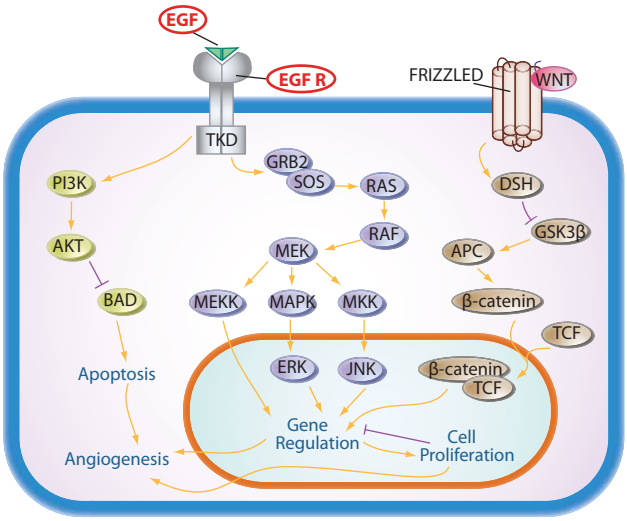
Erenna® EGFR Immunoassay Evaluation Reagent Kit

Biology and Disease

The Epidermal Growth Factor Receptor (EGFR) is a receptor tyrosine kinase that is activated by binding to the epidermal growth factor family. Ligand binding invokes receptor dimerization and auto-trans-phosphorylation of tyrosine residues in the intracellular C-terminal domain. This subsequently activates several intracellular signaling pathways that control cell proliferation and DNA synthesis downstream, including the PI3-Kinase and MAP-Kinase signaling cascades. Over-activity of signal transduction pathways spurred by EGFR signaling have been shown to be associated with the development of lung, breast, colorectal, and ovarian cancer. Many recently developed therapeutic approaches involve inhibition of EGFR activity, and some cancers can be typified by their EGFR status as being responsive or non-responsive to such therapies.



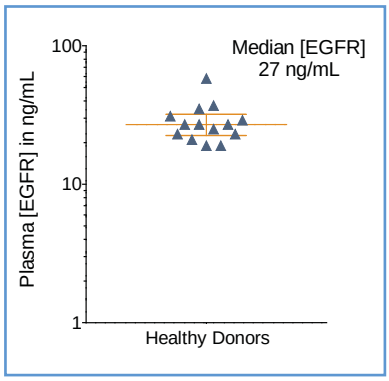
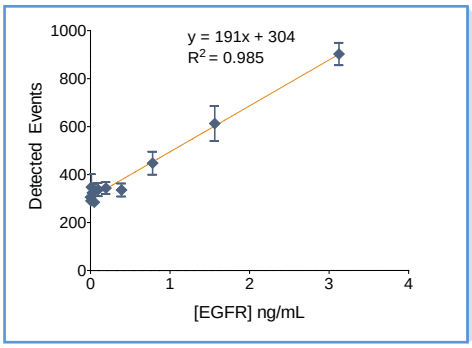


FIGURE 1: [EGFR] in EDTA plasma from 14 healthy donors, with median and interquartile range.

The Erenna® EGFR Immunoassay Evaluation Reagent Kit quantifies EGFR in healthy subjects, who have a median [EGFR] of 27 ng/mL that is well above the detection limit of 207 pg/mL.



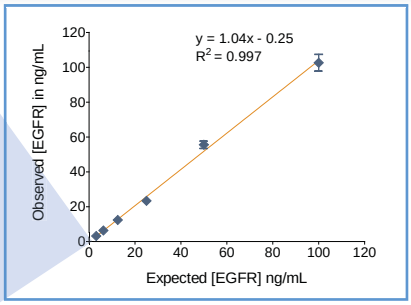
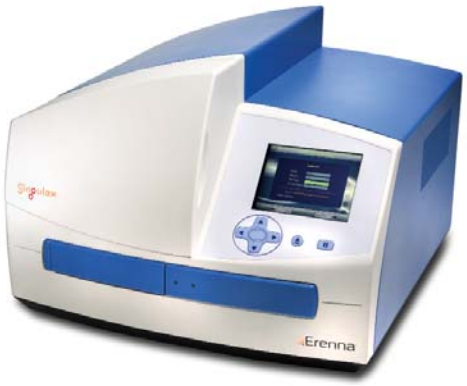


FIGURE 2: Erenna® EGFR Immunoassay Evaluation Reagent Kit low-end standard curve signal (left) and curve fit (above).

TABLE 1: Analytical sensitivity of the Erenna® EGFR Immunoassay Evaluation Reagent Kit[1]

Lower Limit of Detection	207 pg/mL
Lower Limit of Quantification[2]	3125 pg/mL
Upper Limit of Quantification	100,000 pg/mL
Low-end CV% Range	1 - 16%
Low-end CV% Average	8%
Assay Volume	100 µL
Minimum Sample Volume Required[3]	15 µL

[1] see product insert for updated values
[2] LLoQ ≤ 20% CV and ± 20% recovery
[3] based upon median [EGFR] in a healthy reference population



Representative data shown for demonstration purposes only. Individual results may vary depending upon samples tested and protocol used.

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