Test Definition: TBNY

T, B and NK Lymphocyte Quantitation, New York, Blood

Overview

Useful For

Only orderable by New York clients

Serial monitoring of CD4 T-cell count in patients who are HIV-positive

Follow-up and diagnostic evaluation of primary immunodeficiencies, including severe combined immunodeficiency

Immune monitoring following immunosuppressive therapy for transplantation, autoimmunity, and other immunological conditions where such treatment is utilized

Assessment of immune reconstitution post-hematopoietic cell transplantation

Early screening of gross quantitative anomalies in lymphocyte subsets in infection or malignancies

Absolute quantitation of circulating B cells for diagnosis of patients with chronic lymphocytic leukemia as indicated in the 2008 International Workshop on Chronic Lymphocytic Leukemia guidelines

Method Name

Fluorescent Flow Cytometry

NY State Available

Yes

Specimen

Specimen Type

Whole Blood EDTA

Ordering Guidance

This assay **should not be used** for diagnosing lymphocytic malignancies or evaluation of lymphocytosis of unknown etiology. In such cases, order LCMS / Leukemia/Lymphoma Immunophenotyping, Flow Cytometry, Varies, which includes a hematopathology review.

This assay can be used for absolute quantitation of B cells in patients with chronic lymphocytic leukemia.

While this assay can be used to follow patients on B-cell-depleting therapy, like rituximab (eg, Rituxan, Riabni) or ofatumumab (eg, Kesimpta), it may be more reasonable and financially viable to use CD20B / CD20 on B Cells, Blood; includes CD45, CD19 and CD20 markers.

Shipping Instructions

It is recommended that specimens arrive within 24 hours of collection. Collect and package specimen as close to shipping time as possible.

Necessary Information

Date and time of collection are required.

Specimen Required

Container/Tube: Lavender top (EDTA)
Specimen Volume: 3 mL
Collection Instructions: Send whole blood specimen in original tube. **Do not aliquot.**
Additional Information: For serial monitoring, it is recommended that specimen collection be performed at the same time of day.

Specimen Minimum Volume

1 mL

Reject Due To

Gross hemolysis	Reject
Gross lipemia	Reject
Sample viability less than 50%	Reject

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Whole Blood EDTA	Ambient	52 hours	PURPLE OR PINK TOP/EDTA

Clinical & Interpretive

Clinical Information

Lymphocytes in peripheral blood (circulation) are heterogeneous and can be broadly classified into T cells, B cells, and natural killer (NK) cells. There are various subsets of each of these individual populations with specific cell-surface markers and function. This assay provides absolute (cells/mcL) and relative (%) quantitation for the main categories of T cells, B cells, and NK cells, in addition to a total lymphocyte count (CD45+).

Each of these lymphocyte subpopulations have distinct effector and regulatory functions and are maintained in homeostasis under normal physiological conditions. Each of these lymphocyte subsets can be identified by a combination of 1 or more cell surface markers. The CD3 antigen is a pan-T-cell marker, and T cells can be further divided

into 2 broad categories based on the expression of CD4 or CD8 coreceptors. B cells can be identified by expression of CD19, while NK cells are typically identified by the coexpression of CD16 and CD56.

The absolute counts of lymphocyte subsets are known to be influenced by a variety of biological factors, including hormones, the environment, and temperature. The studies on diurnal (circadian) variation in lymphocyte counts have demonstrated progressive increase in CD4 T-cell count throughout the day, while CD8 T cells and CD19+ B cells increase between 8:30 a.m. and noon with no change between noon and afternoon. NK-cell counts, on the other hand, are constant throughout the day.(1) Circadian variations in circulating T-cell counts have been shown to be negatively correlated with plasma cortisol concentration.(2-4) In fact, cortisol and catecholamine concentrations control distribution and, therefore, numbers of naive versus effector CD4 and CD8 T cells.(2) It is generally accepted that lower CD4 T-cell counts are seen in the morning compared to the evening(5) and during summer compared to winter.(6) These data therefore indicate that timing and consistency in timing of blood collection is critical when serially monitoring patients for lymphocyte subsets.

