

# CLINICAL LABORATORY IMPROVEMENT ADVISORY COMMITTEE

June 14, 2001

Food and Drug Administration  
Center for Biologics Evaluation and Research  
Blood Products Advisory Committee

Dear Colleagues:

The Clinical Laboratory Improvement Advisory Committee (CLIAC) advises the Secretary of Health and Human Services on laboratory practice and the public health. The members of CLIAC are concerned that tests for human immunodeficiency virus (HIV) infection might be considered for categorization as waived tests.

We do not believe that the waived test category is appropriate for HIV tests, for several reasons. First, the waived category does not provide any mechanism to assure provision of pre-analytic or post-analytic interventions that are essential to meaningful HIV testing. Second, several recent studies have shown that laboratories performing waived testing frequently fail to follow current manufacturers' instructions or required quality control measures.

We share your concern to make HIV testing more broadly and rapidly available. We urge you to investigate other available avenues (such as moderately complex testing or certificate for limited public health testing) for expanding access to HIV testing, without compromising the quality of the tests or information provided to tested individuals.

Thank you for this opportunity to provide comments.