

Table 1. Baseline demographic and clinical characteristics of study participants

Characteristic	Total (N = 468)	Phase I (n = 238)	Phase II (n = 230)
Median age, years (IQR)	37 (28–45)	40.5 (34-48)	40 (34.5-46)
Female, n (%)	254 (54.3)	120 (50.4)	134 (58.3)
Male, n (%)	126 (26.9)	48 (20.2)	78 (33.9)
EQA proficiency samples, n (%)	48 (10.3)	24 (10.1)	24 (10.4)
No documented sex, n (%)	40 (8.5)	40 (16.8)	0 (0.0)
Median CD4 count, cells/mm ³ (IQR)	224.5 (99.25–428.75)	259 (50.75-412.25)	230 (44-405)
CD4 ≤200 cells/mm ³ , n (%)	242 (51.7)	118 (48.8)	124 (51.2)
ART status			
– ART-naïve, n (%)	384 (82.1)	190 (79.8)	194 (84.3)
– ART-experienced, n (%)	36 (7.7)	24 (10.1)	12 (5.2)
– EQA samples, n (%)	48 (10.3)	24 (10.1)	24 (10.4)
Duration of ART			
– New (no ART), n (%)	384 (82.1)	190 (79.8)	194 (84.3)
– <6 months, n (%)	24 (5.1)	16 (6.7)	8 (3.5)
– >6 to <12 months, n (%)	8 (1.7)	4 (1.7)	4 (1.7)
– ≥12 months, n (%)	4 (0.9)	4 (1.7)	0 (0.0)

Table 2 – Diagnostic performance of VISITECT® CD4 LFA

	VISITECT® CD4 ≤200 cells/μL	VISITECT® CD4 >200 cells/μL	Total
Reference ≤200 cells/μL	TP = 242	FN = 0	242
Reference >200 cells/μL	FP = 23	TN = 203	226
Total	265	203	468