
Lab Dept: Flow and Immunology

Test Name: LYMPHOCYTE ENUMERATION / ALPS PANEL

General Information

Lab Order Codes: LEALP

Synonyms: Helper/Suppressor Ratio; T- cells; T, B, and/or NK phenotyping; T, B, and/or NK enumeration; T&B subsets; Activated T-cells; Autoimmune Lymphoproliferative Syndrome Panel; ALPS

CPT Codes: 86359 – T cells, total count
86360 – T cells; absolute CD4 and CD8 count, including ratio
88184 – Flow cytometry; cytoplasmic or nuclear marker, technical component only; first marker
88185 X8 – Flow cytometry, cell surface, cytoplasmic or nuclear marker, technical component; each additional marker

Test Includes: CD3, CD4(CD3+), CD8(CD3+), CD16+CD56(CD3-), CD19+, HLA DR+/CD3+, TCR $\alpha\beta$ +/CD3+, TCR $\alpha\beta$ +/CD4-/CD8-, TCR $\gamma\delta$ +/CD3+, CD20+/CD5+, relative percentages, absolute values, and a calculated Helper/Suppressor ratio.

Logistics

Test indications: This test can be useful for diagnosing an immunodeficiency and to monitor immune status. It is also useful in the workup of pediatric patients with autoimmune phenomena, lymphadenopathy, splenomegaly, and peripheral lymphocytosis to rule out ALPS as the cause. Clinical manifestations usually occur in pediatric patients with an average age of 22 months at the time of diagnosis.

Lab Testing Sections: Flow Cytometry

Phone Numbers: MIN Lab: 612-813-6280
STP Lab: 651-220-6550

Test Availability: 3 times weekly determined by volume. Transport collected specimen immediately to Flow Cytometry. Routine testing is not available on weekends or holidays. Therefore, specimens cannot be used if drawn the day before a 3 day weekend such as Memorial Day, Labor Day or major holiday that falls on a Monday or Friday.

Turnaround Time: 1 – 3 days

Special Instructions: N/A

Specimen

Specimen Type: Whole blood

Container: Lavender top (EDTA) tube

Draw Volume: 2 mL blood in a 2 mL Lavender (EDTA) tube (preferred)

Collection: Routine blood collection

Special Processing: Lab Staff: Keep specimen at room temperature and forward promptly to the laboratory. **Do Not** centrifuge, refrigerate, or freeze sample.

Patient Preparation: N/A

Sample Rejection: Specimens will not be processed that are clotted, hemolyzed, greater than 72 hours old, collected in the wrong tube type, or that have been held or handled at a temperature other than room temperature.

Interpretive

Reference Range: Age-dependant reference ranges will be provided. The immunophenotypic abnormalities associated with ALPS include TCR $\alpha\beta$ positive CD4 and CD8 negative T-cells (so called double negative Tcells), CD5 positive B-cells and HLA-DR positive T-cells. In ALPS, all three of these subsets are elevated. Other conditions might have one or two of these subsets but ALPS has an increase in all three.

Critical Values: N/A

Limitations: Poor specimen quality will adversely affect the test results (see Specimen section).

The single platform method is linear when the WBC count of the specimen is between 0.2 k/uL and 29.7 k/uL, and its lymphocyte concentration is between 0.1 k/uL and 9.0 k/uL.

Methodology: Single-platform 4-color direct immunofluorescence method. The flow cytometric analysis is based on a CD45 gating strategy. The calculation of absolute values is based upon the total leukocyte and relative lymphocyte values obtained.

This test was developed and its performance characteristics determined by Children's Hospitals and Clinics. It has not been cleared or approved by the US Food and Drug Administration. Analyte specific reagents (ASR's) are used in many laboratory tests necessary for standard medical care and generally do not require FDA approval.

References:

Blessing J et al (Blood, October 15 2001) Immunophenotypic profiles in families with Autoimmune Lymphoproliferative Syndrome, Vol. 98, no. 8

Centers for Disease Control (1997) Revised Guidelines for performing CD4+ T-cell determinations in persons with immunodeficiency virus (HIV). MMWR 46(No. RR-2): 1-29

MultiTEST™ IMK Kit Package Insert. Becton Dickinson Immunocytometry System, December 2000