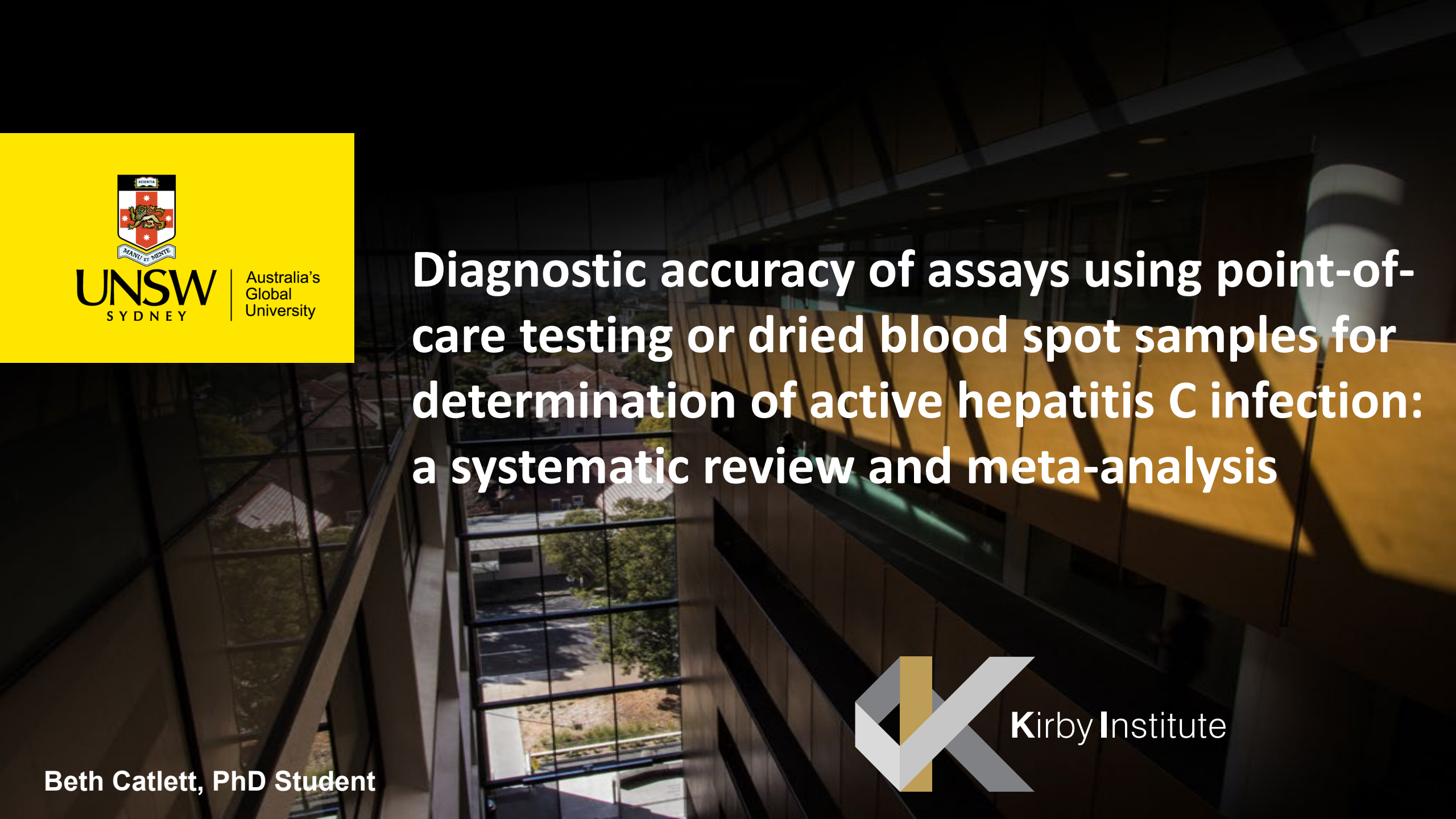

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Diagnostic accuracy of assays using point-of-care testing or dried blood spot samples for determination of active hepatitis C infection: a systematic review and meta-analysis

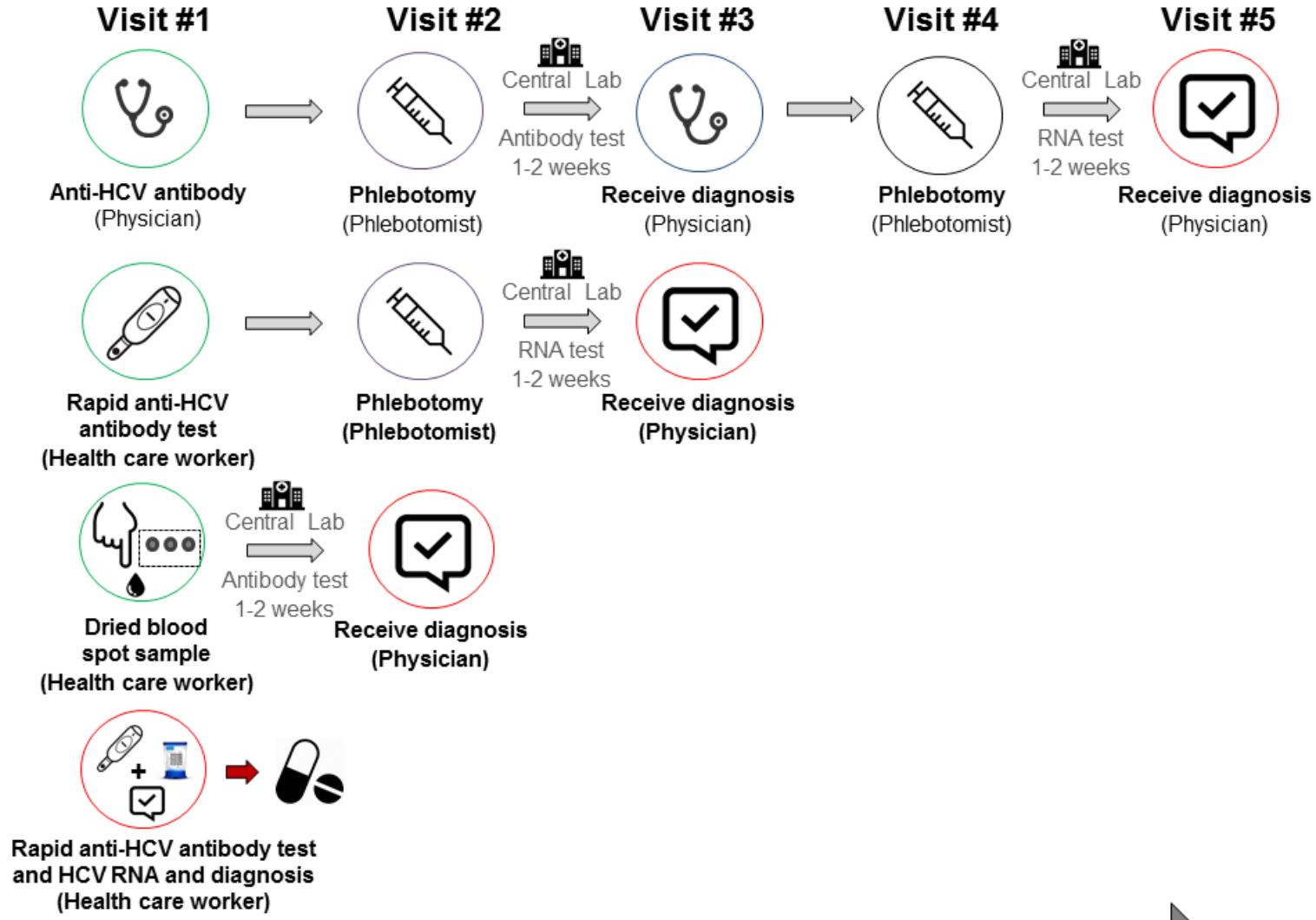
Beth Catlett, PhD Student

Kirby Institute

DECLARATION OF INTEREST

No declaration of interest to declare

Simplifying Hepatitis C Diagnosis



Grebely J, et al Exp Rev Mol Diag 2017

AIM

Assess diagnostic accuracy of assays that use point-of-care testing or dried blood spot samples to detect hepatitis C infection when compared to assays that use plasma, serum, or whole blood samples.

METHODS

- Searches were conducted using MEDLINE, Scopus, Web of Science, Cochrane Central Register of Controlled Trials, PsycINFO and MedRxiv.
- Data was screened and extracted in Covidence.
- Heterogeneity of outcome measures across studies was assessed using a bivariate mixed-effects regression analysis.
- A meta-analysis was conducted in Stata (v14.2) to pool the estimates of odds ratios (based on heterogeneity).
- Risk of bias was assessed using the QUADAS-2 critical appraisal tool.

