



**Table SIII.** Quality assessment of included studies based on the QUADAS-2 tool.

First author/s, year	Risk of bias				Applicability concerns			Justification	(Refs.)
	Patient selection	Index test	Reference standard	Flow and timing	Patient selection	Index test	Reference standard		
Menéndez-Valladares <i>et al</i> , 2015	H	L	L	L	L	L	L	Predefined HbA1c ranges; potential selection bias	(26)
Criel <i>et al</i> , 2016	H	L	L	L	L	L	L	Predefined HbA1c ranges; potential selection bias	(11)
Grant <i>et al</i> , 2017	L	L	L	L	L	L	L	Consecutive sampling; low risk of selection bias	(12)
Wang <i>et al</i> , 2018	L	L	L	L	L	L	L	Consecutive sampling; low risk of selection bias	(27)
Dupuy <i>et al</i> , 2019	UR	L	L	L	L	L	L	Sampling procedure not reported; unclear selection bias	(28)
Dubach <i>et al</i> , 2019	L	L	L	L	L	L	L	Consecutive sampling; low risk of selection bias	(29)
Guadalupe Vargas <i>et al</i> , 2020	UR	L	L	L	L	L	L	Sampling procedure not reported; unclear selection bias	(30)
Şahingöz Erdal <i>et al</i> , 2019	H	L	L	L	L	L	L	Selected clinical population; limited representativeness	(31)
Toro-Crespo <i>et al</i> , 2017	H	L	L	L	L	L	L	Predefined HbA1c ranges; potential selection bias	(32)
Rathod <i>et al</i> , 2024	L	L	L	L	L	L	L	Consecutive sampling; low risk of selection bias	(33)
Saxton <i>et al</i> , 2018	L	L	L	L	L	L	L	Consecutive sampling; low risk of selection bias	(34)

Risk of bias was assessed across four domains: Patient selection, index test, reference standard, and flow and timing. Patient selection was the primary source of potential bias, with several studies judged as high or unclear risk due to the use of predefined HbA1c ranges, recruitment from specific clinical populations, or insufficient reporting of sampling procedures. By contrast, the domains of index test, reference standard, and flow and timing were generally judged as low risk, reflecting standardized execution of POC testing, consistent use of HPLC as the reference standard, and appropriate timing between index and reference measurements without differential verification. Applicability concerns were considered low across studies, as the target populations, index tests, and reference standards were aligned with the objectives of this review. HbA1c, hemoglobin A1c; POC, point-of-care; HPLC, high-performance liquid chromatography; H, high risk; L, low risk; UR, unclear risk, based on QUADAS-2 risk assessment.

**Table SIII.** Characteristics and numeric outcomes of included studies.

<b>First author/s, year</b>	<b>POC device</b>	<b>Comparator device</b>	<b>Specimen type</b>	<b>Study Setting</b>	<b>MD</b>	<b>LoA</b>	<b>Funding source</b>	<b>(Refs.)</b>
Menéndez-Valladares <i>et al</i> , 2015	B-Analyst	Arkray HA-8180	Venous	Tertiary hospital or research center	0.187	-0.230, 0.600	Not reported	(26)
Criel <i>et al</i> , 2016	Afinion	Arkray HA-8160	Not reported	General hospital	-0.201	-0.851, 0.439	Industrial	(11)
Criel <i>et al</i> , 2016	Cobas b101	Arkray HA-8160	Not reported	General hospital	-0.201	-0.622, 0.220	Industrial	(11)
Criel <i>et al</i> , 2016	B-Analyst	Arkray HA-8160	Not reported	General hospital	0.046	-0.183, 0.275	Industrial	(11)
Grant <i>et al</i> , 2017	Quo-Test	BioRad D10	Not reported	Not reported	0.128	-0.458, 0.714	Not reported	(12)
Wang <i>et al</i> , 2018	A1C EZ2.0	Trinity Premier Hb9210	Not reported	Tertiary hospital or research center	0.020	-0.570, 0.610	Institutional	(27)
Wang <i>et al</i> , 2018	A1C EZ2.0	Tosoh G8	Not reported	Tertiary hospital or research center	0.040	-0.570, 0.660	Institutional	(27)
Wang <i>et al</i> , 2018	A1C EZ 2.0	BioRad variant II	Not reported	Tertiary hospital or research center	0.170	-0.520, 0.850	Institutional	(27)
Dupuy <i>et al</i> , 2019	Cobas b101	Tosoh G8	Not reported	Not reported	-0.090	-0.630, 0.450	Not reported	(28)
Dubach <i>et al</i> , 2019	Afinion	Tosoh G8	Venous	Tertiary hospital or research center	-0.265	-0.833, 0.293	Institutional	(29)
Dubach <i>et al</i> , 2019	DCA	Tosoh G8	Venous	Tertiary hospital or research center	-0.210	-0.714, 0.293	Institutional	(29)
GuadalupeVargas <i>et al</i> , 2020	DCA	BioRad variant II	Venous	Tertiary hospital or research center	-0.020	-0.600, 0.550	Institutional	(30)
GuadalupeVargas <i>et al</i> , 2020	i-Chroma	BioRad variant II	Venous	Tertiary hospital or research center	-0.500	-3.740, 2.740	Institutional	(30)
Şahingöz Erdal <i>et al</i> , 2019	Tri-stat POCT	Trinity Premier Hb9210	Venous	Tertiary hospital or research center	-0.090	-1.030, 0.850	Not reported	(31)
Şahingöz Erdal <i>et al</i> , 2019	Tri-stat POCT	Trinity Premier Hb9210	Capillary	Tertiary hospital or research center	-0.060	-1.010, 0.890	Not reported	(31)
Toro-Crespo <i>et al</i> , 2017	Afinion	Tosoh G8	Not reported	Not reported	0.018	-0.056, 0.092	Not reported	(32)

