

Singulex Erenna[®] Immunoassay System

Previously undetectable, quantified.
One molecule at a time.

Complete solution for biomarker research:

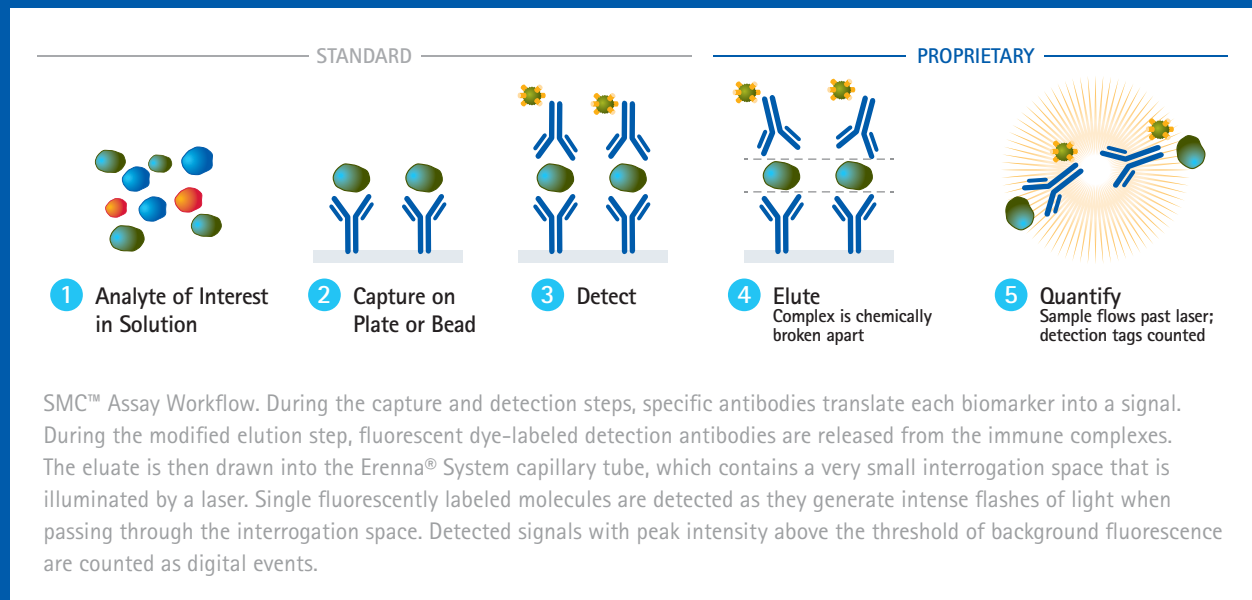
- Instrument
- Assay Kits and Reagents
- Custom Services



Erenna[®] Immunoassay System Powered by SMC[™] Technology

Single Molecule Counting (SMC[™]) Technology Reduced background + increased signal

SMC[™] technology provides maximum immunoassay performance while following a workflow very similar to traditional ELISA technology, as shown below. By combining a unique assay elution step and robust digital counting, SMC[™] technology achieves improved signal-to-noise ratios over traditional immunoassay technologies, thus providing quantification at both low and high levels of expression on one complete system.



Digital counting improves sensitivity and dynamic range

The Erenna[®] instrument captures the sum of all digital events counted. At high concentrations, a proprietary algorithm computes the total sum of all photons recorded. Thus, SMC[™] technology improves assay sensitivity and extends dynamic measuring range far beyond what could be achieved with traditional technologies.

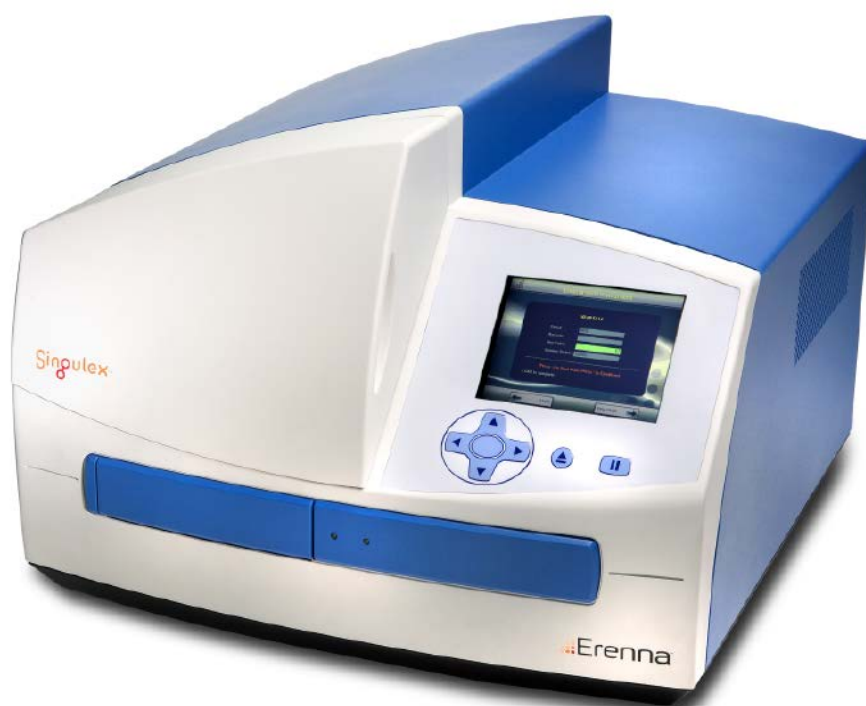
Erenna[®] Immunoassay System Specifications