RESULTS

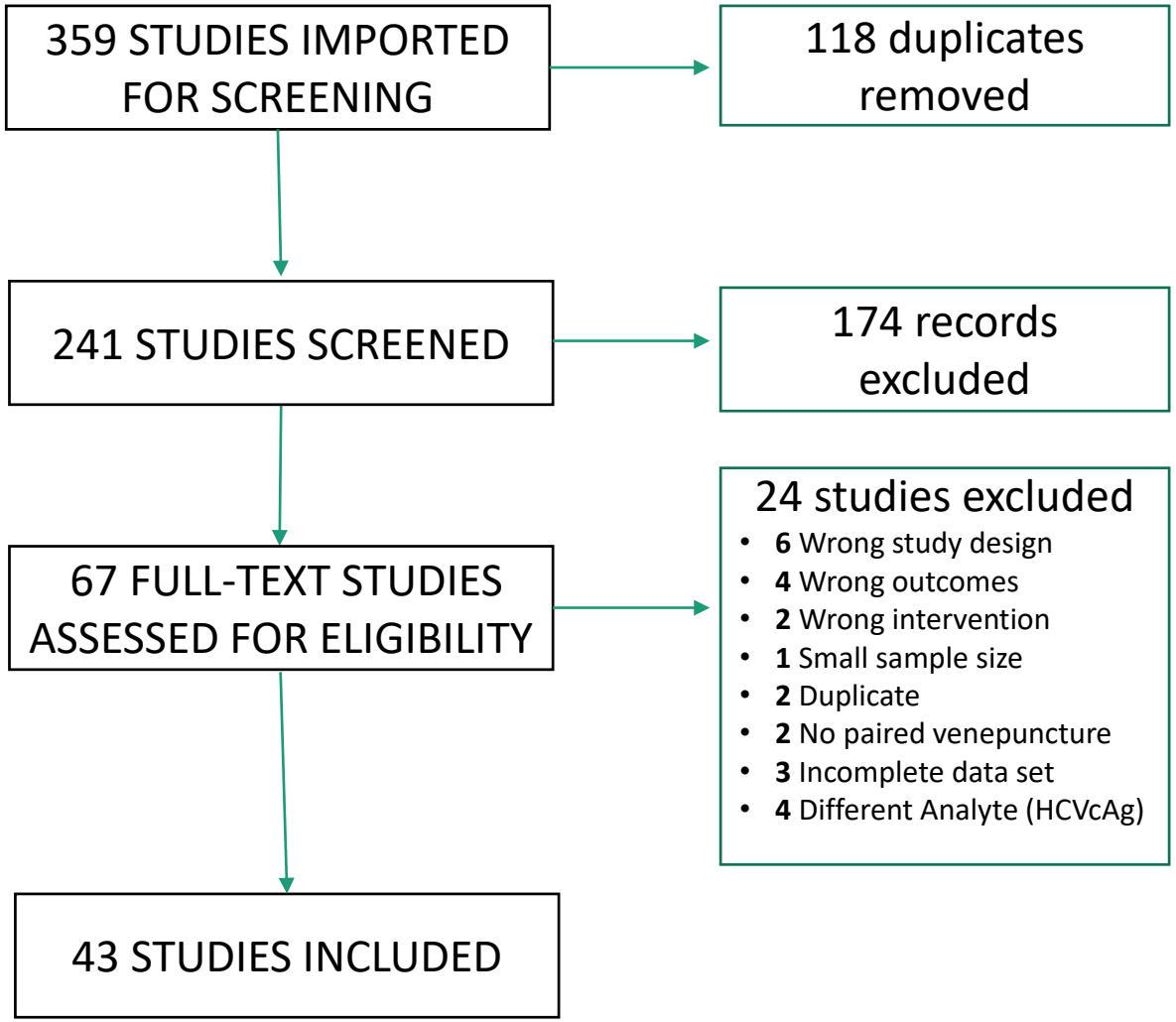


Figure 1. PRISMA FLOW DIAGRAM

RESULTS

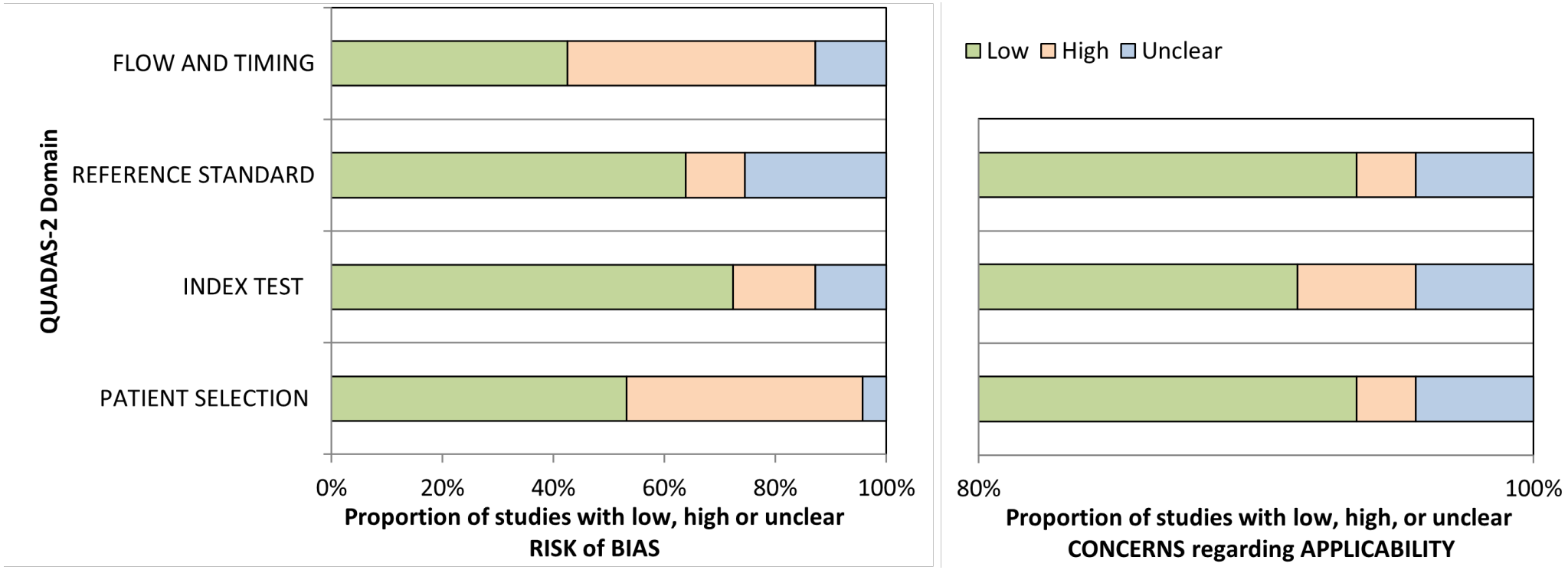
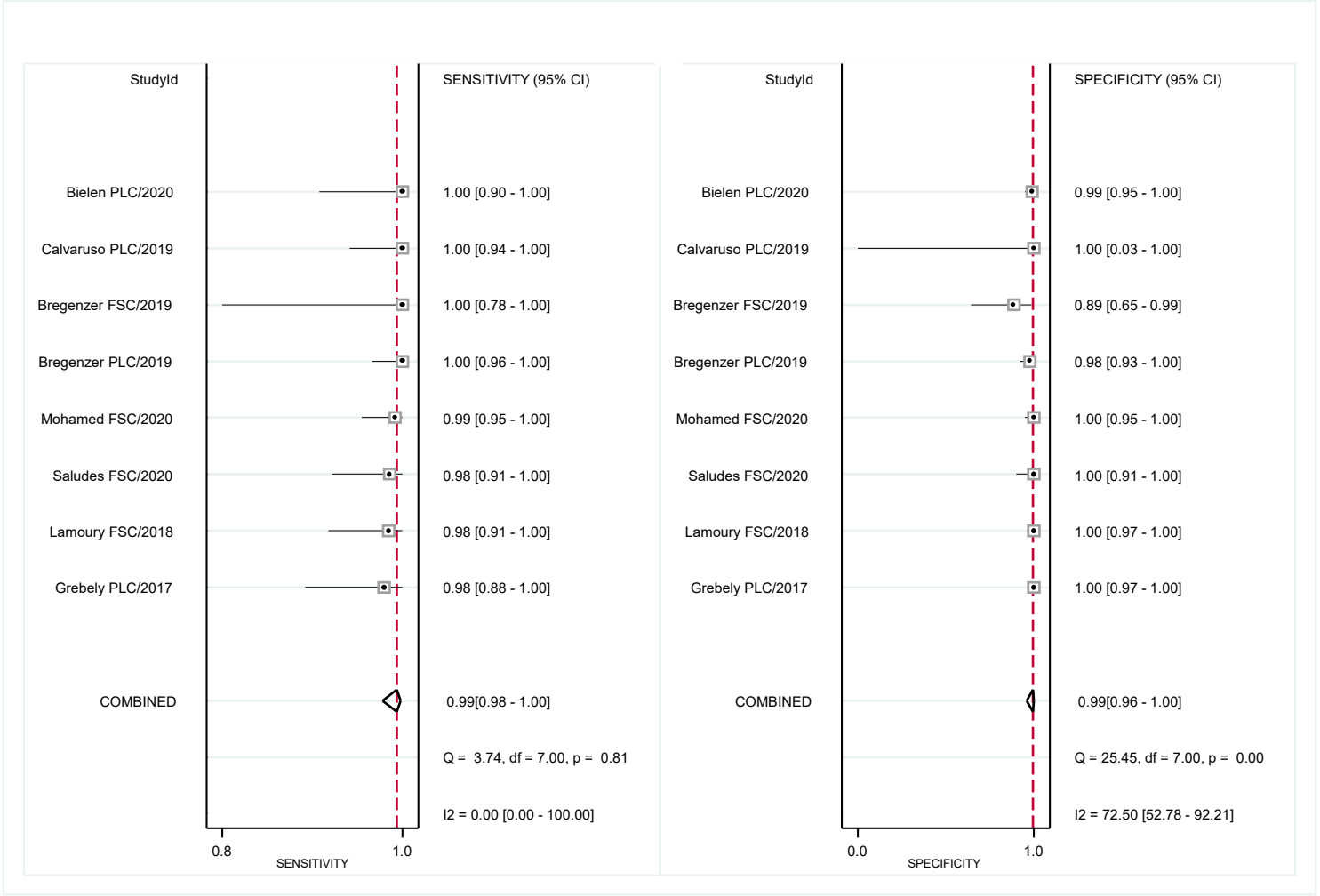


