January 18, 2016

Dear Valued Customer,

As you're aware, on January 1, 2016, the Centers for Medicare and Medicaid Services (CMS) instituted new regulatory guidelines for quality control (QC) testing of CLIA non-waived tests. By this date, clinical labs were required to update their QC testing to use either CMS/CLIA default QC requirements or to implement an Individualized Quality Control Plan (IQCP).

As part of the 2016 changes, CMS no longer recognizes the CLSI M22-A: *Quality Control for Commercially Prepared Microbiological Culture Media* document as a valid method for documenting end user QC requirements. **Since the sole purpose of the QC Voucher was to document media listed in the M22 as exempt from end user QC, we've discontinued supplying QC Vouchers with each shipment. CLSI exempt media are no longer recognized by CMS. CMS now requires all microbiological media and kits be tested by your laboratory using either default CMS/CLIA QC requirements or by your laboratory's IQCP.**

Please note these changes only affect clinical laboratories. We have not made any changes to our QC testing program and samples from lots continue to be tested in our laboratory in accordance with CLSI M22 recommendations and/or the Instructions for Use (IFU) listed under the Technical Support menu at www.HardyDiagnostics.com, where applicable. Therefore, as an alternative to the QC Voucher, we recommend you maintain Certificates of Analysis (CofA) for each lot received as part of your records of our QC testing. Hardy Diagnostics CofA can be obtained on our website, under "Tech Support" tab. You will need the catalog number and lot number in advance to retrieve a lot-specific CofA.

At a minimum, we recommend you perform QC in accordance with regulations and in compliance with accreditation requirements. You should also inspect lots immediately upon receipt for obvious visual defects and check for signs of contamination or deterioration before use. Testing with a positive and negative control, when applicable, is also recommended.

If you have any further questions or concerns, please contact our Technical Services Department at 800.266-2222, option 2 or via email at TechService@HardyDiagnostics.com. Thank you for choosing Hardy Diagnostics as your media supplier.

Sincerely,

Andre Hsiung, M.S., M(ASCP)
Director of Technical Services
800.266.2222, option 2
TechService@HardyDiagnostics.com