Minimum Instrument Performance Specifications

Metric	Specification
Slope	>20 DE/fM*
Background	<100 DE
Limit of detection (LoD)	<1 fM*
Precision	<7% CV†
Dynamic Range	>4 logs

*Determined from calibrator set: 0-300 fM of 150 kD antibody labeled with fluorophore

†DE measurements from 30 fM calibrator, n=20



NETWORK/PC REQUIREMENT

- Microsoft Windows[®] 7 Operating Systems
- A static IP address and an FTP server
- Sgx link Operating and Analysis software included

READ PLATE FORMAT

- 384-well plate

ASSAY FORMAT

- Plate-Based Assays
- Bead-Based Assays

INSTRUMENT DIMENSIONS AND WEIGHT

- H: 400 mm (15.75 in)
- W: 540 mm (21.25 in)
- D: 575.6 mm (22.7 in)
- W: 31.3 kg (69 lbs)

POWER REQUIREMENT

- U.S.: 115 VAC, 50-60 Hz (operating range 90-125 V)
- Int.: 230 VAC, 50-60 Hz (operating range 180-250 V)

SMC™ Immunoassay Menu

For the Singulex Erenna® Immunoassay System

Singulex has engineered an expanding menu of robust SMC™ immunoassays for use on the Erenna® System.

Verified Immunoassay Kits

Analyte	Part No.	Assay Format	LLoQ (pg/mL)	Median Endogenous (pg/mL)	Species *	Sample Type †
KIM-1	03-0118	PBA	3.91	P: 65; S: 75; U: 147	H	P, S, U
AKT1 – pSer473	03-0100	BBA	0.98	NA	H, M, R	L
AKT1 – total	03-0099	BBA	7.8	NA	H, M, R	L
cTnI	03-0092	BBA	0.4	1.75	H, Cy, R, C, GP	P, S
G-CSF	03-0047	BBA	0.08	17	H	P
GM-CSF	03-0067	BBA	0.02	0.2	H	P
GLP-1 – active	03-0024	BBA	0.4	3.46	H, M, R, C	P
GLP-1 – total	03-0025	BBA	0.2	17.8	H, M, R, C	P
IFN-γ	03-0049	BBA	0.2	0.79	H	P
IL-1α	03-0072	BBA	0.39	1.06	H	P
IL-1β	03-0028	BBA	0.2	0.08	H	P
IL-2	03-0051	BBA	0.05	0.21	H	P, S
IL-4	03-0052	BBA	0.04	0.02	H	P
IL-5	03-0053	BBA	3.91	4.52	H	P
IL-6	03-0089	BBA	0.08	1.3	H	P
IL-7	03-0094	BBA	0.39	4.91	H	P, S
IL-8	03-0055	BBA	0.24	3.6	H	P, S
IL-10	03-0056	BBA	0.39	1.01	H	P
IL-12	03-0057	BBA	0.05	0.13	H	P, S
IL-13 (V2)	03-0109	BBA	0.04	0.21	H	P, S
IL-15	03-0058	BBA	0.1	3.38	H	P, S
IL-17A (V2)	03-0103	BBA	0.03	0.12	H	P, S
IL-17F (V2)	03-0102	BBA	0.2	0.86	H	P, S
IL-17A/F Heterodimer (V2)	03-0119	BBA	1.2	2.75	H	P, S
IL-21	03-0014	BBA	0.2	0.53	H	S
IL-22	03-0059	BBA	0.2	3.3	H	P
IL-23	03-0112	BBA	0.1	0.18	H	P, S
TNF-α (Human)	03-0088	BBA	0.1	2.3	H	P
TNF-α (Mouse)	03-0108	BBA	0.4	38.6	M	S
VEGF (Human)	03-0068	BBA	0.2	66.5	H	P

* Optimized for the first species type listed. Other listed species have been tested, but not optimized for peak performance.

