

INDIANA STATE DEPARTMENT OF HEALTH
CLIA CERTIFICATION PROGRAM

ENCLOSURE I TEST METHODOLOGY AND ANNUAL TEST VOLUME LOG
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LABORATORY NAME: _____ CLIA# _____
(Exact Name)

INSTRUCTIONS: Type or print the name of each analyte/test* performed in your laboratory, the name of the instrument/kit used and the Medicare CPT code to be used. Indicate the level of CLIA complexity and provide the annual total patient test volume for each analyte. Include the Proficiency Testing program used. *See Instruction sheet for further details.

ANALYTE / TEST NAME	Specialty	INSTRUMENT or KIT NAME	COMPLEXITY (Cx)	Veri-fied Cx	ANNUAL TEST-VOL	CPT CODE	PROFICIENCY PROGRAM
<i>Example: H. pylori</i>	<i>Chemistry</i>	<i>Delta West Clotest</i>	<i>Waived (W)</i>	√	<i>1000</i>	<i>87072QW</i>	<i>NA</i>

Signature of Director _____ Date _____

INDIANA STATE DEPARTMENT OF HEALTH – CLIA LABORATORY CERTIFICATION PROGRAM

TEST METHODOLOGY LIST AND ANNUAL TEST VOLUME LOG – INSTRUCTIONS

NOTE: Please read and follow instructions carefully. This form must be completed, signed, and returned to the State Agency prior to the processing of your CLIA certification or for making changes in certification status. Attach additional sheets if needed.

LABORATORY NAME: The exact laboratory name that you want to appear on your CLIA certificate.

CLIA#: Your current CLIA number for this location. If it is for new application, leave this space blank.

If the certificate applies to more than one testing site, list the primary location first. List the other locations on a separate page and attach to this form.

ANALYTE / TEST NAME, SPECIALTY:

List each analyte tested, grouped according to the specialty (i.e., Microbiology, Immunology, Chemistry, Hematology, Immunohematology, Pathology, etc.), to which the analyte or test belongs. An analyte is the name of the compound, element, parameter or substance being measured, i.e., glucose, platelets, iron, lead, urine pregnancy/HCG, urine microscopic, etc. List only the testing performed at this laboratory location. **DO NOT** include tests for which **ONLY** the specimen is collected and testing is performed at a different location.

INSTRUMENT/KIT NAME:

Include the manufacturer's name as well as the specific test/kit or product name, e.g., Smuckers, Bio-Test 300, Coulter, Cell-Pak 7000, Sigma, HCG Prompt-PSA, etc.

COMPLEXITY:

List the CLIA test complexity, i.e., Waived (W), Moderate (M), High (H) or Physician Performed Microscopy (PPM). This information may be found in the package insert. It is also available from the manufacturer or distributor. We recommend that the laboratory get this information in writing for their own records and made available to surveyor upon request. Verify the complexity and check the next column.

TEST VOLUME:

Provide the estimated annual patient test volume. Do not include calculated analytes (e.g., A/G ratio, BUN/Creat ratio, LDL, etc.), quality control, proficiency testing or quality assurance numbers. The test volume may be used for calculating CLIA user fees, so be as accurate as possible. Using ranges or > or < is not acceptable.

CPT CODES:

List the actual CPT codes to be used for billing Medicare for reimbursement. If no Medicare /Medicaid reimbursement is expected, write NA (Not Applicable).

PROFICIENCY:

If the test is categorized as Moderate, PPMP or High Complexity, indicate the proficiency testing organization used. For PPMP tests, indicate the commercial or in-house QA (Quality Assurance) program used. For waived tests, indicate either NA or the commercial program (if used).

Make a copy of the form for your records and mail the original to:

INDIANA STATE DEPT. HEALTH
CLIA Laboratory Certification Program Director
2 N. Meridian Street Rm 4A
Indianapolis, IN 46204-3006