



## Nanomix S1 Panel

### Technical Performance

#### Summary:

Nanomix engaged multi-center studies to evaluate the performance of the Nanomix eLab system and the S1 Panel Assay. The studies were performed across four investigational sites. The sites selected were recognized University Health Systems within the United States including point of care locations and affiliates within those health systems.

- Baylor Medical University
- University of CA, San Francisco
- Thomas Jefferson University
- University of CA, Davis

The clinical evaluation included three areas of performance including Precision and Reproducibility, Equivalence to FDA cleared POC devices and Reference Range of population in non-laboratory, POC settings.

#### Precision and reproducibility of the S1 in POC setting and use:

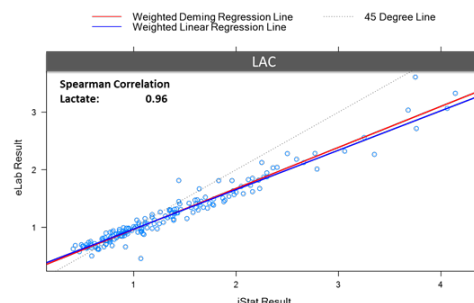
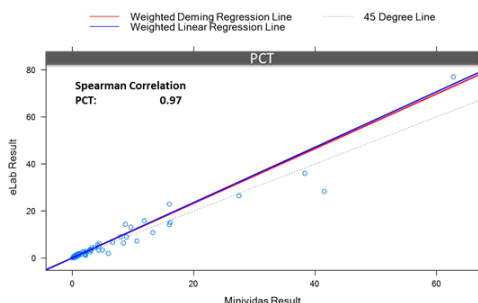
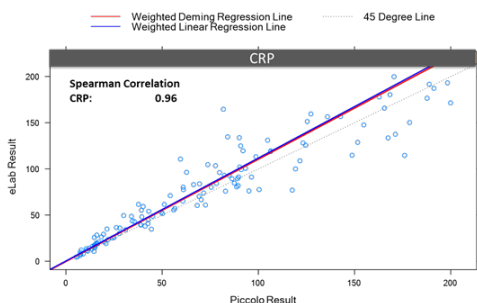
N=270  
3 POC sites  
6 Operators

Analyte	Test Sample	N	Mean	Variance Components: SD [%CV]				
				Site/ Instrument	Operator (Site)	Day (Operator)	Repeat- ability	Total
CRP	S1	90	8.66	0.29 [3%]	0.00 [0%]	0.00 [0%]	0.91 [10%]	0.95 [11%]
	S2	88	32.52	0.00 [0%]	0.00 [0%]	1.46 [4%]	3.23 [10%]	3.54 [11%]
	S3	90	118.96	1.94 [2%]	0.00 [0%]	0.00 [0%]	13.84 [12%]	13.98 [12%]
LAC	S1	90	1.62	0.03 [2%]	0.00 [0%]	0.00 [0%]	0.09 [6%]	0.09 [6%]
	S2	88	2.92	0.03 [1%]	0.00 [0%]	0.00 [0%]	0.29 [10%]	0.29 [10%]
	S3	90	6.49	0.00 [0%]	0.19 [3%]	0.37 [6%]	0.82 [13%]	0.92 [14%]
PCT	S1	90	0.68	0.01 [1%]	0.00 [0%]	0.02 [2%]	0.06 [10%]	0.07 [10%]
	S2	88	2.62	0.00 [0%]	0.10 [4%]	0.13 [5%]	0.24 [9%]	0.30 [11%]
	S3	90	50.52	0.00 [0%]	1.67 [3%]	1.51 [3%]	4.67 [9%]	5.18 [10%]

#### Equivalence of the eLab S1: CRP, PCT, and Lactate to FDA cleared POC devices:

N=186  
3 POC sites

S1 Panel Assay	Equivalence	Reference System
C-reactive protein (CRP)	0.96	Piccolo
Procalcitonin (PCT)	0.97	Mini-Vidas
Lactate (LAC)	0.96	i-STAT



Piccolo and i-STAT are registered trade names of Abbott, Mini-Vidas is a registered trade name of BioMerieux



## Nanomix S1 Panel

### Normal reference range:

N=160  
3 POC sites

S1 Panel Assay	Sample Type	Upper Limit (95 <sup>th</sup> Percentile)
C-reactive protein (CRP)	Plasma	5.312 mg/L
Procalcitonin (PCT)	Plasma	0.018 ng/mL
Lactate (LAC)	Plasma	1.943 mmol/L

### Results from internal verification studies:

#### Analytical Performance Characteristics

	CRP	LAC	PCT
LOB	1.254 mg/L	0.012 mmol/L	0.026 ng/mL
LOD	1.473 mg/L	0.035 mmol/L	0.046 ng/mL
LLOQ	2.5 mg/L	0.3125 mmol/L	0.1 ng/mL
ULOQ	300 mg/L	7.5 mmol/L	220 ng/mL
Reportable Range	2.5 – 200 mg/L	0.3 – 7.5 mmol/L	0.2 - 200 ng/mL
Linear Range	1.25 - 300 mg/L	0.21 -15 mmol/L	0.02 - 220 ng/mL
Assay cutoff	7.5 mg/L	2 mmol/L	<0.5 ng/mL (low risk) >2 ng/mL (high risk)

### Comparison to LAC International reference standard