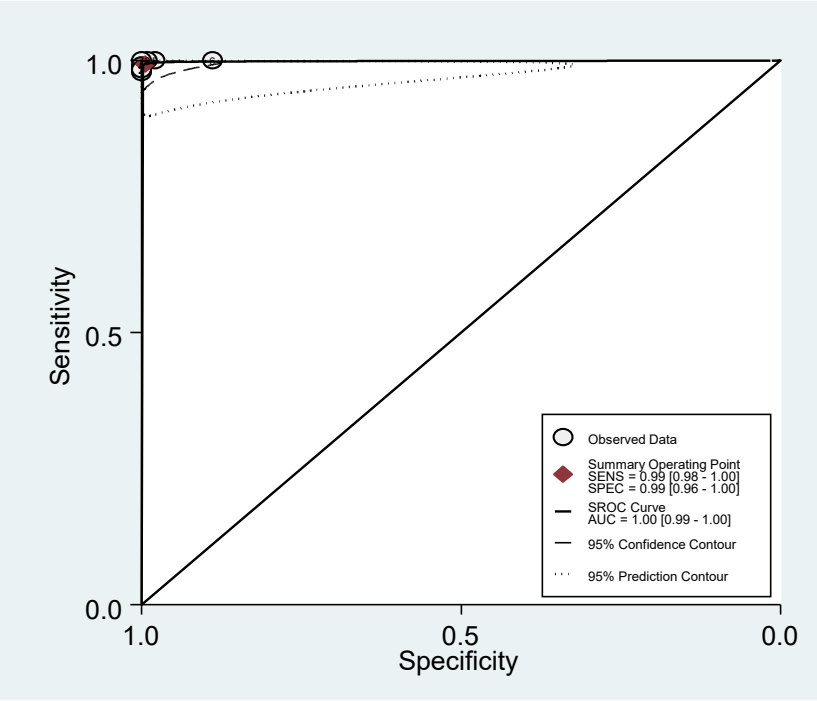
Figure 2. Graphical Display for Risk of Bias QUADAS-2 results

RESULTS

	Overall HCV RNA testing (K=43)	
	k (%)	n (%)
Study design		
Clinical Trial	1 (2)	100 (1)
Cohort Study	22 (52)	4077 (46)
Laboratory Based	8 (19)	1032 (12)
Case-Control Study	1 (2)	925 (11)
Cross-Sectional Study	6 (14)	1690 (19)
Prospective Study	5 (11)	980 (11)
Study setting		
Hospital	5 (12)	1940 (22)
Hospital outpatient/ tertiary clinic	16 (37)	2545 (29)
Drug treatment	3 (7)	297 (3)
NSP	1 (2)	51 (1)
Multiple Settings	4 (9)	1288 (15)
Other	14 (33)	2683 (30)
Population		
General population	8 (19)	2313 (26)
HIV/HCV coinfection	1 (2)	25 (0)
People who inject drugs	9 (21)	2006 (23)
People who use drugs	1 (2)	51 (1)
People receiving OAT	1 (2)	147 (2)
Mixed Populations	3 (7)	371 (4)
Other	20 (47)	3891 (44)
Country income status		
Low income	0 (0)	0 (0)
Lower-middle income	9 (20)	2933 (33)
Upper-middle income	3 (7)	278 (3)
High income	31 (73)	5593 (64)

