Overview

Useful For
Identifying phenotypically aberrant T-cell population in peripheral blood as part of the diagnostic workup for Sezary syndrome

Roughly assessing the circulating tumor burden in mycosis fungoides, if the phenotype of the neoplastic cells is distinctive enough

Reflex Tests

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

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<tr>
<td>FIRST</td>
<td>Flow Cytometry, Cell Surface, First</td>
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<td>Yes</td>
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<tr>
<td>ADD1</td>
<td>Flow Cytometry, Cell Surface, Addl</td>
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</table>

Testing Algorithm

This Sezary panel is ordered in cases of suspected Sezary syndrome or cutaneous T-cell lymphoma (CTCL) with peripheral blood involvement. For cases without a previously confirmed diagnosis of Sezary syndrome, a triage panel will also be performed to exclude a B-cell lymphoproliferative disorder. If there is a significant phenotypically distinct T-cell population detected, a V-beta panel for proof of clonality may be ordered by the signing pathologist.

A triage panel is always performed. 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
Test Definition: SZDIA
Sezary Diagnostic Flow Cytometry, B

Specimen

Specimen Type
Whole blood

Advisory Information
This test is not appropriate for monitoring patients with a diagnosis of Sezary syndrome, SZMON / Sezary Monitoring Flow Cytometry, Blood is more appropriate for that situation.

Specimen Required
Specimen Type: Blood

Collection Container/Tube:
Preferred: Yellow top (ACD)
Acceptable: EDTA, Heparin

Specimen Volume: 6 mL

Collection Instructions:
1. 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

<table>
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<tr>
<th>Condition</th>
<th>Status</th>
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<tbody>
<tr>
<td>Gross hemolysis</td>
<td>Reject</td>
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<tr>
<td>Gross lipemia</td>
<td>OK</td>
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Specimen Stability Information

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<th>Temperature</th>
<th>Time</th>
<th>Special Container</th>
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<tbody>
<tr>
<td>Whole blood</td>
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</tr>
<tr>
<td></td>
<td>Refrigerated</td>
<td>72 hours</td>
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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/µL 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 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 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, and there are circulating normal CD4-positive T-cells, which usually cannot be excluded from the analysis, 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, a CD4:CD8 ratio of greater than or equal to 10:1 in a gated T-cell population is also considered abnormal and part of the 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 the 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:


-Sezary Panel: CD2, CD3, CD4, CD5, CD7, CD8, CD26 and CD45


PDF Report
No

Day(s) and Time(s) Test Performed
Specimens are processed Monday through Sunday and 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
Test Definition: SZDIA
Sezary Diagnostic Flow Cytometry, B

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

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<th>Order LOINC Value</th>
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