

Test Definition: FSJCV

STRATIFY JCV Antibody (with Index) with Reflex to Inhibition Assay

Overview

Reflex Tests

| Test Id | Reporting Name | Available Separately | Always Performed |
|---------|---------------------|----------------------|------------------|
| FSJIN | STRATIFY JCV Ab INH | No | No |

Testing Algorithm

If the Index Value is between 0.20-0.40 (Inconclusive), STRATIFY JCV DxSelect Antibody Inhibition Assay will be performed at an additional charge.

Method Name

ELISA

NY State Available

Yes

Specimen

Specimen Type Serum

Specimen Required Collection Container/Tube: Preferred: Red top Acceptable: Serum gel, lavender top (EDTA) Submission Container/tube: Plastic vial Specimen Volume: 1 mL

Collection Instructions:

- 1. Draw blood in a plain, red-top tube; serum gel tube is acceptable.
- 2. Centrifuge and aliquot 1 mL of serum into a plastic vial.
- 3. Send refrigerate.

Specimen Minimum Volume

0.5 mL

Reject Due To

| Gross | Reject |
|-----------|--------|
| hemolysis | |



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| Gross lipemia | Reject |
|---------------|--------|
| Gross icterus | Reject |

Specimen Stability Information

MAYO CLINIC

LABORATORIES

| Specimen Type | Temperature | Time | Special Container |
|---------------|--------------------------|---------|-------------------|
| Serum | Ambient | 7 days | |
| | Refrigerated (preferred) | 14 days | |
| | Frozen | 90 days | |

Clinical & Interpretive

Clinical Information

The STRATIFY JCV(R) DxSelect(TM) Antibody Test is an enzyme-linked immunosorbent assay (ELISA) designed to detect JCV antibodies to help identify individuals who have been exposed to the virus. Samples with low level reactivity in the detection assay are retested in a confirmation (inhibition) assay to confirm presence or absence of JCV-specific antibodies.

Retrospective analyses of post marketing data from various sources, including observational studies and spontaneous reports obtained worldwide, suggest that the risk of developing PML may be associated with relative levels of serum anti-JCV antibody as measured by anti-JCV antibody index.(1)

Reference Values

Index interpretive criteria: <0.20 Negative 0.20-0.40 Indeterminate >0.40 Positive

Interpretation

Negative: Antibodies to JCV not detected.

Indeterminate: Low level reactivity detected, see Inhibition Assay result for the final antibody result.

Positive: Antibodies to JC virus (JCV) detected indicating the patient has been exposed to JCV at an undetermined time.

Clinical Reference

1. TYSABRI(natalizumab) US Prescribing Information

Performance

PDF Report



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No

Day(s) Performed

Monday through Saturday

Report Available

4 to 8 days

Performing Laboratory Location

Quest Diagnostics

Fees & Codes

Fees

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

CPT Code Information

86711

LOINC[®] Information

| Test ID | Test Order Name | Order LOINC [®] Value |
|-----------|---------------------------|---------------------------------|
| FSJCV | STRATIFY JCV DxSelect RFL | Not Provided |
| | | |
| Result ID | Test Result Name | Result LOINC [®] Value |
| Z6367 | Natalizumab Therapy? | Not Provided |
| Z6368 | Index Value | 100977-8 |
| | | |