



# COLA Primers

## Accreditation

COLA PRIMER #2

# *Calculating Annual Test Volume (ATV)*

## ● Introduction ●

Clinical laboratories that perform non-waived testing, including Provider Performed Microscopy procedures (PPM) are required to calculate their annual test volume (ATV). The Centers for Medicare and Medicaid Services (CMS) use this information to calculate CLIA certificate fees.

As part of COLA’s deeming agreement with CMS, COLA surveyors are required to collect your ATV information and verify it for accuracy at the onsite survey.

This COLA Primer will help you calculate your ATV accurately. Use the following information to calculate your ATV and record it on the Annual Test Volume form located at the end of this Primer. Completed forms can then be faxed to COLA at (410)-381-8611 or uploaded to your laboratory’s COLAcentral Document Repository.

## ● What Not to Include in Your Annual Test Volume ●

- -Do **not** include waived tests in your ATV
- -Do **not** include tests that are automatically calculated. Examples of some calculated tests include: MCH, MCHC, A/G ratio, T7, calculated LDL
- -Do **not** include quality control runs in your ATV
- -Do **not** include proficiency testing samples in your ATV

## ● Counting Guidelines ●

Test
<p><b>Microbiology:</b> each susceptibility panel per organism regardless of the number of antibiotics in the panel = 1 test; each culture on a single specimen type regardless of how many organisms are identified or tests are performed to identify them = 1 test; if a gram stain or AFB smear is performed from the primary source, count it as 1 test.</p> <p><i>Example:</i> Gram stain and culture on one wound swab = 2 tests</p>
<p><b>General immunology:</b> each allergen tested = 1 test</p>
<p><b>Hematology:</b> each <i>measured</i> component of a complete blood count = 1 test; each measured flow cytometry analyte that is ordered and reported = 1 test; each WBC differential = 1 test</p> <p><i>Example:</i> a CBC with <i>measured</i> <u>HGB</u>, <u>HCT</u>, <u>WBC</u>, <u>RBC</u>, <u>PLT</u> and a <u>differential</u> = 6 tests</p>

<b>Immunohematology:</b> each ABO = 1 test; each Rh = 1 test; each antibody screen = 1 test; each crossmatch = 1 test; each antibody identification = 1 test
<b>Histopathology:</b> each block (not slide) = 1 test. DO NOT COUNT autopsy services. <i>(For those laboratories that perform special stains on histology slides, add the number of special stains, IHC, ISH, and FISH performed on slides to the total number of specimen blocks prepared by the laboratory. Do not count control-only slides.)</i>
<b>Cytology:</b> each slide (not case) for both Pap smears and non-gynecologic cytology = 1 test
<b>Urinalysis:</b> each microscopic exam = 1 test; <b><i>non-waived</i></b> urine dipstick strip = 1 test* *(regardless of the number of reagent pads on the strip)
<b>Chemistry:</b> each non-calculated test = 1 test; each non-calculated analyte in a profile = 1 test <b>Examples:</b> Troponin = 1 test                      Basic Metabolic Panel (BMP) = 7 tests
<b>Parasitology:</b> per stool <b>sample</b> <b>Example:</b> One stool sample for direct slide +concentration+trichrome = 1 test Three separate stool samples for direct slide+concentration+trichrome = 3 tests
<b>PPM procedure:</b> each procedure = 1 test
<b>Genetics:</b> each reportable result = 1 test

● **At the Survey** ●

At the time of your COLA survey, please have copies available of all documentation used to support your annual test volume calculations. The surveyor will 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 multiplying by 50. Have the attached Annual Test Volume form completed and signed for your surveyor.

If there is a discrepancy large enough to place the lab in a new CMS fee schedule, your COLA surveyor will inform you of this change.

