

Overview

Useful For

Detecting cell-surface antigens on malignant cells that are potential therapeutic antibody targets, specifically CD20

Determining the eligibility of patients for monoclonal antibody therapies

Monitoring response to the therapeutic antibody

Testing Algorithm

A complete diagnostic B-cell, T-cell, or acute immunophenotyping panel is **not** performed. In some cases, a limited morphologic evaluation will be performed.

Method Name

Immunophenotyping

NY State Available

Yes

Specimen

Specimen Type

Varies

Ordering Guidance

This test should **not** be used as a shortened diagnostic panel. For a complete diagnostic B-cell, T-cell, or acute immunophenotyping panel, order LCMS / Leukemia/Lymphoma Immunophenotyping, Flow Cytometry, Varies.

This test evaluates CD20 expression only. For CD52 expression, order CEE52 / CD52 Cell Expression Evaluation, Varies. For CD49d expression, order CEE49 / CD49d Cell Expression Evaluation, Varies.

Shipping Instructions

Specimen must arrive within 96 hours of collection.

Necessary Information

The following information is required:

1. The therapeutic monoclonal antibody being used or considered
2. The pertinent hematologic diseases that have been diagnosed or considered
3. Specimen source
4. Date and time of collection

Specimen Required

Submit only 1 of the following specimens:

Specimen Type: Blood

Container/Tube:**Preferred:** Yellow top (ACD)**Acceptable:** Green top (sodium heparin) or lavender top (EDTA)**Specimen Volume:** 10 mL**Collection Instructions:**

1. Send specimen in original tube. **Do not aliquot.**
2. Label specimen as blood.

Specimen Stability Information: Ambient/Refrigerated**Specimen Type:** Bone marrow**Container/Tube:****Preferred:** Yellow top (ACD)**Acceptable:** Green top (sodium heparin) or lavender top (EDTA)**Specimen Volume:** 1-5 mL**Collection Instructions:**

1. Label specimen as bone marrow.
2. Submission of bilateral specimens is not required.

Specimen Stability Information: Ambient/Refrigerated**Forms**

If not ordering electronically, complete, print, and send a [Hematopathology/Cytogenetics Test Request](#) (T726) with the specimen.

Specimen Minimum Volume

Blood: 3 mL

Bone Marrow Aspirate: 1 mL

Reject Due To

All specimens will be evaluated at Mayo Clinic Laboratories for test suitability

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Varies	Varies	4 days	

Clinical and Interpretive

Clinical Information

Monoclonal antibodies are critical tools for detecting cellular antigens in various hematologic diseases and are used to provide critical prognostic information (CD49d). Monoclonal antibodies are also used as therapeutic agents in a variety of hematologic diseases. For example:

- Anti-CD20 (Rituxan): B-cell malignant lymphomas and multiple myeloma
- Anti-CD52 (Campath-1H): B-cell chronic lymphocytic leukemia and T-cell disorders

This list will undoubtedly expand over time to include other antibodies.

It may be necessary to document expression of these markers by the malignant cells prior to initiating the respective monoclonal antibody therapy. Expression of these markers may also be required for follow-up to monitor the impact of treatment on residual normal counterparts (eg, CD20-positive lymphocytes in patients treated with anti-CD20).

The distribution of these cellular antigens is well established in normal, reactive, and in various malignant disorders. The laboratory has several years of experience with therapeutic antibody monitoring of Mayo Clinic patients as part of the routine B-cell, T-cell, or acute immunophenotyping panels.

Reference Values

Normal individuals have B lymphocytes, T lymphocytes, or myeloid cells that express the corresponding cell-surface antigens in question.

Interpretation

The immunophenotyping report will summarize the pattern of antigenic expression on malignant cells and, if appropriate, the normal cellular counterparts that correspond to the therapeutic monoclonal antibody target.

Cautions

No significant cautionary statements.

Clinical Reference

1. Davis AT: Monoclonal antibody-based therapy of lymphoid neoplasms: what's on the horizon? *Semin Hematol.* 2000;37(4 Suppl 7):34-42
2. Czuczman MS, Grillo-Lopez AJ, White CA, et al: Treatment of patients with low-grade B-cell lymphoma with the combination of chimeric anti-CD20 monoclonal antibody and CHOP chemotherapy. *J Clin Oncol.* 1999;17:268-276
3. Flynn JM, Byrd JC: Campath-1H monoclonal antibody therapy. *Curr Opin Oncol.* 2000;12:574-581
4. Kreitman RJ, Wilson WH, Bergeron K, et al: Efficacy of the anti-CD22 recombinant immunotoxin BL22 in chemotherapy-resistant hairy-cell leukemia. *N Eng J Med.* 2001;345:241-247
5. Shanafelt TD, Geyer SM, Bone ND, et al: CD49D expression is an independent predictor of overall survival in patients with CLL: a prognostic parameter with therapeutic potential. *Br J Haematol.* 2008;140:537-546

Performance

Method Description

Flow cytometric immunophenotyping of peripheral blood, bone marrow, or tissue-derived lymphocytes is performed to assess the expression of the cell-surface antigen corresponding to the monoclonal antibody therapeutic target. The following antibody panels will be used:

-Anti-CD20 assessment: kappa/lambda/CD19/CD20

(Keren P, McCoy Jr JP, Carey J, eds: Flow Cytometry in Clinical Diagnosis. 4th ed. ASCP Press; 2007)

PDF Report

No

Day(s) Performed

Monday through Friday

Report Available

1 to 4 days

Specimen Retention Time

2 weeks

Performing Laboratory Location

Rochester

Fees and 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 Regional Manager. For assistance, contact [Customer Service](#).

Test Classification

This test was developed using an analyte specific reagent. Its performance characteristics were determined by Mayo Clinic in a manner consistent with CLIA requirements. This test has not been cleared or approved by the US Food and Drug Administration.

CPT Code Information

88184-Flow cytometry; first cell surface, cytoplasmic or nuclear marker

88185 x 3-Flow cytometry; additional cell surface, cytoplasmic or nuclear marker

88187-Flow Cytometry Interpretation, 2 to 8 Markers

LOINC® Information

Test ID	Test Order Name	Order LOINC Value
CEE20	CD20 Cell Expression Evaluation, V	In Process

Result ID	Test Result Name	Result LOINC Value
CK164	CEE20 Result	No LOINC Needed
CK165	Final Diagnosis	22637-3