



College of American Pathologists

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May 16, 2006

Thomas Happe, MT(ASCP)
President
Maine Standards Company
765 Roosevelt Trail, Ste. 9A
Windham, ME 04062

Dear Mr. Happe:

This confirms that medical diagnostics laboratories are not required to use CAP linearity survey materials as a condition of CAP accreditation. Laboratories inspected and accredited by CAP may use any linearity verification materials that are recommended by the manufacturers of their diagnostic test machines or that are appropriate for use on a particular instrument.

To the extent that products manufactured by Maine Standards Company or other manufacturers are either recommended by diagnostic instrument manufacturers or are cleared and labeled under Section 510(k) of the Act of 1976, such standards are appropriate for use in CAP-inspected medical diagnostics laboratories to meet the requirements of AMR and calibration verification.

Sincerely,

Denise Driscoll, MS, MT(ASCP) SBB
Director, Laboratory Accreditation Programs (LAP)

cc: Mike Miller, Senior Vice President, Operations
Marcia B. Geotsalitis, Vice President, LAP