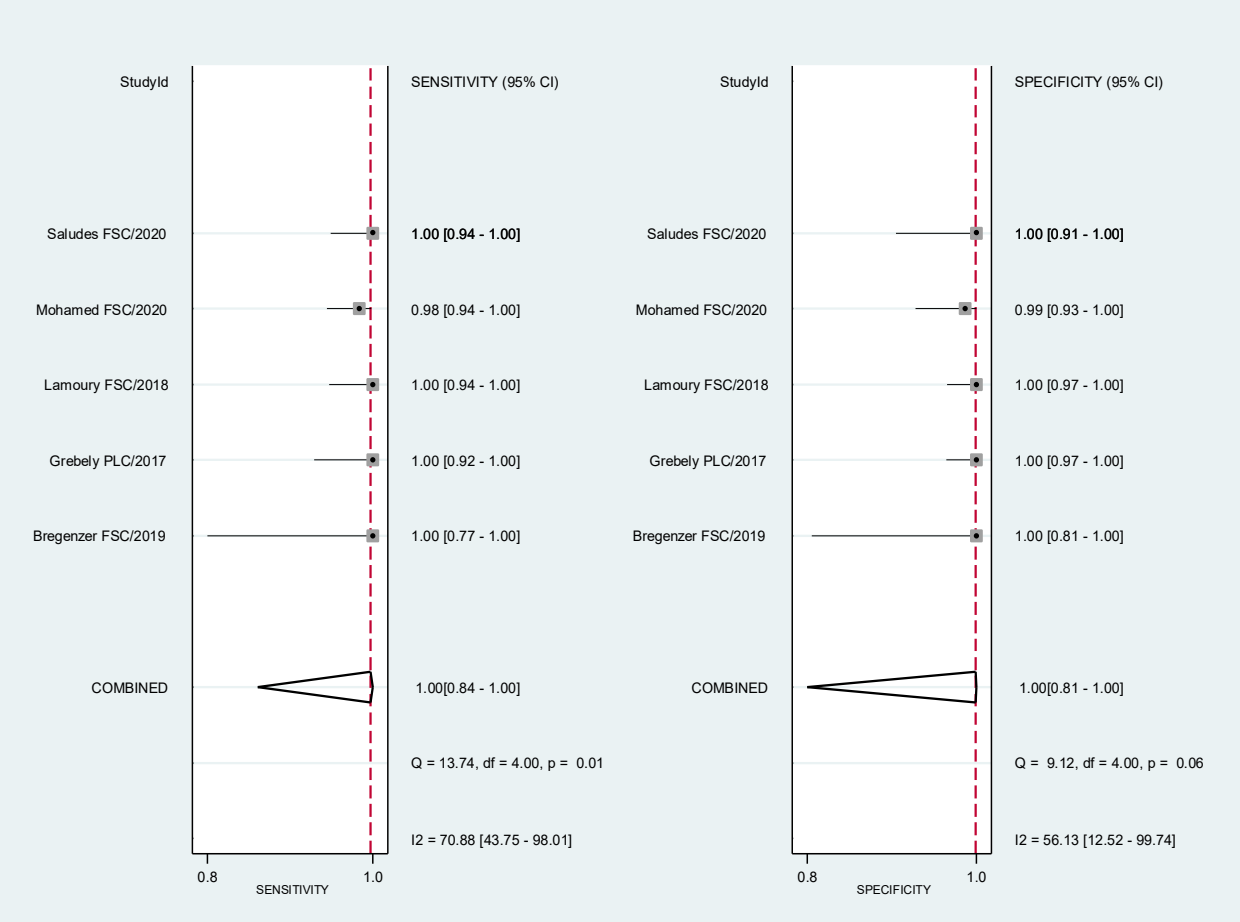
Analysis of hepatitis C RNA detection in Finger-stick point of care testing compared to venous blood sample

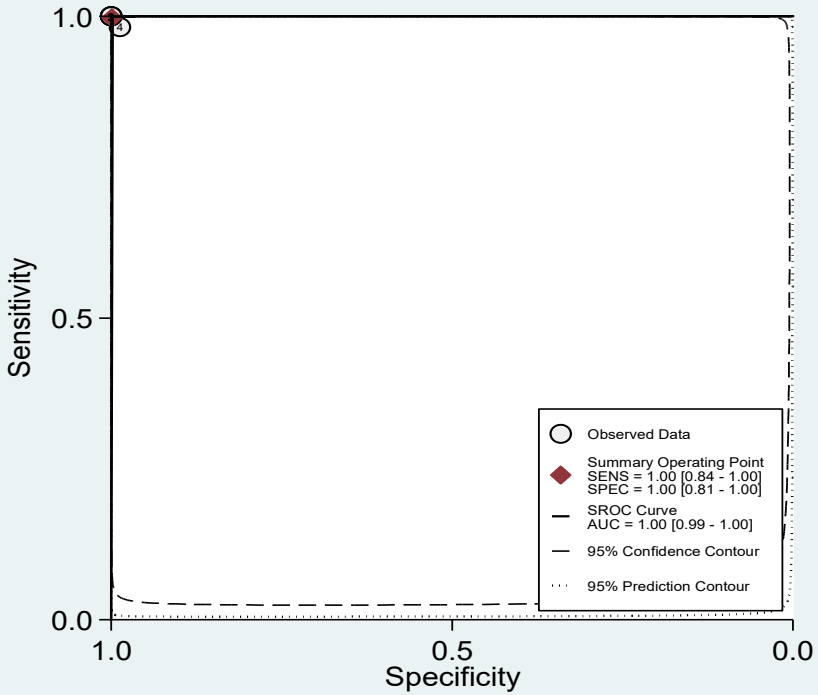




Sen 99% (98-100%)
Spec 99% (96-100%)

Analysis of hepatitis C RNA quantification in Finger-stick point of care testing vs. venous blood samples





Sen 100% (84-100%)
Spec 100% (81-100%)

