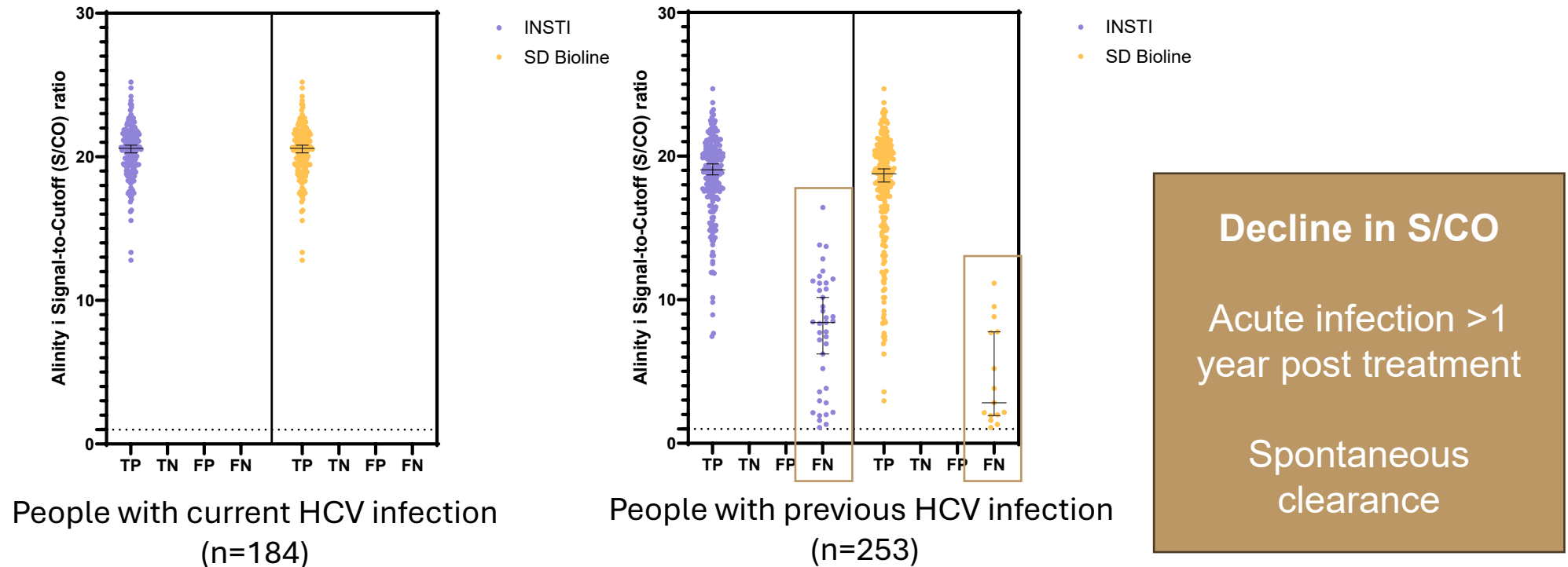
Diagnostic performance of point-of-care assays compared with lab testing.
Probit regression assessed performance by lab reference signal-to-cutoff ratio (S/CO).

Results: Performance characteristics – ETHOS (n=398)

