**SYNOPSIS & OBJECTIVE**

In several cancers, molecular testing has added prognostic value and utility in the clinical setting. A 31-gene expression profile (31-GEP) test has been developed and validated for determining metastatic risk in cutaneous melanoma, with Class 1 and 2 results indicating low and high risks, respectively. As melanoma staging and guideline recommendations continue to evolve, it is important to consider the evidence supporting the use of clinicopathologic and molecular factors in melanoma patient care. Herein, published evidence supporting the 31-GEP test, including clinical validity, analytical validity, and clinical utility, are reviewed. From clinical validity evidence spanning eight peer-reviewed articles (n=1268 total patients) including two prospective studies, the 31-GEP test consistently demonstrated accuracy to identify patients with CM at high risk for recurrence, metastasis, and melanoma-specific mortality. Published analytical validity data verified the reliability of 31-GEP testing with inter- and intra-assay concordance of 99% and 100%, respectively, and 98% technical success on specimens with sufficient tumor content. Clinical utility data from three studies (n=494 total patients) and two physician surveys indicate that the 31-GEP test results significantly impact management decisions for approximately 1 of 2 patients, consistent with the impact of genomic testing in other cancers. In contrast to other prognostic melanoma GEP tests that have been reported, the 31-GEP test has published evidence from multiple retrospective and prospective clinical validity studies beyond initial development, along with published analytical validity and clinical utility data, in support of its use for melanoma risk assessment and patient management decisions.

**BACKGROUND & METHODS**

- The 31-GEP test predicts a CM patient’s risk of recurrence, metastasis, or melanoma-specific mortality at 5 years after diagnosis.
- The 31-GEP test is performed in a CAP-accredited/CLIA-certified laboratory using high-throughput RT-PCR assays as previously described. Clinical validity, analytical validity, and clinical utility studies surrounding the 31-GEP are reviewed herein.

**CLINICAL VALIDITY**

Evidence supports consistent ability of the 31-GEP test to accurately identify recurrence, metastasis, and melanoma-specific mortality in CM patients.

**ANALYTICAL VALIDITY**

Technical success studies demonstrate 99% inter- and 100% intra-assay concordance.

**CONCLUSION**

In review of the literature, the value of the 31-GEP test for use in prognosis and clinical management decision making is supported by evidence from the 3 pillars of molecular tests: clinical validity, clinical utility, and analytical validity.

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**REFERENCES**

15. Berg AS et al. DERM2018 Conference 2018