Overview

Useful For
Monitoring response to therapy in patients with previously diagnosed Sezary syndrome or mycosis fungoides

Reflex Tests

<table>
<thead>
<tr>
<th>Test ID</th>
<th>Reporting Name</th>
<th>Available Separately</th>
<th>Always Performed</th>
</tr>
</thead>
<tbody>
<tr>
<td>FCIMS</td>
<td>Flow Cytometry Interp, 9-15 Markers</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>FCINS</td>
<td>Flow Cytometry Interp, 16 or greater</td>
<td>No</td>
<td>No</td>
</tr>
</tbody>
</table>

Additional Tests

<table>
<thead>
<tr>
<th>Test ID</th>
<th>Reporting Name</th>
<th>Available Separately</th>
<th>Always Performed</th>
</tr>
</thead>
<tbody>
<tr>
<td>FIRST</td>
<td>Flow Cytometry, Cell Surface, First</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>ADD1</td>
<td>Flow Cytometry, Cell Surface, Addl</td>
<td>No</td>
<td>Yes</td>
</tr>
</tbody>
</table>

Testing Algorithm
Sezary panel is ordered in cases with previously diagnosed Sezary syndrome or cutaneous T-cell lymphoma (CTCL) with peripheral blood involvement. For cases without a previously confirmed diagnosis or previously performed immunophenotyping at our laboratory, the ordered test will be changed to SZDIA / Sezary Diagnostic Flow Cytometry, Blood, which includes a triage panel to exclude a B-cell lymphoproliferative disorder and a Sezary panel.

The panel is charged based on number of markers tested (FIRST for first marker, ADD1 for each additional marker). In addition, reflex testing may occur to fully characterize a disease state or clarify any abnormalities from the screening test. Reflex tests will be performed at an additional charge for each marker tested (ADD1 if applicable).

Method Name
Immunophenotyping

NY State Available
Yes

Specimen

Specimen Type
Whole blood

Advisory Information
This test is for monitoring response to therapy in patients who have been diagnosed with Sezary syndrome or mycosis fungoides. For patients who do not have a diagnosis of Sezary syndrome, SZDIA / Sezary Diagnostic Flow Cytometry, Blood is the appropriate test to order.

**Specimen Required**

**Collection Container/Tube:**

- **Preferred:** Yellow top (ACD)
- **Acceptable:** Lavender top (EDTA), green top (heparin)

**Specimen Volume:** 6 mL

**Collection Instructions:**

1. Send in original tube. Do not transfer blood to other containers.
2. Label specimen as blood.

**Forms**

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

**Specimen Minimum Volume**

1 mL

**Reject Due To**

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Gross hemolysis</td>
<td>Reject</td>
<td></td>
</tr>
<tr>
<td>Gross lipemia</td>
<td>OK</td>
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</tbody>
</table>

**Specimen Stability Information**

<table>
<thead>
<tr>
<th>Specimen Type</th>
<th>Temperature</th>
<th>Time</th>
<th>Special Container</th>
</tr>
</thead>
<tbody>
<tr>
<td>Whole blood</td>
<td>Ambient (preferred)</td>
<td>72 hours</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Refrigerated</td>
<td>72 hours</td>
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</table>

**Clinical and Interpretive**

**Clinical Information**

Sezary syndrome is a leukemic form of cutaneous T-cell lymphoma (CTCL). By definition, it is associated with systemic skin involvement (erythroderma) and the presence of at least 1000/mcL of circulating cells with irregular nuclear features (Sezary cells). Morphologic assessment of the number of Sezary cells has been proven to have low reproducibility. Therefore, WHO/European Organization for Research and Treatment of Cancer (EORTC) classification of skin tumors adopted alternative methods to assess circulating T-cells in order to establish the diagnosis of Sezary syndrome. These include CD4:CD8 ratio of more than 10:1, and selective loss of CD7 and/or CD26 on 40% and 30% of the CD4-positive T-cell population, respectively. It is important to recognize that the later criteria (fulfilled by peripheral blood flow cytometry immunophenotyping) are relative, and not in direct correlation with
Test Definition: SZMON
Sezary Monitoring Flow Cytometry, B

absolute counts of Sezary cells defined by morphology.

Reference Values
An interpretive report will be provided. This test will be processed as a laboratory consultation. An interpretation of the immunophenotypic findings and, if available, morphologic features will be provided by a board-certified hematopathologist for every case.

Interpretation
Sezary cells typically show loss of CD7 and/or CD26. As loss of these markers is not completely sensitive or specific for Sezary cells, the WHO/European Organization for Research and Treatment of Cancer (EORTC) classification of skin tumors proposed cutoffs of 30% for CD26 loss and 40% for CD7 loss on CD4-positive T-cells, as diagnostic criteria for Sezary syndrome. In addition, CD4:CD8 ratio of greater than or equal to 10:1 in a gated T-cell population is also considered abnormal, and part of diagnostic algorithm for Sezary syndrome.

In mycosis fungoides staging studies the cutoffs are even less clearly defined. The clinical outcome was worse in patients with more than 5% of circulating lymphocytes showing Sezary-like morphology. However, flow cytometry immunophenotyping is deemed useful for relative quantification of these cells only if they can be separated by aberrant expression of other surface markers. In majority of cases, this cannot be accomplished to the proposed cutoff point (5% of circulating lymphocytes).

The test will be resulted as "No phenotypically aberrant T-cell population detected" if there is no specific phenotype that allows separation of potentially abnormal CD4-positive T-cells, loss of CD26 (and/or CD7) is present in less than 30% (40%), and CD4:CD8 ratio is less than 10:1. If any of the above aberrancies are present, the test will be resulted as "Phenotypically distinct T-cell population is detected" with a description of phenotype, percentage of total CD4-positive population and percentage of total analyzed events. In addition, the phenotype will be compared to that of any distinct T-cell population previously seen in the same patient by our laboratory.

Cautions
Correlation with clinical features is necessary for diagnosis of Sezary syndrome. This analysis can only describe a cell population with aberrant phenotype, but the significance of this finding in isolation is uncertain.

Clinical Reference
Performance

Method Description
Flow cytometry immunophenotyping of peripheral blood is performed using the following antibodies:


PDF Report
No

Day(s) and Time(s) Test Performed
Specimens are processed Monday through Sunday.

Results are reported Monday through Saturday.

Analytic Time
1 day

Maximum Laboratory Time
3 days

Specimen Retention Time
14 days

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 U.S. Food and Drug Administration.

CPT Code Information
88184-Flow cytometry; first cell surface, cytoplasmic or nuclear marker x 1

88185-Flow cytometry; additional cell surface, cytoplasmic or nuclear marker (each)

88188-Flow Cytometry Interpretation, 9 to 15 markers (if appropriate)
88189-Flow Cytometry Interpretation, 16 or more markers (if appropriate)

**LOINC® Information**

<table>
<thead>
<tr>
<th>Test ID</th>
<th>Test Order Name</th>
<th>Order LOINC Value</th>
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<tbody>
<tr>
<td>SZMON</td>
<td>Sezary Monitoring Flow Cytometry, B</td>
<td>In Process</td>
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<table>
<thead>
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<th>Test Result Name</th>
<th>Result LOINC Value</th>
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<tbody>
<tr>
<td>CK130</td>
<td>Sezary Monitoring</td>
<td>No LOINC Needed</td>
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<td>CK131</td>
<td>Final Diagnosis</td>
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<tr>
<td>CK132</td>
<td>Special Studies</td>
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<tr>
<td>CK133</td>
<td>Microscopic Description</td>
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