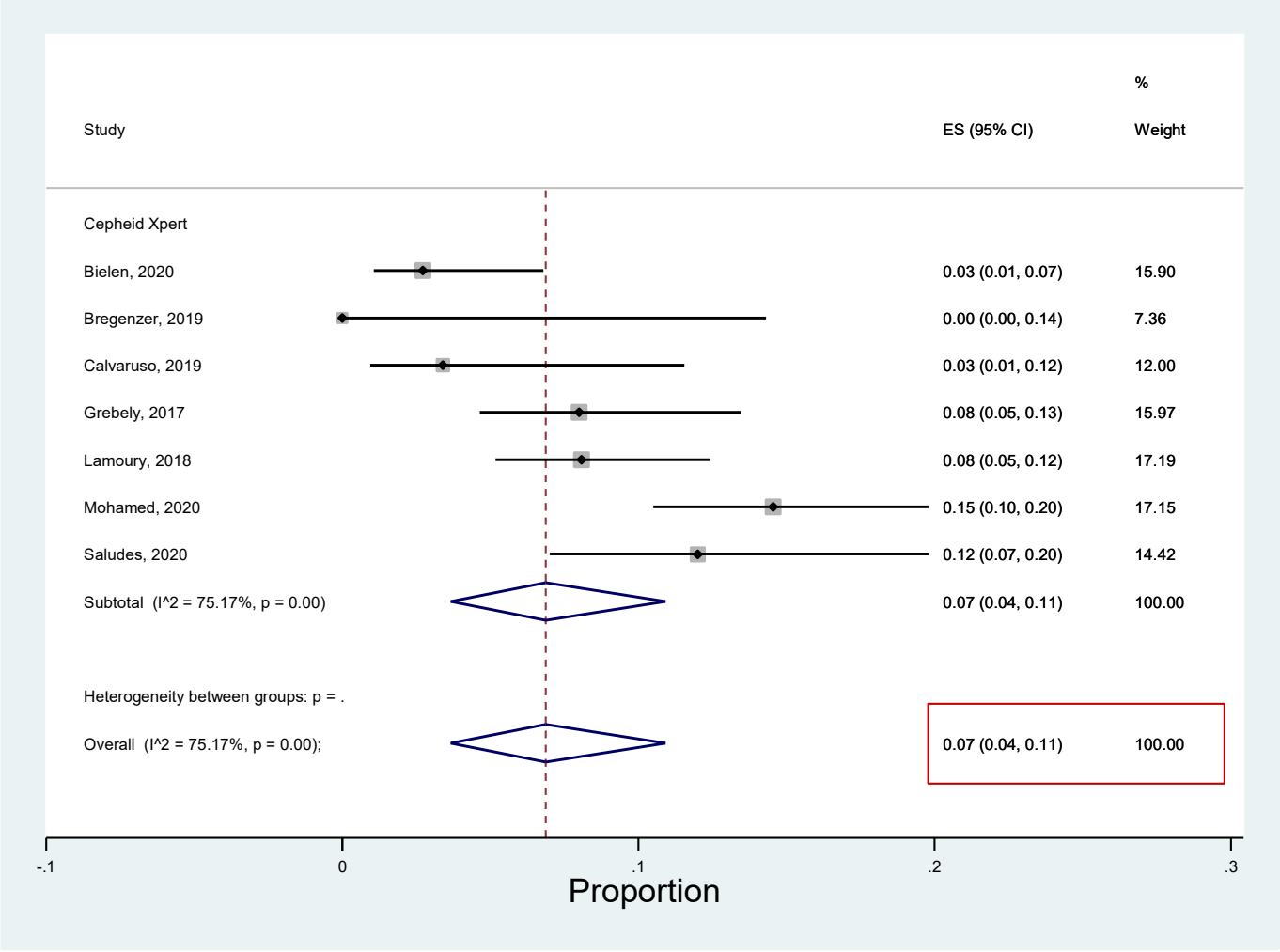
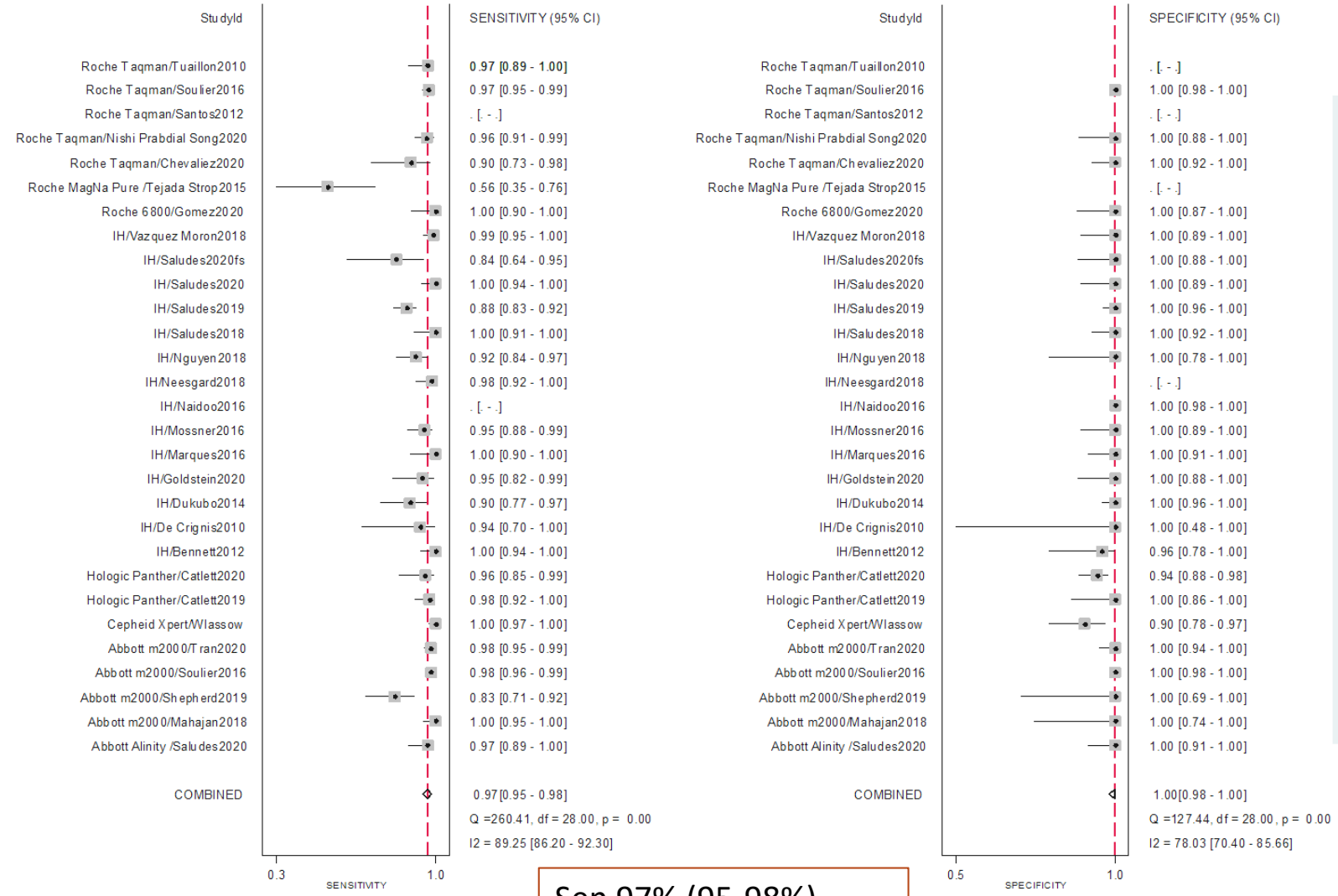
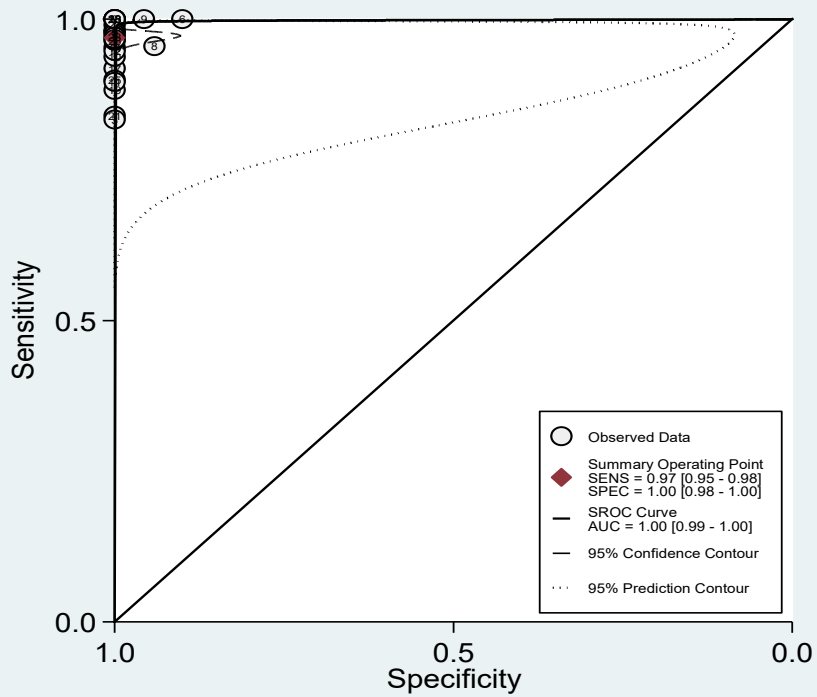


