

## Test Summary

# TA90 Immune Complex

testcode

### Clinical Use

- Assess prognosis after curative resection of malignant melanoma
- Monitor patients for melanoma recurrence after curative resection

### Clinical Background

Existing prognostic factors such as lymph node status and tumor thickness and depth are helpful for predicting which melanomas will metastasize after curative resection. However, even patients whose tumors are considered relatively low-risk, based on standard prognostic factors, can develop metastasis and locoregional recurrence. Markers that accurately detect subclinical metastasis and predict recurrence may help determine which patients should receive adjuvant therapy.

TA90 is a 90-kd tumor-associated antigen that is expressed by >70% of melanomas. After curative resection of malignant melanoma, patients with occult metastasis may exhibit elevated levels of a TA90-IgG immune complex (TA90-IC).<sup>1</sup> Several reports have indicated that TA90-IC is a sensitive and specific marker of recurrence in patients with malignant melanoma and is associated with shortened survival.<sup>1-4</sup> Patients with TA90-IC detected early after curative resection of American Joint Committee on Cancer (AJCC) Stage I to III melanoma were found to have significantly lower 5-year overall survival (36% vs 84%,  $p < 0.001$ ) and disease-free survival (24% vs 74%,  $p < 0.001$ ) than TA90-IC-negative patients.<sup>2</sup> In that study, TA90-IC status was independent of standard prognostic factors, including lymph-node status; Breslow depth was the only other significant predictor of outcome in multivariate analysis. Similar results were found for patients with thick ( $\geq 4$  mm) melanomas.<sup>3</sup>

Serial monitoring of TA90-IC levels after curative resection of Stage I to III melanoma may also help predict recurrence, even in patients who are initially TA90-IC negative. Kelley et al found that 58 of 74 (78%) patients who developed distant metastasis had at least 2 consecutive positive TA90-IC results, first elevated an average of 19 months before clinical evidence of recurrence.<sup>2</sup> Only 20 of 88 (23%) patients without metastasis had at least 2 positive TA90-IC results; when

patients who received a polyvalent melanoma vaccine (known to elicit TA90-IC formation) were excluded, the sensitivity (92%) and specificity (86%) of the assay increased. Thus, detection of TA90-IC might be helpful in selecting patients for early intervention, when adjuvant therapy may be most effective.

### Individuals Suitable for Testing

- Patients who have recently undergone curative resection of malignant melanoma
- Patients being followed up for recurrence of malignant melanoma

### Specimen Requirements

1 mL frozen serum in no-additive red-top tube; 0.1 mL minimum. Quick freeze ( $-70$  °C) is recommended. Transport on dry ice.

For prognosis or baseline determinations, collect sample 30 to 60 days after curative resection.

### Method

- Enzyme-linked immunosorbent assay (ELISA)
  - Murine anti-TA90 monoclonal capture antibody
  - Goat antihuman immunoglobulin detection antibody, Fab-conjugated with alkaline phosphatase
- Analytical sensitivity: 0.410 optical density (OD)
- Analytical specificity: no known cross-reactivity with other tumor markers
- Alias: TA90-IC
- CPT code\*: 86294

### Reference Range

Negative

### Interpretive Information

TA90-IC positivity soon after curative resection of Stage I to III or thick ( $\geq 4$  mm) melanoma is associated with lower rates of overall and disease-free survival (Table 1) and a greater risk of recurrence (Table 2). During serial monitoring, positivity is associated with recurrence and appears, on average, 19 months before clinical or radiologic evidence of recurrence.<sup>2</sup> The results of this assay should be interpreted in light of other relevant clinical and laboratory findings.

Table 1. TA90-IC Status and Survival

	5-Year Overall Survival (OS)			5-Year Disease-Free Survival (DFS)		
	TA90-IC-positive	TA90-IC-negative	P value	TA90-IC-positive	TA90-IC-negative	P value
Stage I-III melanoma* <sup>2</sup>	36%	84%	<0.001	24%	74%	<0.001
Thick melanoma (≥4 mm)* <sup>1,3</sup>	26%	84%	<0.001	10%	73%	<0.001

\*TA90-IC measured within 6 months after tumor resection

<sup>1</sup>Estimated 5-year OS and DFS (median follow-up period was 25 months)

Table 2. Sensitivity and Specificity of TA90-IC Assay for Predicting Recurrence After Curative Resection of Melanoma

	Sensitivity	Specificity
Stage I-III melanoma		
Soon after curative resection <sup>1</sup>	77%	76%
Serial monitoring during follow-up <sup>2</sup>	78%	77%
Thick melanoma (≥4 mm)		
Soon after curative resection <sup>3</sup>	70%	85%

## References

1. Kelley MC, Jones RC, Gupta RK, et al. Tumor-associated antigen TA-90 immune complex assay predicts subclinical metastasis and survival for patients with early stage melanoma. *Cancer*. 1998;83:1355-1361.
2. Kelley MC, Gupta RK, Hsueh EC, et al. Tumor-associated antigen TA90 immune complex assay predicts recurrence and survival after surgical treatment of stage I-III melanoma. *J Clin Oncol*. 2001;19:1176-1182.
3. Chung MH, Gupta RK, Essner R, et al. Serum TA90 immune complex assay can predict outcome after resection of thick (≥4 mm) primary melanoma and sentinel lymphadenectomy. *Ann Surg Oncol*. 2002;9:120-126.
4. Litvak DA, Gupta RK, Yee R, et al. Endogenous immune response to early- and intermediate-stage melanoma is correlated with outcomes and is independent of locoregional relapse and standard prognostic factors. *J Am Coll Surg*. 2004;198:27-35.

\*The CPT codes provided are based on AMA guidelines and are for informational purposes only. CPT coding is the sole responsibility of the billing party. Please direct any questions regarding coding to the payor being billed.

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