Auria: CLIA Validation

The process of the validation of Auria for use as a Lab Developed Test (LDT) offered through the high complexity CLIA laboratory at Namida Lab was designed using the validation guidelines distributed through CLIA and CAP, reviewed and approved by Namida's Medical Director, and reviewed by the Arkansas State Health Department. Once Namida's CLIA license was approved in Arkansas we then procured licenses in 49 states excluding NY.

Data provided met the CLIA requirements on test performance specifications including precision, analytical accuracy, analytical sensitivity and specificity, reportable range, linearity, clinical accuracy, clinical specificity, and clinical sensitivity. Having met the CLIA regulatory requirements, we provide the required evidence to support the clinical implementation of this test as an LDT for the intended use as a pre-screen for breast cancer.

Table 1: Summary of Analytical Validation

Study Parameter	**Sample Description** (Name, Number, Replicates)	**Results**	**Comparison to Acceptance Criteria** (Pass/Fail)
Accuracy	20 spiked LGF samples	Percent recover between 80 - 120% for all samples	Pass
Intra-Assay Precision	24 replicates of 3 concentrations per analyte	All %CV less than or equal to 15%	Pass
Inter-Assay Precision	Duplicates of 3 concentrations 1x day for 5 days	All %CV less than or equal to 15%	Pass
Sensitivity	20 replicates of blank per protein	S100A8 11% 21.10 pg/ml S100A9 14% CV 24.32 pg/ml	Pass
Linearity	7 unknown concentrations	Percent difference less than 15% for all samples	Pass

Table 2: Summary of Clinical Validation

Study Parameter	**Sample Description** (Name, Number, Replicates)	**Results**	**Comparison to Acceptance Criteria** (Pass/Fail)
Accuracy	26 samples 3 replicates each sample	92%	Pass
Sensitivity	52 LGF samples in duplicate	92%	Pass
Specificity	50 LGF samples in duplicate	54%	Pass