

**METHOD CHANGE & TEST  
TITLE CHANGE**

**NOTIFICATION DATE:** June 9, 2014

**EFFECTIVE DATE:** July 14, 2014

**HUMAN PAPILLOMAVIRUS (HPV) TYPING IN SITU DNA  
HYBRIDIZATION**  
Test ID: 80172

**EXPLANATION:** Due to recent disruptions in commercially-prepared in-situ hybridization reagents, effective July 14, 2014, test 80172 will be performed using alternative reagents. Consequently, detection of some high-risk genotypes will not be possible and to reflect part of this change, the test title will change. The new methodology will continue to detect the presence of both low-risk types 6 and 11, however only the following high-risk HPV genotypes will be detected: 16, 18, 31, 33, & 51. As before, results will reflect the presence of (positive), or absence of (negative) the aforementioned low-risk and high-risk types. The previous methodology detected additional high-risk genotypes 35, 39, 45, 52, 56, 58, and 66. If the case result is reported as negative yet is still considered suspicious for high-risk HPV infection, a Pathology Consultation (test code 70012) can be added per the ordering physician. In the context of the consultation, the Mayo Pathologist may choose to perform a new high-sensitivity assay for high-risk genotypes termed HPV High Risk E6/E7, RNA ISH. This assay detects additional high-risk genotypes including 16, 18, 26, 31, 33, 35, 39, 45, 51, 52, 53, 56, 58, 59, 66, 68, 73, and 82. At the current time, HPV High Risk E6/E7, RNA ISH, is not a stand-alone orderable test and can only be performed in conjunction with a Pathology Consultation.

**CURRENT METHODOLOGY:** Nucleic Acid Hybridization-In Situ

**NEW METHODOLOGY:** Nucleic Acid Hybridization-In Situ

**CURRENT PUBLISHED OR REPORTING NAME:** Human Papillomavirus (HPV) Typing In Situ DNA Hybridization

**NEW PUBLISHED OR REPORTING NAME:** Human Papillomavirus (HPV) Typing, DNA In Situ Hybridization

**CPT CODE:** 88365 (with GC modifier) - In Situ Hybridization (e.g. FISH), each probe

**ANALYTIC TIME:** 5 Days

**DAYS SET UP:** Monday through Friday

**QUESTIONS:** Contact your Mayo Medical Laboratories' Regional Manager or  
Richard R. Einerson, MML Laboratory Technologist Resource Coordinator  
Telephone: 800-533-1710