SD Bioline and INSTI HCV Ab compared to Abbott Alinity i

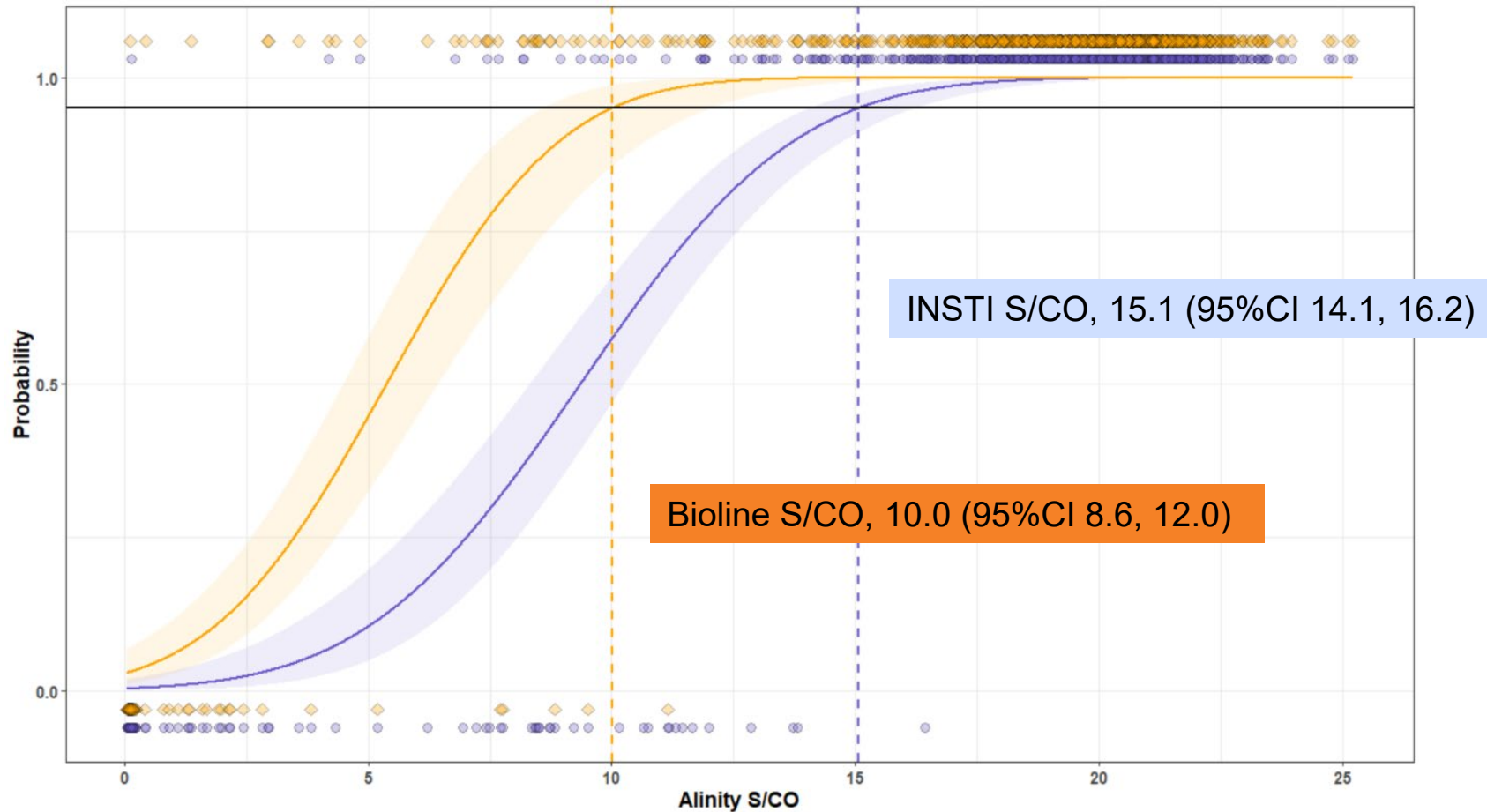
	TN n	TP n	FN n	FP n	Sensitivity % (95%CI)	Specificity % (95%CI)	PPV % (95%CI)	NPV % (95%CI)
All; HCV antibody prevalence, 70%								
SD Bioline	119	262	16	1	94% (91%, 97%)	100% (95%, 100%)	100% (98%, 100%)	88% (82%, 93%)
INSTI HCV Ab	120	239	39	0	86% (81%, 90%)	100% (97%, 100%)	100% (99%, 100%)	76% (68%, 82%)
Current HCV infection (HCV RNA detected); HCV antibody prevalence, 100%								
SD Bioline	-	25	0	-	100% (86%, 100%)	-	100% (86%, 100%)	Stored samples, n=159 Sensitivity, 100%
INSTI HCV Ab	-	25	0	-	100% (86%, 100%)	-	100% (86%, 100%)	
Past HCV infection (HCV RNA not detected); HCV antibody prevalence, 100%								
SD Bioline	-	237	16	-	94% (90%, 96%)		100% (99%, 100%)	
INSTI HCV Ab	-	214	39	-	85% (80%, 89%)		100% (98%, 100%)	

Results: Comparative diagnostic performance



Comparative diagnostic performance of SD Bioline and INSTI HCV Ab test
by Alinity i anti-HCV antibody titre

Results: Comparative diagnostic performance



Difference in diagnostic performance between SD Bioline and INSTI using Probit regression.

Conclusion

- In comparison with Abbott Alinity i, both point-of-care HCV antibody assays, SD Bioline HCV and INSTI HCV Antibody Test, demonstrated:
 - High specificity (>99%)
 - Lower sensitivity (SD Bioline > INSTI): Importance of HCV Ab titre (S/CO)
- Excellent sensitivity among people with current HCV infection (100%)
 - Accurately identify all participants who would require treatment.
- Implications: Individual (current HCV diagnosis) vs population (surveillance)?
- Right test, right person, right setting



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Results: Enrolment characteristics

Baseline characteristics	All N=557	ETHOS N=398	SIMPLIFY N=71	DEFEAT N=69	TARGET3D N=19
Median age (IQR)	46 (39, 53)	46 (39, 53)	49 (43, 53)	49 (43, 55)	44 (28, 55)
Female, n (%)	149 (27)	113 (28)	19 (27)	15 (22)	2 (11)
Current OAT, n (%)	347 (62)	247 (62)	46 (65)	54 (78)	0 (0)
Ever incarcerated, n (%)	348 (62)	281 (71)	35 (49)	32 (46)	0 (0)
Injected drugs ever, n (%)	551 (99)	398 (100)	71 (100)	69 (100)	13 (68)
Injected drugs last month, n (%)	371 (67)	280 (70)	54 (76)	32 (46)	5 (26)
History of HCV treatment, n (%)	190 (34)	189 (48)	0 (0)	0 (0)	1 (5)
HCV Ab - reference, n (%)	437 (78)	278 (70)	71 (100)	69 (100)	19 (100)
HCV RNA, n (%)	184 (33)	25 (6)	71 (100)	69 (100)	19 (100)