Abnormalities in the number and percent of T (CD3+, CD4+, CD8+), B (CD19), and NK (CD16+CD56) lymphocytes have been described in a number of different disease conditions. In patients who are infected with HIV, the CD4 count is measured for AIDS diagnosis and for initiation of antiviral therapy. The progressive loss of CD4 T lymphocytes in patients infected with HIV is associated with increased infections and complications. The US Public Health Service has recommended that all patients who are HIV-positive be tested every 3 to 6 months for the level of CD4 T lymphocytes.

Lymphocyte subset quantitation is also very useful in the evaluation of patients with primary immunodeficiencies of all ages, including follow-up for newborn screening for severe combined immunodeficiency and immune monitoring following immunosuppressive therapy for transplantation, autoimmunity, or any other relevant clinical condition where immunomodulatory treatment is used.

It is also helpful as a preliminary screening assay for gross quantitative anomalies in any lymphocyte subset, whether related to malignancies or infection.

The 2008 guidelines for diagnosis and treatment of chronic lymphocytic leukemia (CLL) from the International Workshop on Chronic Lymphocytic Leukemia(7) recommend changing the diagnostic criteria for CLL from an absolute lymphocyte count greater than 5 x 10(9)/L to a circulating B-cell count greater than 5 x 10(9)/L(8,9) previously defined in the 1996 National Cancer Institute guidelines for CLL. This flow cytometric assay enables accurate quantitation of circulating B cells using a single platform technology with absolute quantitation through the use of flow cytometry beads.

Reference Values

The appropriate age-related reference values will be provided on the report.

Interpretation

HIV treatment guidelines from the US Department of Health and Human Services and the International Antiviral Society-USA Panel recommend antiviral treatment in all patients with HIV infection, regardless of CD4 T-cell count.(10,11) Additionally, antibiotic prophylaxis for *Pneumocystis jiroveci* infection is recommended for patients with CD4 count less than 200 cells/mcL. For other opportunistic infections, see the recommendations from the Centers for Disease Control and Prevention, the National Institutes of Health, and the HIV Medicine Association of the Infectious Diseases Society of America.(12)

Cautions

Lymphocyte subset counts should be appropriately interpreted in context of the clinical presentation and other immunological parameters and relevant laboratory test results.

For serial monitoring of lymphocyte subsets, it is recommended that the patient be evaluated at the same time of the day to account for diurnal variation.

For follow-up of infants identified by newborn screening for severe combined immunodeficiency (SCID) and severe T-cell lymphopenia, SCID should be considered as a potential diagnosis in infants with less than 300 autologous CD3 T cells/mcL. Infants with 300 to 1500 autologous CD3 T cells/mcL may have leaky SCID, Omenn syndrome, or variant SCID depending on other clinical and molecular features.

In infants identified by newborn screening for SCID, T-cell lymphopenia is defined as having up to 1500 autologous CD3T cells/mcL.

This assay **should not be used** for diagnosing lymphocytic malignancies or evaluation of lymphocytosis of unknown etiology, though the latter may be identified through this assay in a screening assessment. In such cases, LCMS / Leukemia/Lymphoma Immunophenotyping, Flow Cytometry, Varies will be recommended, which includes a hematopathology review.

Clinical Reference

1. Carmichael KF, Abayomi A. Analysis of diurnal variation of lymphocyte subsets in healthy subjects and its implication in HIV monitoring and treatment. 15th Intl Conference on AIDS, Bangkok, Thailand, 2004, Abstract # B11052. Afr J Med Med Sci. 2006;35(1):53-57
2. Dimitrov S, Benedict C, Heutling D, Westermann J, Born J, Lange T. Cortisol and epinephrine control opposing circadian rhythms in T-cell subsets. Blood. 2009;113(21):5134-5143
3. Dimitrov S, Lange T, Nohroudi K, Born J. Number and function of circulating antigen presenting cells regulated by sleep. Sleep. 2007;30(4):401-411
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6. Paglieroni TG, Holland PV. Circannual variation in lymphocyte subsets, revisited. Transfusion. 1994;34(6):512-516
7. Hallek M, Cheson BD, Catovsky D, et al. Guidelines for the diagnosis and treatment of chronic lymphocytic leukemia: a report from the International Workshop on chronic lymphocytic leukemia updating the National Cancer Institute Working Group 1996 guidelines. Blood. 2008;111(12):5446-5456
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10. Panel on Antiretroviral Guidelines for Adults and Adolescents: Guidelines for the use of antiretroviral agents in adults and adolescents living with HIV. Department of Health and Human Services; Updated September 12, 2024. Accessed August 27, 2025. Available at

