

Comparison of STRATIFY JCV and IMMUNOWELL JCV Assays for Anti-JCV Antibody Detection: A Multicenter Study Across Tuscan Neurology Centers

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Introduction

- **Progressive multifocal leukoencephalopathy (PML)** is a severe complication caused by the John Cunningham virus (JCV) in patients with Multiple Sclerosis (MS) treated with Natalizumab.
- **PML risk stratification** is crucial for clinical management, based on multiple factors including: i) serum anti-JCV antibody status, ii) prior use of immunosuppressants, iii) duration of NTZ treatment.
- Two assays are available for detecting anti-JCV antibodies in serum: **STRATIFY JCV™ test** and **IMMUNOWELL JCV™ test**.

Objective

This study aims to assess the concordance between the two tests and to evaluate potential differences in classifying PML risk in pwMS.

Methods

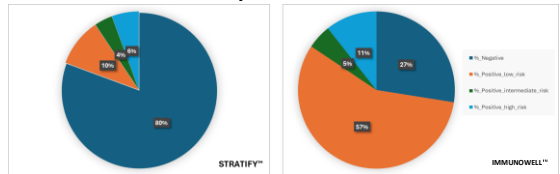
This is a multicenter, retrospective study conducted across neurology centers in Tuscany (Italy). Serum samples from pwMS receiving Natalizumab or about to start a new therapy were tested for anti-JCV antibodies using **both assays**. Paired samples were collected simultaneously or within one month. Based on the JCV index values, patients were stratified into four PML risk categories (negative, low, intermediate, high) —according to the manufacturer-defined thresholds for each assay. Risk concordance between the tests was evaluated using cross-tabulation and weighted Cohen's kappa.

Results

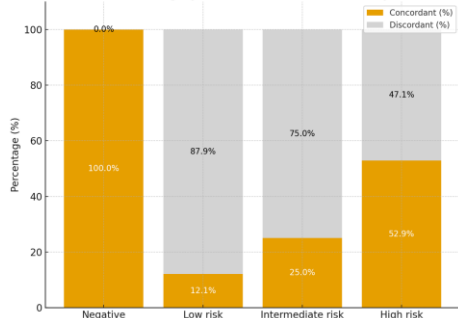
Demographic data

Variable	Value
Patients enrolled <i>n</i>	160
Gender	
Male <i>n</i> (%)	38.0 (23.75)
Female <i>n</i> (%)	122.0 (76.25)
Mean age (<i>SD</i>)	41.8 (11.7)
Mean age at diagnosis (<i>SD</i>)	31.3 (10.7)
Treatment history	
Naïve <i>n</i> (%)	102.0 (63.8)
Non-naïve <i>n</i> (%)	58.0 (36.2)
Years of illness <i>n</i> (<i>SD</i>)	10.53 (8.45)

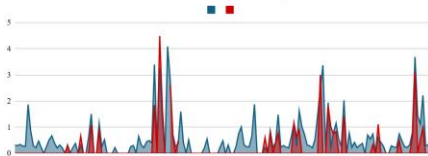
Risk Distribution by STRATIFY™ vs IMMUNOWELL™



Risk Category Concordance Between Assays



Immunowell vs Stratify



The overall agreement, assessed by **weighted Cohen's kappa**, was **0.34** (95% CI: 0.23–0.45, $p < 0.0001$), indicating fair concordance between the two tests in risk stratification.

Conclusions

- **Significant discrepancy** between STRATIFY JCV™ and IMMUNOWELL JCV™ in PML risk stratification.
- **High concordance** for negative results (100%) but **lower concordance** in positive risk categories.
- The choice of assay may significantly influence **risk categorization** and subsequent **treatment decisions**.

Disclosures

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