

## Overview

### Useful For

Detecting cell-surface antigens on malignant cells that are potential therapeutic antibody targets, specifically CD52

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 CD52 expression only. For CD20 expression, order CEE20 / CD20 Cell Expression Evaluation, Varies. For CD49d expression, order CEE49 / CD49d Cell Expression Evaluation, Varies.

### Shipping Instructions

**Specimen must arrive within 4 days 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. Diagnostic immunophenotype of the neoplastic cells (when available, a pathology and/or flow cytometry report should be included).
4. Specimen source
5. Date and time of collection

**Specimen Required**

Submit only 1 of the following specimens:

**Specimen Type:** Whole Blood

**Container/Tube:**

**Preferred:** Yellow top (ACD solution A or B)

**Acceptable:** Lavender top (EDTA) or Green top (sodium heparin)

**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 < or =4 days

**Specimen Type:** Bone marrow

**Container/Tube:**

**Preferred:** Yellow top (ACD solution A or B)

**Acceptable:** Lavender top (EDTA) or Green top (sodium heparin) **Specimen Volume:** 1-5 mL

**Collection Instructions:**

1. Submission of bilateral specimens is not required.
2. Label specimen as bone marrow.
3. Send bone marrow specimen in original tube. **Do not aliquot.**

**Specimen Stability Information:** Ambient/Refrigerated < or =4 days

**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 & Interpretive****Clinical Information**

Monoclonal antibodies are critical tools for detecting cellular antigens in various hematologic diseases and are used to provide critical prognostic information (eg, 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. Salles G, Barrett M, Foa R, et al. Rituximab in B-cell hematologic malignancies: A review of 20 years of clinical experience. *Adv Ther.* 2017;34(10):2232-2273. doi:10.1007/s12325-017-0612-x
2. Bachy E, Seymour JF, Feugier P, et al. Sustained progression-free survival benefit of rituximab maintenance in patients with follicular lymphoma: Long-term results of the PRIMA study. *J Clin Oncol.* 2019;37(31):2815-2824. doi:10.1200/JCO.19.01073
3. Cross M, Dearden C. B and T cell prolymphocytic leukaemia. *Best Pract Res Clin Haematol.* 2019;32(3):217-228. doi:10.1016/j.beha.2019.06.001
4. Braun T, von Jan J, Wahnschaffe L, Herling M. Advances and perspectives in the treatment of T-PLL. *Curr Hematol Malig Rep.* 2020;15(2):113-124. doi:10.1007/s11899-020-00566-5
5. Strati P, Parikh SA, Chaffee KG, et al. CD49d associates with nodal presentation and subsequent development of lymphadenopathy in patients with chronic lymphocytic leukaemia. *Br J Haematol.* 2017;178(1):99-105. doi:10.1111/bjh.14647

### 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 panel will be used:

- Anti-CD52 assessment: CD52/CD19/CD3/CD45

(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 Saturday

**Report Available**

1 to 4 days

**Specimen Retention Time**

14 days

**Performing Laboratory Location**

Rochester

**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 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 |
|---------|------------------------------------|--------------------|
| CEE52   | CD52 Cell Expression Evaluation, V | 100991-9           |

| Result ID | Test Result Name | Result LOINC® Value |
|-----------|------------------|---------------------|
| CK166     | CEE52 Result     | No LOINC Needed     |
| CK167     | Final Diagnosis  | 22637-3             |