New Test	3002249	Regulatory T-Cell Panel, *FOXP3*	TREGSFOXP3

Test not New York DOH approved at any laboratory. An approved NPL form must accompany specimen.

Methodology: Quantitative Flow Cytometry
Performed: Sun-Sat
Reported: 1-3 days

Specimen Required: Collect: Lavender (K₂ EDTA) or Pink (K₂ EDTA).
Specimen Preparation: Transport 4 mL whole blood. (Min: 1 mL) Specimens must be analyzed within 48 hours of collection.
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Clotted or hemolyzed specimens.
Stability (collection to initiation of testing): Ambient: Unacceptable; Refrigerated: 48 hours; Frozen: Unacceptable

Reference Interval:

Available Separately	Components	Reference Interval (Adults 19 & older)
No	**TREGS CD4+CD25+FOXP3+CD127- Percent**	1.0-7.0 percent of CD4
No	**TREGS CD4+CD25+FOXP3+CD127-**	8-48 cells/µL

Interpretive Data: Regulatory T cells (Tregs) suppress the immune response, predominately through the transcription factor FOXP3. The major Treg population is CD4+, CD25+, CD127- with expression of intracellular FOXP3. Decreased Tregs occur in autoimmune disorders including allergy and asthma. Low numbers or compromised function of Tregs are found in graft vs host disease following bone marrow transplantation. Increasing Tregs is a potential cell therapy and decreasing Tregs may enhance immune surveillance of cancer cells. Monitoring Tregs may reflect the mechanism of disease and can assess the efficacy of treatment.

Severe FOXP3 compromise identified by low or absent Tregs is characteristic of the IPEX syndrome, which stands for Immune dysregulation, Polyendocrinopathy, Enteropathy, and X-linked syndrome. However, some FOXP3 mutations may completely inhibit function, yet still allow detection of the intracellular protein by immunologic methods, so absent Tregs by flow cytometry is sufficient, but not necessary for diagnosis.

See Compliance Statement A: www.aruplab.com/CS

Note: Pediatric ranges were not established.

CPT Code(s): 86356 x4

New York DOH approval pending. Call for status update.

HOTLINE NOTE: Refer to the Test Mix Addendum for interface build information.