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| **DEPARTMENT OF HEALTH SERVICES**  Division of Quality Assurance  F-01735 (05/2016) | | | | | **STATE OF WISCONSIN**  Page 1 of 2 | | | | | |
| **CLINICAL LABORATORY IMPROVEMENT AMENDMENTS (CLIA)**  **LABORATORY TEST METHODOLOGY REPORT** | | | | | | | | | | |
| Name – Laboratory (Exact Name) | | | | | | | | CLIA No. | | |
| **Carefully read and follow instructions on page 2.** | | | | | | | | | | |
| **Analyte / Test Name** | **Specialty** | **Instrument or Kit Name** | | **Complexity Level** | | **Complexity Verified** | **Estimated**  **Annual Test Volume** | | | **Proficiency Program** |
| **Ex:** *H. pylori* | **Ex:** *Bacteriology* | **Ex:** *Delta West CLOtest* | | **Ex:** *Waived (W)* | | **Ex:** *Yes* | **Ex:** *1000* | | | **Ex:** *N/A* |
|  |  |  | |  | | Yes |  | | |  |
|  |  |  | |  | | Yes |  | | |  |
|  |  |  | |  | | Yes |  | | |  |
|  |  |  | |  | | Yes |  | | |  |
|  |  |  | |  | | Yes |  | | |  |
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|  |  |  | |  | | Yes |  | | |  |
|  |  |  | |  | | Yes |  | | |  |
|  |  |  | |  | | Yes |  | | |  |
| **SIGNATURE** – CLIA Laboratory Director or Authorized Representative | | | Name – CLIA Laboratory Director or Authorized Rep. *(Print or type.)* | | | | | | Date Signed | |

### CLIA LABORATORY TEST METHODOLOGY REPORT – INSTRUCTIONS

**READ AND FOLLOW INSTRUCTIONS CAREFULLY.** This form must be completed, signed, and returned to the state agency prior to the processing of your Clinical Laboratory Improvement Amendments (CLIA) certification or for making changes in certification status. Attach additional sheets, if needed.

Name – Laboratory: Provide the exact laboratory name that will appear on your CLIA certificate.

CLIA No.: Provide 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** and **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; e.g., glucose, platelets, iron, lead, urine pregnancy/HCG, urine microscopic. 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., Quidel QuickVue H. pylori, UniCel DxH Coulter 600, Abbott Architect c4000 Immunoassay System, Siemens Clinitek Advantus Urinalysis System.

Complexity: Identify the CLIA test complexity; e.g., Waived (W), Moderate (M), High (H), or Physician Performed Microscopy (PPM). This information may be found in the manufacturer’s packaging insert or the FDA CLIA database at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfclia/search.cfm>. We recommend that the laboratory get this information in writing for their records and make available to surveyor upon request.

Complexity Verified: Verify the complexity and check the “Yes” checkbox.

Test Volume: Provide the estimated annual patient test volume. Do not include calculated analytes (e.g., A/G ratio, BUN/Creat ratio, LDL), 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.

Proficiency: If the test is categorized as Moderate, PPMP, or High Complexity, indicate the proficiency testing organization used. For waived tests, indicate either NA (Not Applicable) or the commercial program (if used).

Example:

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Analyte / Test Name | **Specialty** | **Instrument or Kit Name** | **Complexity Level** | **Complexity Verified** | **Estimated Annual Test Volume** | **Proficiency Program** |
| *H. pylori* | *Chemistry* | *Delta West CLOtest* | *Waived (W)* | *Yes* | *1000* | *N/A* |

Make a copy of this completed form for your records and mail, email, or fax the original to:

Wisconsin Department of Health Services

DQA / Licensing, Certification and CLIA Section

1 W. Wilson St., Rm. 450

P.O. Box 2969

Madison, WI 53701-2969

Email: [DHSDQACLIA@dhs.wisconsin.gov](mailto:DHSDQACLIA@dhs.wisconsin.gov)

Fax: 608-264-9847