Toro-Crespo <i>et al</i> , 2017	B-Analyst	Tosoh G8	Not reported	Not reported	0.124	0.085, 0.162	Not reported	(32)
Rathod <i>et al</i> , 2024	HemoCue HbA1c 501	Tosoh GX	Venous	Tertiary hospital or research center	0.100	-0.500, 0.700	Institutional	(33)
Saxton <i>et al</i> , 2018	DCA	Trinity Premier Hb9210	Venous	Not reported	0.320	-0.050, 0.700	Institutional	(34)
Saxton <i>et al</i> , 2018	Afinion	Trinity Premier Hb9210	Venous	Not reported	0.560	0.160, 0.970	Institutional	(34)

Characteristic and numeric outcomes are summarized that support quantitative synthesis. For meta-analysis, all method comparison metrics were harmonized to a common effect size defined as the mean difference (POC - HPLC) in % HbA1c. If not directly reported, 95% LoA were calculated as the mean difference  $\pm 1.96 \times SD$ . When only the 95% CI for the mean difference was available, the SD was back-calculated using the assuming a normal distribution. Studies reporting only graphical Bland-Altman plots without extractable numerical data were excluded from quantitative synthesis. Studies that combined venous and capillary samples without separate reporting were classified under 'not reported' for the purpose of descriptive stratification. All POC devices were factory-calibrated using lot-specific code cards or chips. POC, point-of-care; MD, mean difference; LoA, limits of agreement; HPLC, high-performance liquid chromatography; HbA1c, hemoglobin A1c; SD, standard deviation; CI, confidence interval.

