

Out of Scope Discussions

Related to the scope of the CLIA Regulations Assessment Workgroup: According to 42 CFR 493.2001, the Clinical Laboratory Improvement Advisory Committee (CLIAAC) will review and make recommendations related to quality systems standards or other issues at the request of HHS. With respect to laboratory developed tests or methods developed in-house, CMS, FDA, and CDC have not requested a discussion or review of the existing CLIA regulations related to governing the development of these tests or methods, including the inclusion of performance specifications, clinical correlation, or clinical validity. Therefore, this topic is not open for discussion by CLIAAC.