● **References** ●

Centers for Medicare and Medicaid (CMS). CMS-116 form. Revised April 20, 2020. 7500 Security Boulevard, Baltimore, Maryland 21244-1850. 877-267-2323

<p>Use this form to report your test volume to COLA. CMS requires all moderate (including PPM) and high complexity testing laboratories to calculate their test volume for submission on their CMS 116 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 laboratories and to verify that information at the time of survey.</p>	<b>COLA ID:</b>	
	<b>Laboratory Name &amp; Address:</b>	

**Procedure for Calculating Test Volume**

All moderate complexity, high complexity, and PPM tests performed by your laboratory each year should be counted. The following should **NOT** be included in the count:

- Tests that are calculated, such as MCH, MCHC, calculated hematocrit, T7, A/G ratio
- Waived tests
- QC, PT, or other testing for quality assessment purposes

For a chart to assist you with calculating all other tests to be counted, visit [www.colacentral.com](http://www.colacentral.com) and log in. Go to the Education Center tab, select "Resources" then select "COLA Primers." COLA Primer #2: Calculating Annual Test Volume. This document includes details on counting tests. **For example:**

- Non-waived Urinalysis dipstick testing is counted as one test, regardless of the number of pads on the dipstick.
- Urine microscopic exams are counted as one test.
- Count each chemistry or blood gas test as individual tests, even if they are performed as part of a profile.
- Count each **measured** and reported component of a CBC or flow cytometry as an individual test, such as WBC, RBC, platelet, hemoglobin, and MCV or hematocrit.
- Manual or automated WBC differentials are counted as one test.
- Count each individual Immunohematology test (ABO, Rh, antibody screen, crossmatch, etc.) as one test each.
- Count each culture type as one per specimen, regardless of the number of identifications.
- Count each antimicrobial susceptibility test as one test, regardless of the number of drugs tested.

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 multiplying by 50.



Use this form to report your test volume to COLA. CMS requires all moderate (including PPM) and high complexity testing laboratories to calculate their test volume for submission on their CMS 116 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 laboratories and to verify that information at the time of survey.	<b>COLA ID:</b>	
	<b>Laboratory Name &amp; Address:</b>	

**Annual Test Volume**

Click the box next to the annual test volume range into which your laboratory falls. Please remember to click only one box. Do not count specialties in which you only perform waived tests.

- |   |  |  |
|---|--|--|
| <input type="checkbox"/> Less than 2,000 or Waived Laboratory   | <input type="checkbox"/> 500,001 – 1,000,000   | <input type="checkbox"/> 9,000,001 – 10,000,000  |
| <input type="checkbox"/> 2,000 – 10,000, 0 – 3 specialties      | <input type="checkbox"/> 1,000,001 – 2,000,000 | <input type="checkbox"/> 10,000,001 – 11,000,000 |
| <input type="checkbox"/> 2,000 – 10,000, 4 or more specialties  | <input type="checkbox"/> 2,000,001 – 3,000,000 | <input type="checkbox"/> 11,000,001 – 12,000,000 |
| <input type="checkbox"/> 10,001 – 25,000, 0 – 3 specialties     | <input type="checkbox"/> 3,000,001 – 4,000,000 | <input type="checkbox"/> 12,000,001 – 13,000,000 |
| <input type="checkbox"/> 10,001 – 25,000, 4 or more specialties | <input type="checkbox"/> 4,000,001 – 5,000,000 | <input type="checkbox"/> 13,000,001 – 14,000,000 |
| <input type="checkbox"/> 25,001 – 50,000                        | <input type="checkbox"/> 5,000,001 – 6,000,000 | <input type="checkbox"/> 14,000,001 – 15,000,000 |
| <input type="checkbox"/> 50,001- 75,000                         | <input type="checkbox"/> 6,000,001 – 7,000,000 | <input type="checkbox"/> More than 15,000,000    |
| <input type="checkbox"/> 75,001 – 100,000                       | <input type="checkbox"/> 7,000,001 – 8,000,000 |  |
| <input type="checkbox"/> 100,001 – 500,000                      | <input type="checkbox"/> 8,000,001 – 9,000,000 |  |

By typing my name below, I hereby represent that I am duly authorized to provide this Annual Test Volume calculation on behalf of \_\_\_\_\_

Completed by : \_\_\_\_\_ Date \_\_\_\_\_