Figure 3: Forrest plot of proportion of invalid results among Hepatitis C RNA Finger-stick POC testing **ES = proportion invalid

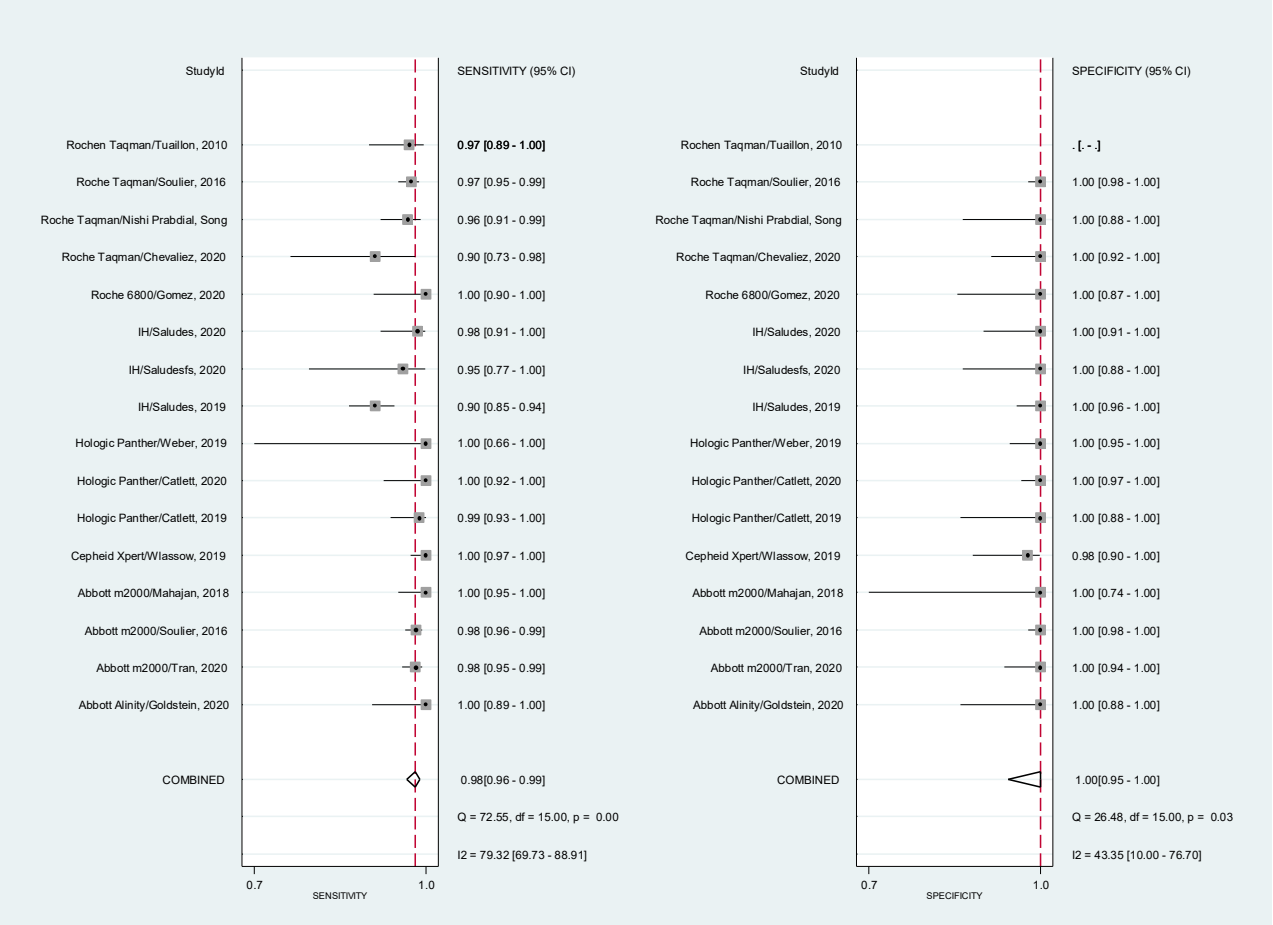
Analysis of hepatitis C RNA detection in DBS vs. venous blood samples

