

# **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**

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
Z6369	JCV Antibody	70173-0