

## Biology and Disease

Granulocyte Macrophage-Colony Stimulating Factor (GM-CSF) is a cytokine produced by T cells, B cells, macrophages, mast cells and fibroblasts in response to inflammation or infection. Its primary role is to stimulate granulocyte and monocyte production in the bone marrow. Once GM-CSF has bound to its receptor, the activated complex propagates a signaling cascade that increases macrophage counts in order to fight infection. Thus increased GM-CSF can be observed during episodes of infectious disease and in a spectrum of inflammatory disorders such as Crohn's disease. Conversely, a lack of GM-CSF resulting from autoantibody production has been linked to pulmonary alveolar proteinosis, leukemia, and neutropenia.

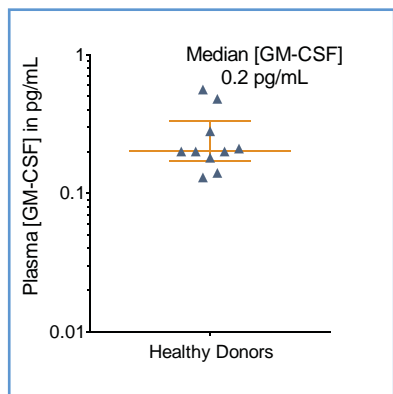
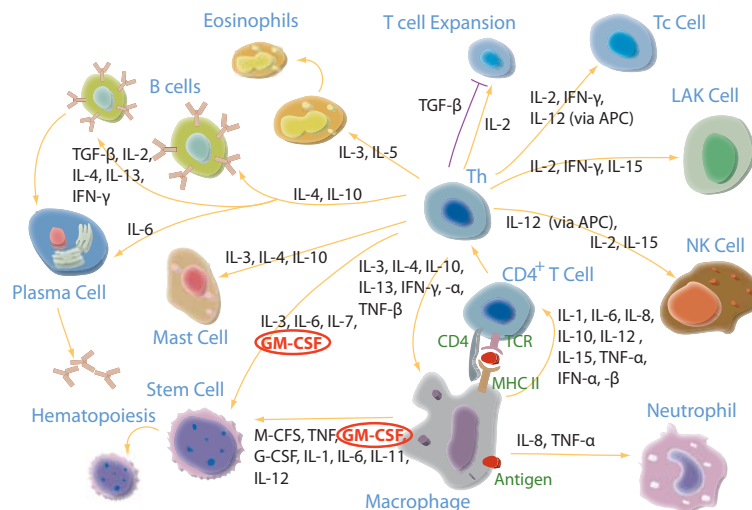


FIGURE 1: [GM-CSF] in EDTA plasma from 10 healthy donors, with median and interquartile range.

The Erenna® GM-CSF Immunoassay Kit reliably quantifies GM-CSF in EDTA plasma from healthy subjects, who have a median [GM-CSF] of 0.2 pg/mL that is well above the detection limit of 0.004 pg/mL.

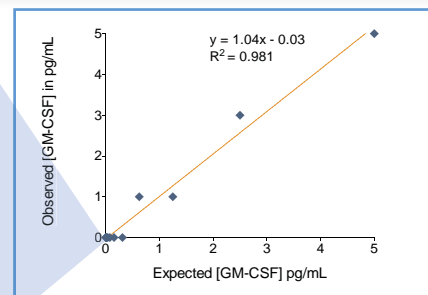
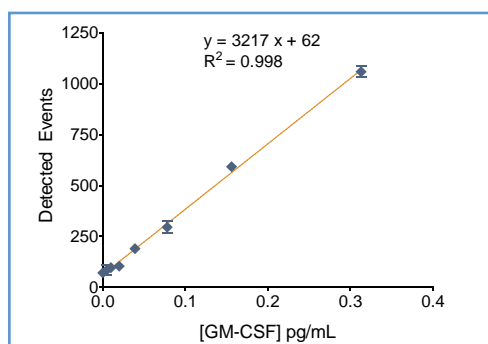


FIGURE 2: Erenna® GM-CSF Immunoassay Kit low-end standard curve signal (left) and curve fit (above).

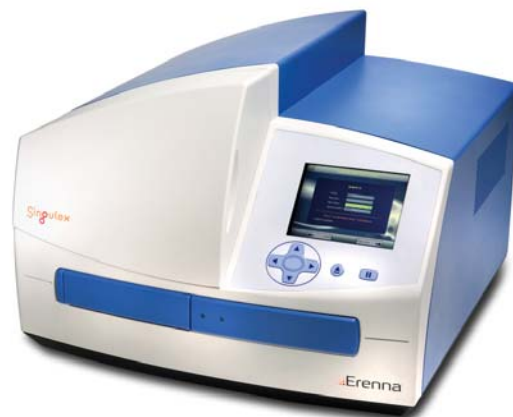
TABLE 1: Analytical sensitivity of the Erenna® GM-CSF Immunoassay Kit<sup>1</sup>.

|   |                   |
|---|-------------------|
| Lower Limit of Detection                    | 0.004 pg/mL       |
| Lower Limit of Quantification <sup>2</sup>  | 0.02 pg/mL        |
| Upper Limit of Quantification               | 5 pg/mL           |
| Low-end CV% Range                           | 1 - 11%           |
| Low-end CV% Average                         | 6%                |
| Recommended Sample Volume                   | 100 µL            |
| Minimum Sample Volume Required <sup>3</sup> | 50 µL             |
| Matrices Validated                          | human EDTA plasma |

<sup>1</sup> see product insert for updated values

<sup>2</sup> LLoQ ≤ 20% CV and ± 20% recovery

<sup>3</sup> based upon median [GM-CSF] in a healthy reference population



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