

Supplementary Table S1. Definition and scoring criteria of key performance indicators (KPIs) for analytical (A) and operational (B) evaluation of diagnostic performance

A. Analytical performance indicators						
KPI	Unit/Definition	5 (Excellent)	4 (High)	3 (Moderate)	2 (Low)	1 (Poor)
Sensitivity	% true positive rate	>98	96-98	92-96	85-92	<85
Specificity	% true negative rate	>99	97-99	95-97	90-95	<90
Accuracy	% correct classification vs reference	>99	97-99	94-97	90-94	<90
Agreement with reference method	Concordance with standard laboratory assay (%)	>98	95-98	90-95	85-90	<85
B. Operational performance indicators						
KPI	Unit/Definition	5 (Excellent)	4 (High)	3 (Moderate)	2 (Low)	1 (Poor)
Time to result	minutes (total analytical turnaround time)	<120	120-150	150-200	200-250	>250
Cost per test	€ per analysis	<10	10-15	15-25	25-35	>35
Portability	Operational mobility	Fully portable (handheld / RTU system)	Portable with minor setup	Transportable with basic infrastructure	Limited mobility, controlled transport required	Non-portable, laboratory-bound
Skill requirements	Operator expertise required	No specialized training required	Basic training required	Standard laboratory skills required	Advanced laboratory skills required	Highly specialized expertise required
Robustness	Stability under environmental/operational variability	Fully robust under variable conditions (temperature, matrix, operator variability)	High robustness with minor sensitivity to variation	Moderate robustness, some dependence on controlled conditions	Low robustness, sensitive to environmental variation	Requires strictly controlled conditions