**Table SIV.** Summary of pooled mean differences and heterogeneity statistics across all subgroup analyses.

Classification	Subgroup	% HbA1c (NGSP)		mmol/mol (IFCC)		Heterogeneity statistics			
		MD	95% CI	MD	95% CI	Q	$\tau^2$	I <sup>2</sup>	H <sup>2</sup>
POC device model	i-Chroma	-0.50	-0.80, -0.20	-5.5	-8.7, -2.2	—	—	—	—
	Afinion	0.03	-0.34, 0.40	0.3	-3.7, 4.4	831.9	0.14	99.39	163.70
	DCA	0.03	-0.27, 0.34	0.3	-3, 3.7	392.1	0.07	99.35	153.47
	Cobas b101	-0.14	-0.25, -0.03	-1.5	-2.7, -0.3	6.7	0.01	85.04	6.69
	Tri-stat POCT	-0.08	-0.15, 0.00	-0.9	-1.6, 0	0.2	0.00	0.00	1.00
	A1C EZ 2.0	0.08	-0.02, 0.17	0.9	-0.2, 1.9	60.9	0.01	96.97	32.97
	B-Analyst	0.12	0.04, 0.20	1.3	0.4, 2.2	28.2	0.01	92.72	13.74
	HemoCue	0.10	0.05, 0.15	1.1	0.5, 1.6	—	—	—	—
	Quo-Test	0.13	0.07, 0.19	1.4	0.8, 2.1	—	—	—	—
POC analytical principle	Chromatographic immunoassay	-0.50	-0.8, -0.2	-5.5	-8.7, -2.2	—	—	—	—
	Boronate affinity chromatography	0.04	-0.09, 0.17	0.4	-1, 1.9	1195.3	0.05	98.99	99.38
	Non-chromatographic immunoassay	0.02	-0.11, 0.15	0.2	-1.2, 1.6	593.1	0.03	98.73	78.54
Specimen type	Venous	0.02	-0.18, 0.22	0.2	-2, 2.4	1279.6	0.09	99.43	175.49
	Capillary	-0.06	-0.17, 0.05	-0.7	-1.9, 0.5	—	—	—	—
	Not reported	0.01	-0.07, 0.09	0.1	-0.8, 1.0	194.4	0.02	97.33	37.45
HPLC principle	Ion-exchange chromatography	-0.03	-0.12, 0.06	-0.3	-1.3, 0.7	482.6	0.03	97.97	49.20
	Boronate-affinity HPLC	0.15	-0.09, 0.4	1.6	-1, 4.4	815.2	0.08	99.54	219.33
Exclusion of variants	Excluded	0.00	-0.1, 0.11	0.0	-1.1, 1.2	135.8	0.02	97.77	44.89
	Not reported	0.03	-0.11, 0.17	0.3	-1.2, 1.9	1583.4	0.06	99.12	113.06
Study setting	Tertiary hospital or research center	-0.04	-0.14, 0.07	-0.4	-1.5, 0.8	370.0	0.03	98.26	57.40
	General hospital	0.05	0.01, 0.08	0.5	0.1, 0.9	53.0	0.02	94.98	19.91
	Not reported	0.18	-0.01, 0.36	2.0	-0.1, 3.9	686.6	0.05	99.22	129.01
Risk of study	High	-0.02	-0.12, 0.08	-0.2	-1.3, 0.9	152.2	0.02	95.96	24.73
	Low	0.10	-0.07, 0.26	1.1	-0.8, 2.8	1462.8	0.06	99.51	202.76
	Unclear	-0.16	-0.41, 0.08	-1.7	-4.5, 0.9	11.5	0.04	96.77	30.97
Funding source	Industrial	-0.11	-0.28, 0.05	-1.2	-3.1, 0.5	53.0	0.02	94.98	19.91

Institutional	0.03	-0.14, 0.21	0.3	-1.5, 2.3	1522.0	0.08	99.57	231.47
Not reported	0.04	-0.06, 0.14	0.3	-1.5, 2.3	94.9	0.02	95.05	20.20

Values are reported as %HbA1c and converted to mmol/mol using the IFCC-NGSP master equation. Random-effects pooling was performed using REML with Knapp-Hartung adjustment. Heterogeneity indices ( $Q$ ,  $\tau^2$ ,  $I^2$ ,  $H^2$ ) are presented for subgroups with more than one comparison; subgroups represented by a single comparison have non-estimable heterogeneity ( $I^2$ ,  $\tau^2$ ), shown as “—”. “Not reported” reflects missing moderator information without inferential interpretation. HbA1c, hemoglobin A1c; NGSP, National Glycohemoglobin Standardization Program; IFCC, International Federation of Clinical Chemistry and Laboratory Medicine; POC, point-of-care; MD, mean difference; CI, confidence interval; HPLC, high-performance liquid chromatography.

**Table SV.** Univariable random-effects meta-regression (REML, Knapp-Hartung adjustment).

<b>Moderator</b>	<b>k</b>	<b>R<sup>2</sup></b>	<b>p</b>	<b>Interpretation</b>
POC analytical principle	20	6.4%	0.15	Small explanatory contribution; weak positive trend for immunoassay.
Specimen type	20	0%	0.93	Venous/capillary differences, no explanation.
Setting	20	20.6%	0.067	Decentralized settings tended toward greater positive bias (borderline).
Study-level risk of bias	20	4.9%	0.20	Minimal explanatory value; association not significant.
Variant exclusion	20	0%	0.71	No explanatory value; exclusion reporting had no impact.
Funding source	20	0%	0.56	No explanatory contribution.
POCmodel	20	0%	0.66	No meaningful discrimination between devices
HPLC analytical principle	20	11.2%	0.10	Weak positive trend for boronate-based HPLC systems (borderline).

Meta-regression models were fitted using random-effects REML estimation with Knapp-Hartung adjustments. Each moderator was evaluated in a separate univariable model. Residual heterogeneity remained significant in every model ( $Q_{res} p < 0.001$ ), indicating that none of the tested moderators accounted for the extreme between-study dispersion.  $R^2$  represents the proportion of between-study variance explained by the moderator. “p” refers to the omnibus model test. REML, restricted maximum likelihood; POC, point-of-care; HPLC, high-performance liquid chromatography.

