CERTIFICATION REQUIREMENTS FOR LABORATORIES PARTICIPATING IN ACTG STUDIES

I. SPECIFIC CERTIFICATION REQUIREMENTS FOR VISIT AND -OLOGY

	IMMUNOLOGY	VIROLOGY	PHARMACOLOGY
	CD4/CD8	HIV Viral Loads	TDM (real-time PK)
Screening	CLIA	CLIA	Not Applicable
Pre-Entry	CLIA	CLIA	Not Applicable
On-study testing	CLIA/IQA	CLIA/VQA	CLIA

II. DEFINITIONS

2.1 CLIA: Clinical Laboratory Improvement Act (CLIA) Certification – Federal requirement for labs performing tests used to treat, diagnose, or manage patient care. Required for screens and on-study tests.

2.2 ACTG protocol assays under CLIA certification requirement: HIV Viral loads (HIV RNA Quantitation), genotypic resistance assays, and phenotypic resistance assays (including Virtual Phenotype™). Also included are: HIV proviral DNA quantitation, HIV cultures, HCV RNA quantitation, **HBV DNA quantitation**, CMV DNA quantitation if these assays are used in making eligibility decisions, confirming HIV, CMV, HCV and HBV infection, or making treatment decisions.

2.3 IQA: DAIDS Immunology Quality Assurance (IQA) Program – participation and certification required for labs performing CD4/CD8 flow cytometry assays on subjects enrolled in ACTG studies.

2.4 VQA: DAIDS Virology Quality Assurance (VQA) Program – participation and certification required for labs performing viral loads as primary endpoints in ACTG studies. VQA Certification requirements also apply to HIV genotypic and phenotypic resistance assays, qualitative and quantitative HIV DNA assays and the quantitative HIV microculture assay.

Procedure: ACTG Lab Man Certification Requirements for Labs Participating in ACTG Studies

Prepared by: ACTG Laboratory Technologist Committee

Preparation Date: 01 June 2004

Date Implemented into the Laboratory: _____

Updated on:

_____

_____

Reviewed by: Date:

_____

_____

_____

_____

_____

_____

_____

_____

_____

Supersedes Archived Protocol: DAIDS Virology Manual for HIV Laboratories, Version January 1997