https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/adult-adolescent-arv/guidelines-adult-adolescent-arv.pdf
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12. Panel on Guidelines for the Prevention and Treatment of Opportunistic Infections in Adults and Adolescents With HIV. Guidelines for the Prevention and Treatment of Opportunistic Infections in Adults and Adolescents With HIV. National Institutes of Health, HIV Medicine Association, and Infectious Diseases Society of America. Accessed August 19, 2025. Available at https://clinicalinfo.hiv.gov/en/guidelines/adult-and-adolescent-opportunistic-infection
13. Schmid I, Krall WJ, Uittenbogaart CH, Braun J, Giorgi JV. Dead cell discrimination with 7-amino-actinomycin D in combination with dual color immunofluorescence in single laser flow cytometry. Cytometry. 1992;13(2):204-208. doi:10.1002/cyto.990130216

Performance

Method Description

The T-, B-, and natural killer-cell surface marker assay uses monoclonal antibodies to identify the various membrane antigens, and flow cytometry to enumerate the number of cells expressing these differentiation antigens. CD14 is used to exclude monocytes, thereby improving accuracy and enhancing the purity of the lymphocyte population. The results are reported as the percent of lymphocytes that are total T cells (CD3+), CD3+CD4+ T cells, CD3+CD8+ T cells, natural killer (CD16+56+, CD3-), and B-lymphocytes (CD19+), and the absolute number of each cell type per mL of blood. The assay is a 7-color no-wash procedure, and the absolute counts are calculated from internal bead standards. In addition, the total lymphocyte count and CD4:CD8 ratio are reported. 7-AAD is used to assess the percentage of viable cells for both the leukocyte and the lymphocyte populations, reported as % Sample Viability and % Lymphocyte Viability, respectively.(Hoffman RA, Kung PC, Hansen WP, Goedstien G. Simple and rapid measurement of human T lymphocytes and their subclasses in peripheral blood. Proc Natl Acad Sci USA. 1980:77[8]:4914-4917; Mandy FF, Nicholson JK, McDougal JS; CDC. Guidelines for performing single-platform absolute CD4+ T-cell determinations with CD45 gating for persons infected with human immunodeficiency virus. Centers for Disease Control and Prevention. MMWR Recomm Rep. 2003;52[RR-2]:1-13)

PDF Report

No

Day(s) Performed

Monday through Sunday

Report Available

3 to 4 days

Specimen Retention Time

4 days

Performing Laboratory Location

Fees & Codes

Fees

- Authorized users can sign in to Test Prices for detailed fee information.
- Clients without access to Test Prices can contact Customer Service 24 hours a day, seven days a week.
- Prospective clients should contact their account representative. For assistance, contact Customer Service.

Test Classification

This test was developed and its performance characteristics determined by Mayo Clinic in a manner consistent with CLIA requirements. It has not been cleared or approved by the US Food and Drug Administration.

CPT Code Information

86355
86357
86359
86360

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
TBNY	T, B and NK Lymphocyte QN, New York	80721-4

Result ID	Test Result Name	Result LOINC® Value
4054	% CD16+CD56 (NK cells)	8112-5
4055	CD16+CD56 (NK cells)	20402-4
3324	CD19 (B Cells)	8116-6
3322	CD3 (T Cells)	8122-4
3319	% CD4 (T Cells)	8123-2
3325	CD4 (T Cells)	24467-3
3326	CD8 (T Cells)	14135-8
3327	4/8 Ratio	54218-3
3321	CD45 Total Lymph Count	27071-0
3318	% CD19 (B Cells)	8117-4
3316	% CD3 (T Cells)	8124-0
3320	% CD8 (T Cells)	8101-8
6657	Comment	80722-2
622952	% Sample Viability	33193-4
622953	% Lymphocyte Viability	33193-4