**Table SVI.** Leave-one-out influence analysis.

Removed comparison	$\theta$ (%)	95% CI	$\tau^2$	Q	I <sup>2</sup> (%)	P-value	(Refs.)
Menéndez-Valladares <i>et al</i> , 2015 (i-Chroma, BioRad variant II)	0.032	-0.065 to 0.129	0.0398	1794.5	98.88	0.493	(26)
Dubach <i>et al</i> , 2019 (Afinion, Tosoh G8)	0.030	-0.075 to 0.134	0.0424	1622.5	98.92	0.559	(29)
Dubach <i>et al</i> , 2019 (DCA, Tosoh G8)	0.026	-0.080 to 0.132	0.0443	1636.0	98.95	0.609	(29)
Criel <i>et al</i> , 2016 (Afinion, Arkray HA-8160)	0.025	-0.081 to 0.132	0.0447	1771.6	99.00	0.625	(11)
Criel <i>et al</i> , 2016(Cobas b101, Arkray HA-8160)	0.026	-0.081 to 0.132	0.0446	1717.8	98.98	0.619	(11)
Dupuy <i>et al</i> , 2019 (Cobas b101, Tosoh G8)	0.019	-0.089 to 0.128	0.0470	1742.7	99.02	0.713	(28)
Şahingöz Erdal <i>et al</i> , 2019(Tri-stat POCT, Trinity Premier Hb9210) (venous)	0.019	-0.090 to 0.128	0.0469	1795.4	99.04	0.717	(31)
Şahingöz Erdal <i>et al</i> , 2019 (Tri-stat POCT, Trinity Premier Hb9210) (capillary)	0.017	-0.092 to 0.127	0.0472	1799.7	99.05	0.740	(31)
GuadalupeVargas <i>et al</i> , 2020 (DCA, BioRad variant II)	0.015	-0.094 to 0.125	0.0476	1782.8	99.03	0.770	(30)
Toro-Crespo <i>et al</i> , 2017(Afinion, Tosoh G8)	0.013	-0.096 to 0.123	0.0477	1802.8	99.05	0.800	(32)
Wang <i>et al</i> , 2018 (A1C EZ2.0, Trinity Premier Hb9210)	0.013	-0.096 to 0.123	0.0478	1741.5	98.93	0.802	(27)
Wang <i>et al</i> , 2018 (A1C EZ2.0, Tosoh G8)	0.012	-0.097 to 0.122	0.0478	1769.8	98.94	0.818	(27)
Criel <i>et al</i> , 2016 (B-Analyst, Arkray HA-8160)	0.012	-0.098 to 0.121	0.0477	1791.9	98.99	0.822	(11)
Rathod <i>et al</i> , 2024(HemoCue HbA1c 501, Tosoh GX)	0.009	-0.100 to 0.118	0.0474	1810.0	99.03	0.864	(33)
Toro-Crespo <i>et al</i> , 2017(B-Analyst, Tosoh G8)	0.008	-0.101 to 0.116	0.0471	1810.7	98.99	0.883	(32)
Grant <i>et al</i> , 2017(Quo-Test, BioRad D10)	0.008	-0.101 to 0.116	0.0470	1810.7	99.03	0.885	(12)
Wang <i>et al</i> , 2018 (A1C EZ 2.0, BioRad variant II)	0.005	-0.103 to 0.113	0.0463	1800.5	98.93	0.918	(27)
Menéndez-Valladares <i>et al</i> , 2015 (B-Analyst, Arkray HA-8180)	0.005	-0.103 to 0.112	0.0460	1799.1	98.96	0.931	(26)
Saxton <i>et al</i> , 2018 (DCA, Trinity Premier Hb9210)	-0.002	-0.105 to 0.101	0.0419	1564.5	98.78	0.967	(34)
Saxton <i>et al</i> , 2018(Afinion, Trinity Premier Hb9210)	-0.012	-0.099 to 0.075	0.0282	881.7	98.25	0.773	(34)
Full model (no removal)	0.014	-0.089 to 0.117	0.0449	1810.7	98.96	0.779	-

Leave-one-out influence diagnostics were performed under a random-effects REML model with Knapp-Hartung adjustment. Each row represents the updated pooled estimate after removing one device-specific comparison. All estimates remained directionally consistent, and no single comparison materially shifted the pooled mean difference or heterogeneity metrics, indicating minimal influence of individual studies. CI, confidence interval;REML, restricted maximum likelihood.