Technical Alert

Human Papilloma Virus (HPV) Test Enhancements

TO: Medical Staff and Clients

FROM: Dr. A. Christian Whelen, PhD, M.S., D(ABMM)
V.P. - Technical Director (Microbiology)

Terrie Koyamatsu, M(ASCP)
Manager, DLS Microbiology

Dr. Wesley Kim, MD
Medical Director DLS and QMC West

Dr. Ana Ortega-Lopez, MD
Medical Director QMC Punchbowl, North Hawaii and Molokai

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SUBJECT: **HPV Testing has migrated from a lab developed test to an FDA-approved system**

Hawaii Pathologists Laboratory (HPL) and Diagnostic Laboratory Services (DLS) recently consolidated the Molecular Diagnostics Laboratory under DLS. We believe this collaboration will greatly enhance the services we can provide.

We are pleased to announce the launch of an FDA-approved HPV assay on SurePath and Thin-Prep Liquid-Based Cytology specimens. The Roche Cobas™ 4800 Human Papillomavirus test test utilizes PCR amplification of target DNA and nucleic acid hybridization for the qualitative detection of 14 high-risk types in a single analysis.

The test specifically identifies HPV 16 and HPV 18 while concurrently detecting the rest of the high risk types (31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68) at clinically relevant infection levels. This assay has similar sensitivity and specificity compared to the other FDA approved assays on the market, as demonstrated by our extensive validation which included both specimens from our previous system and others from around the country.

You will now see three separate results from your HPV Test (order code 7614): HPV 16, HPV 18, and OTHER High Risk HPV. This eliminates the need to order a HPV 16/18 Reflex test and eliminates that separate charge.

Order code 7614	Specimen container:	SurePath or ThinPrep
	Optimum specimen volume:	1 mL
	Transport:	Ambient
	Turn around time:	Up to 5 days

Please refer any questions to: Kristen Croom, Director, Pathology, Clinical Laboratory and Molecular Services at HPL at (808) 691-4271, Terrie Koyamatsu, Manager - DLS Microbiology Laboratory at 589-5196, or DLS Client Services at 589-5101.