



TEST VOLUME VERIFICATION

The Centers for Medicare & Medicaid Services (CMS) requires all moderate and high complexity testing laboratories to calculate their test volume for submission on their CMS 116 application form.

This information is used by CMS to calculate applicable certification fees. As part of COLA's deeming agreement with CMS, we are required to collect test volume information from all COLA labs and to verify that information at the time of survey.

This Fast Facts explains how a lab should calculate its test volume. COLA surveyors, using the CMS method for calculation, will efficiently estimate and confirm test volume during the on-site visit.

Use this information to calculate your annual test volume and fill in the circle next to the corresponding range on the "Annual Test Volume Report Form" included with this fact sheet. Once you've completed the form, fax it back to COLA at (410) 381-8611.

Procedure for Calculating Test Volume

All moderate, high complexity, and PPM tests performed by your laboratory each year should be counted except:

- Tests that are automatically calculated, such as MCH, MCHC, calculated hematocrit, T7, or LDL.
- Waived tests.
- QC, PT, or other testing for quality assurance purposes.

The chart on the following page will assist you with calculating all other tests not included in the preceding list.

At the time of your COLA survey, please have copies available of all documentation used to support your test volume calculations so that the surveyor can verify your calculations.

The surveyor will calculate your annual test volume by counting each test as detailed above for a typical one-week period, adding them together, and then multiplying by 50.

The COLA surveyor will also count how many specialties the laboratory tests. Specialties included in this count are Chemistry, Hematology, Microbiology, and Immunology. (Specialties in which only waived tests are performed will not be counted.) This total will be compared to the total annual volume reported on your CMS 116 form.

If there is a discrepancy large enough to place the lab in a new CMS fee schedule, we will inform you of the discrepancy. If you have any questions on this process, please call the COLA Information Resource Center at (800) 981-9883.

Counting Guidelines

This chart represents tests encountered most often in the laboratory and is not meant to be all-inclusive of the tests which must be counted as part of your annual test volume.

Procedure	How to Count
All PPM tests performed in labs doing moderate and high complexity tests	Count as one each
Non-waived automated urinalysis dipstick	Count as one test, regardless of the number of reagent pads on the test strips.
Urine microscopic	Count as one test.
Chemistry tests & blood gases	Count each test individually even if performed as a part of a profile.
Allergens	Count each allergen individually even if performed as part of a panel.
CBC	Count each measured CBC parameter (WBC/RBC/platelet/hemoglobin/MCV) individually.
Manual or automated WBC differentials	Count manual or automated WBC differentials as one test regardless of the number of parameters reported.
Immunohematology tests	Count each individual immunohematology test (ABO, Rh, Antibody screen, antibody identification, crossmatch or other immunohematology test) as one test each.
Cultures	Count each culture type as one per specimen regardless of the extent of identification, number of organisms isolated, and number of tests/procedures required for identification [e.g., If a sputum is received, count each testing subspecialty as a test: routine culture and gram stain (1), AFB culture and smear (1), and mycology (1), total test count is three.
Antimicrobial susceptibility tests	Count each test as one, regardless of the number of disks.
Direct parasite smear/concentration	Count as one.
Trichrome	Count as one.



Annual Test Volume Report Form

Please complete this form as soon as possible and fax it to COLA at the number listed at the bottom of the page. Thank you.

COLA ID#

CLIA ID#

Lab Name

Lab Name (cont.)

Lab Street Address

Lab Street Address (cont.)

City

State

Zip Code

Phone Number

E-mail Address

Annual Test Volume

Completely fill in the circle next to the annual test volume range into which your lab falls. Please remember to darken only one circle. (Do not count specialties in which you only perform waived tests.)

- Less than 2,000 tests
- 2,000 to 10,000 tests with 3 specialties or less
- Less than 10,000 tests with 4 specialties or more
- 10,000 to 25,000 tests with 3 specialties or less
- 10,000 to 25,000 tests with 4 specialties or more
- 25,000 to 50,000 tests
- 50,000 to 75,000 tests
- 75,000 to 100,000 tests
- 100,000 to 500,000 tests
- 500,000 to 1 million tests
- More than 1 million tests

Date

Completed by _____

Signature