Miraca Life Sciences currently offers Melanoma FISH testing to aid in the diagnosis of Melanoma. This protocol is based on the validation of a fluorescence in situ hybridization (FISH) molecular assay for the evaluation and classification of histologically ambiguous melanocytic neoplasms. We are confident that this approach will: 1) greatly improve the classification of melanocytic neoplasms with conflicting morphologic features; 2) significantly impact the management of your patients; and 3) place your practice at the cutting edge of medical innovation.

Although the majority of melanomas can be distinguished from benign nevi on the basis of histologic criteria, for a significant subset of melanocytic proliferations there exist conflicting features that preclude a definitive consensus diagnosis for even the most expert pathologists (Corona, Mele et al. 1996). The morphologic limitations in the diagnosis of these histologically borderline lesions leads to both under- and over-diagnosis of melanoma.

Over 95% of primary melanomas demonstrate a high rate of chromosomal aberrations in comparison to nevi (Bastian, Olshen et al. 2003; Curtin, Fridlyand et al. 2005) The identification of common chromosomal aberrations in melanomas that are typically absent in benign nevi, has lead to the development and validation of a set of FISH probes on chromosomes 6 and 11 that can aid in the diagnosis of melanoma in histologically ambiguous cases (Gerami, Jewell et al. 2009; Newman, Lertsburapa et al. 2009; Gerami, Mafee et al. 2010).

The following 4 FISH probes: RREB1 (6p25), centromere 6, MYB (6q23), and CCND1 (11q13) accurately distinguished melanoma from benign nevi with a high sensitivity and specificity in a large series of over 300 cases, and correctly identified as melanoma all 6 cases that later metastasized within a cohort of 27 histologically ambiguous lesions (Gerami, Jewell et al. 2009). To date, over 575 primary melanomas, 44 metastatic melanomas, and 451 nevi have been validated in the literature by this FISH test, with an overall sensitivity and specificity estimated at approximately 82% and 95%, respectively. Miraca Life Sciences has validated the melanoma FISH assay, and offered the test beginning August 2, 2010. We strictly adhere to the published algorithmic approach. All the FISH results are interpreted independently by two experienced FISH certified technologists working closely with a board certified dermatopathologist and a board certified cytogeneticist, and their results are compared for consistency. As an additional quality assurance measure, we control for false positive results due to polyploidy when indicated, by analyzing a centrosome X probe.

Due to its utility in improving diagnostic accuracy in ambiguous melanocytic lesions, Miraca Life Sciences Dermatopathologists also utilize the test reflexively for melanocytic neoplasms.
for which a definitive histologic classification is not possible due to conflicting morphologic
criteria. The test can be performed on routinely processed formalin fixed paraffin-embedded
tissue, and utilizes DNA probe hybridization, fluorescence microscopy, and cytogenetic
interpretation. The test is similar to other diagnostic FISH assays, and is typically reimbursed
by government and third party insurance. Also, your patients will only be billed for routine co-
pay and deductibles as part of the total pathology charge, as no balance billing will be
assessed.

We are very excited about this test offering and are confident that your patients will benefit
from this information. Miraca Life Sciences plans to continue to be at the forefront of molecular
testing, and we will be notifying you of additional tests as they become available and as the
scientific literature warrants. Please call 866-588-3280 if you have any additional questions.

Julie D.R. Reimann MD, PhD

Director, Dermatologic Molecular Pathology

References:


