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Sent: Friday, July 30, 2010 12:24 PM
To: Genetic Testing Registry (NIH/OD/OSP)
Subject: RFI - Comments RE GTR

Comment 1 - with respect to regulatory clearances of an assay - in addition to citing FDA clearance (510k) or approval (PMA), one could cite CLIA 42CFR493.1253(b)(2) - Establishment of Performance Specifications. Citation of this regulatory compliance requirement would indicate to laboratorians that the assay was performed in a CLIA-registered laboratory and was either a modified FDA-cleared or approved test system or an in-house, laboratory developed test (LDT) for which the laboratory has established performance specifications (i.e., accuracy, precision, analytical sensitivity, analytical specificity to include interfering substances, reportable range of test results for the test system, reference intervals (normal values), and any other performance characteristic required for test performance). (see Federal Register announcement, section III. Request for Comments, paragraph 6d)

Comment 2 - with respect to limitations of the test - Federal Register announcement, section III. Request for Comments, paragraph 6g - the examples imply that "screening" is not "diagnostic" testing. This is not a correct statement as "screening" merely implies a lower level of diagnostic testing that will often require referral for further, higher level/more specific testing. Both levels are diagnostic (i.e., can be used for patient treatment decisions) when performed by a CLIA-registered laboratory.

V/R

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