March 2004 Washington State Medical Test Site Rules

PRE-INSPECTION SELF-ASSESSMENT CHECKLIST
MODERATE COMPLEXITY TESTING KITS

EXAMPLES:	SPECIALTY	TEST (ANALYTE)
	Bacteriology	Group A Strep antigen
	General Immunology	Mononucleosis; *Helicobacter pylori*; Rheumatoid factor
	Endocrinology	Serum HCG (serum pregnancy test)
	Virology	Influenza antigen

TEST COMPLEXITY:
These tests may be categorized as waived, moderate or high complexity testing, depending on the analyte and the specific test kit.

Refer to a current Waived Test List (available from the LQA Office or online at: www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/search.cfm) to determine if a specific test system (exact name and manufacturer) is waived. Follow all manufacturers' instructions for performing the waived test.

If the specific test system (exact name and manufacturer) is **not** listed on the Waived Test List, it is moderate or high complexity. (Call the LQA Office for assistance or go online: www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/search.cfm).

The following requirements apply to test kits of **moderate** complexity:

PROFICIENCY TESTING:
Required for all non-waived Strep, mononucleosis, rheumatoid factor and serum HCG test kits. For all non-waived H. pylori test kits, must perform biannual verification of accuracy.

PERSONNEL

___ The director, supervisor and testing personnel meet personnel qualifications for moderate complexity testing [42 CFR Part 493 subpart M (CLIA) - Available from the LQA Office or online at: www.phppo.cdc.gov/clia/regs/toc.asp]

___ Documentation of personnel education, experience, training for the testing performed

___ Assessment of personnel competency initially, at 6 months and annually thereafter

___ Training is provided to personnel when problems are identified

___ Laboratory safety policies are written and staff members adhere to them

QUALITY CONTROL

___ Procedures are written including: specimen collection and handling, test performance; result interpretation; reporting protocol; quality control; quality assurance. (Product inserts may be used if all information is addressed)

___ Test kits and reagents are properly labeled, stored at the proper temperature and used within expiration date

___ Each new lot or shipment of testing kits are checked with external positive and negative controls and results are recorded

___ If procedural controls are part of each patient test, the results of the procedural controls are documented each day of patient testing

___ If procedural controls are **not** part of each patient test, positive and negative external controls are performed each day of patient testing

___ If titers are reported, a control with a known titer must be run each day of patient testing. (Acceptable agreement may be considered plus or minus one dilution)

QUALITY ASSURANCE

___ Policies are written and there is evidence of review of quality control, quality assurance, proficiency testing (or biannual verification) and patient test results

___ Policies are written regarding specimen acceptance/rejection

___ Policies are written defining critical values (as applicable)

___ Documentation of corrective actions when problems are identified

___ Assure that adequate space and facilities are available

___ Adhere to local, state and federal regulations for hazardous waste disposal

RECORDKEEPING

___ Patient test orders include: patient name or identifier; name and address or identifier of person ordering the test; date and time of specimen collection; source of specimen; patient age (or date of birth) and sex

___ Patient test records include: name or identifier; date received; date tested; person who performed the test

___ Patient test reports include: name and address of where tests were performed; patient name and identifier; date reported; normal ranges; specimen source and limitations

___ Records are kept for 2 years of lot numbers and expiration dates of kits and dates when placed into use

___ The following records are maintained for 2 years: Requisitions; test records; reports; quality control; quality assurance; proficiency testing; and biannual verification of accuracy data

___ Temperature records of space where kits and other testing materials are stored (i.e., refrigerator and/or room temperatures)