KEY: H = human; M = mouse; R = rat; GP = guinea pig; Cy = cynomolgus monkey; C = canine

† Optimized for use in sample type(s) listed. KEY: P = EDTA plasma; S = serum; L = lysate; U = urine

Validation Criteria for Verified Immunoassays

A comprehensive set of criteria evaluating ultimate quantitative performance are used to qualify Verified Immunoassays.

Lower limit of quantitation

Lowest point on standard curve with CV <20% and accuracy within 20% of expected values.

Inter- and intra-assay precision

Samples run on multiple plates over multiple days. Spiked and un-spiked samples within 20% across experiments.

Spike recovery

Minimum of 10 samples spiked with acceptable recovery between 80-120%.

Dilutional linearity

Assays target a quantifiable range of 3-4 logs.

Endogenous range

Minimum of 10 samples from individual donors assessed for ability to quantify baseline biomarker levels.

Plate-Based Discovery Immunoassay Kits

Analyte	Part No.	LLOQ (pg/mL)	Sample Type
Mouse IL-17A	03-0123	0.98	Serum
Mouse IL-17F	03-0125	1.95	Serum
Mouse IL-21	03-0126	9.8	Serum
Mouse IL-22	03-0127	100	Serum

Discovery Immunoassays are provided as complete kits to run on your Erenna® platform.

- **LOW-COST**
- **REPRODUCIBLE LLOQ**
- **SIMPLE WORKFLOW**
- **MINIMAL SAMPLE VOLUME**

Ongoing Biomarker Research at Singulex

Singulex has worked with a number of other biomarkers for use in research programs, demonstrating the versatility of the platform across a variety of disease areas. Contact us to see how you may accelerate your own research in these disease areas.

Prototype Erenna[®] SMC[™] Immunoassays

NEUROLOGY

- Aβ-40
- Aβ-42
- VILIP-1

INFLAMMATION

- mouse IL-2
- mouse IL-4
- mouse IL-5
- mouse IL-10
- mouse IL-13
- mouse VEGF
- mouse TNF-α
- mouse IFN-γ

METABOLISM

- Glucagon
- Insulin
- Active GLP-1 (Plate)
- Total GLP-1 (Plate)

CARDIOVASCULAR

- Endothelin

TOXICOLOGY

- skeletal TnI (fast)
- skeletal TnI (slow)
- NGAL
- Cystatin C

ONCOLOGY

- EGFR
- MMP2
- MMP2/TIMP2
- TIMP-2
- tJNK1
- pJNK1
- tJNK2
- pJNK2
- tERK2
- pERK2
- tGSK3β
- pGSK3β

Build and Optimize Your Own Immunoassays

Development Kit	Catalog No.
Erenna [®] Detection Antibody Labeling Kit (for Plate and Bead Based Assay Development)	03-0076
Erenna [®] Capture Antibody Labeling Kit (for Bead Based Assay Development)	03-0077
Erenna [®] Bead Based Immunoassay Development Kit	03-0078
Erenna [®] Plate Based Immunoassay Development Kit	03-00128
Erenna [®] Assay Buffer Optimization Kit (for Plate and Bead Based Assay Optimization)	03-0122

Expert Custom Services

Custom Services are available when time and resources require an expert outsource partner helping to accelerate programs from discovery into clinical trials. Our capabilities include:

Collaborative Biomarker Discovery & Development

- Fit-for-purpose Sample Testing (non-GLP)
- Immunoassay Development
- Biomarker Validation (to sponsor requirements)

Biomarker Assay Services for Biotherapeutic Discovery

- Pharmacokinetics
- Pharmacodynamics
- Immunogenicity

Antibody Derivatization/Labeling and Characterization

- Antibody Screening and Selection
- Antibody Labeling
- Assay Stability Testing

SMC™ Assay Kit Development

- Proprietary or Commercial SMC™ Assay Kit Development
- Assay Kit Verification and Validation
- Assay Kit Manufacturing
- Method Transfer to CRO



Learn more about our services at: www.merckmillipore.com/singulex

Ordering Information and Technical Support for Singulex Erenna[®] System and SMC[™] Immunoassays

Singulex life science customer support

Telephone: (United States): **510.995.3880**

Toll Free: **888.995.6955**

LifeScienceInfo@singulex.com

Singulex life science technical support

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