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).