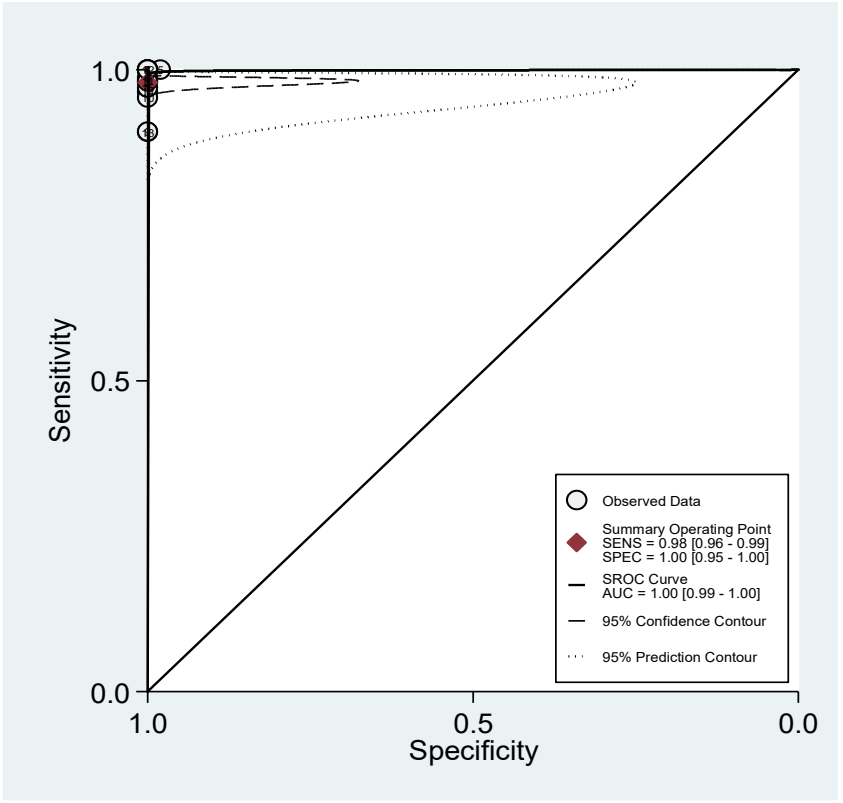




Sen 97% (95-98%)
Spec 100% (98-100%)

Analysis of hepatitis C RNA quantification in DBS vs. venous blood samples





Sen 98% (96-99%)
Spec 100% (95-100%)

DISCUSSION

- Good diagnostic accuracy observed across assays that detect HCV RNA using finger-stick and DBS sample types.
- However, standardization of sample elution methods and assay protocols (in-house) is lacking for HCV RNA DBS testing.
- The relatively high proportion of invalid results among finger-stick capillary samples is concerning and requires further research to determine best practice for sample collection and instrument operator training.
- Assay validation and registration with governing bodies for DBS use with commercial of the shelf assays or in-house methods required.

ACKNOWLEDGEMENTS

Hajarizadeh B
Wheeler A
Bharat C
Cunningham E
Dore GJ
Applegate TA
Grebely J

Cunningham P

International Collaborators
Wolfson-Stofko B
Khandaker-Hussain B *(Macquarie University, Sydney)*
Feld J *(Viral Hepatitis Care Network, University Health Network, Toronto, Canada)*
Martró E *(Microbiology Department, Laboratori Clínic Metropolitana Nord, Hospital Universitari Germans Trias i Pujol, Institut d'Investigació Germans Trias i Pujol (IGTP), Badalona (Barcelona), Spain)*
Chevaliez S (*French National Reference Centre for viral hepatitis B, C and Delta, Department of Virology, Hôpital Henri Mondor, Université Paris-Est, Créteil)*
Pawlotsky JM *(French National Reference Centre for viral hepatitis B, C and Delta, Department of Virology, Hôpital Henri Mondor, Université Paris-Est, Créteil)*