



IL-22 (INTERLEUKIN-22)

The high-sensitivity Singulex IL-22 assay will help researchers understand the complex interplay of IL-22 in the immune system to strength immunity or promote inflammatory response.

BIOLOGY AND DISEASES

Interleukin-22 (IL-22), also known as IL-10-related T-cell-derived inducible factor (IL-TIF), is a member of the IL-10 cytokine family. Mainly produced by activated T-cells and natural killer cells, IL-22 binds to a receptor complex with two components, CRF2-4 and IL-22R. The signaling cascade is said to up-regulate pro-inflammatory cytokines and antimicrobial peptides, and induce production of acute-phase reactants in liver and hepatoma cells. The biological function of IL-22 is associated with many inflammatory disorders, including Crohn's disease, inflammatory bowel disease, psoriasis, rheumatoid arthritis and ulcerative colitis.

THERAPIES

IL-22 remains an attractive therapeutic target because of its pro-inflammatory properties. A research study has characterized a naturally occurring antagonist for the cytokine, designated IL-22 Binding Protein (IL-22BP). This protein has successfully demonstrated inhibitory activity by binding to IL-22 and preventing its interaction with the IL-22 receptor complex. Antibodies directed to neutralize IL-22 activity in mice have shown promising results for the prevention of psoriasis-like disease. Together, these reports suggest that anti-IL-22 therapy might be a new approach to treating inflammatory disorders.

UNMET NEED

Drug efficacy and dosing studies rely on accurate measurement of disease markers and could benefit by the inclusion of protein biomarkers. For example, clinical trials of psoriasis frequently report the Psoriasis Area and Severity Index (PASI) as a measure of disease progression. Unfortunately, current solid-phase ELISA technology has not been able to establish a direct correlation between PASI scores with plasma IL-22 concentrations, even though IL-22 concentration is known to be elevated in psoriasis patients. This stresses the need for an assay method with greater sensitivity and robustness to perform treatment studies.

SINGULEX ANSWER

The Singulex IL-22 assay, optimized for use on the Erenna System, has an LLoQ of 0.2 pg/mL and a reading range of 0.04–400 pg/mL. The high sensitivity, accuracy and precision of the Singulex assay will aid in the design and execution of efficient drug treatment studies.

This assay will allow investigators to:

1. Measure the efficacy and dosing of anti-IL-22 therapies designed to interfere with pro-inflammatory activities of IL-22.
2. Design robust clinical and preclinical studies when IL-22 concentration is used as a therapeutic endpoint for drugs targeting inflammatory disorders.
3. Understand how IL-22 concentrations change in patients as they transition from a healthy to diseased state.

ERENNA TECHNOLOGY ACCESS PROGRAM.

Through the Erenna Technology Access Program (ETAP), Singulex offers an interactive, results-driven solution to biomarker challenges faced by the pharmaceutical industry during product development. Singulex assists the development programs of our ETAP collaborators by developing customer-driven assays and access to a menu of fully-validated assays. Participants in ETAP gain access to the Singulex Erenna Immunoassay System, our proven expertise developing high-value immunoassays and our world-class customer support. Together with Singulex, our ETAP collaborators are expanding the utility of protein biomarkers and using them as tools to measure disease progression, drug efficacy and toxicity.

TABLE 1: Analytical sensitivity of the Singulex IL-22 assay.

Lower Limit of Detection (LoD)	0.04 pg/mL
Lower Limit of Quantification (LLoQ)	0.2 pg/mL
Reading Range	0.04-400 pg/mL

Erenna® System



TABLE 2: IL-22 assay low-end standard curve data.

[IL-22] pg/mL	Detected Events	Std Dev	CV
1.65	618	15	2%
0.55	241	17	7%
0.18	97	6	7%
0.06	60	3	6%
0.02	49	8	17%
0.01	44	7	16%
0.00	35	7	19%

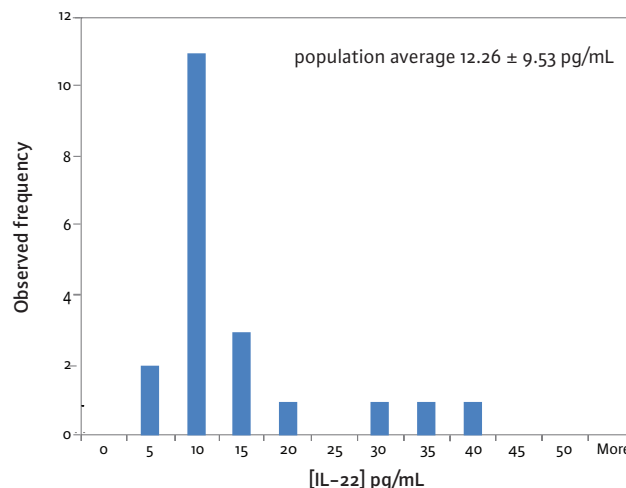


FIGURE 1: Plasma IL-22 concentration in healthy human subjects.

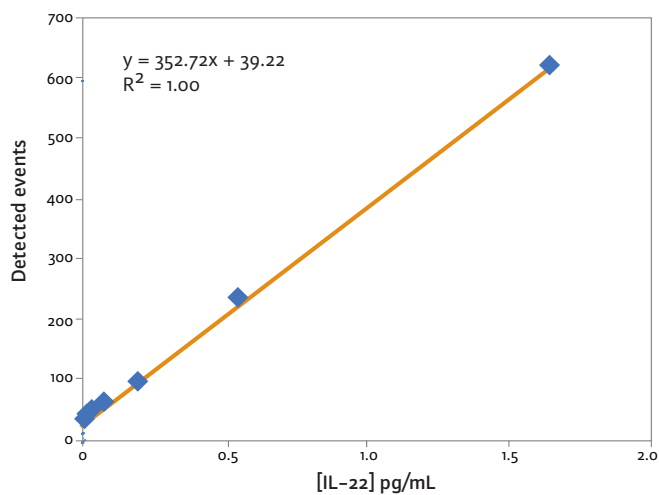


FIGURE 2: IL-22 low-end standard curve signal.

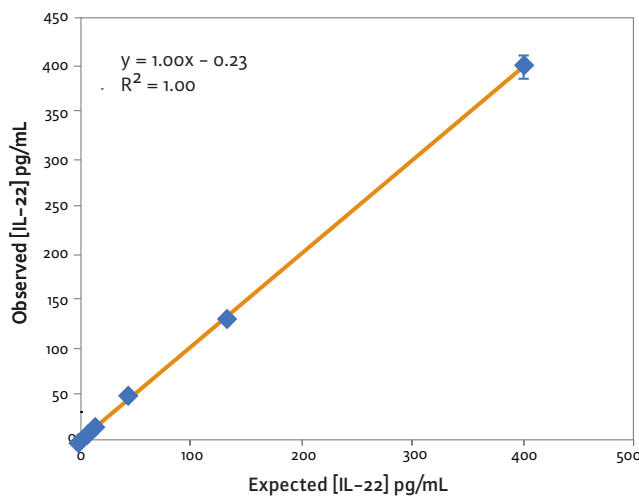


FIGURE 3: IL-22 assay curve fit.

These standard curves are for representational purposes only. A standard curve must be run with each assay.

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