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Guidelines for Reporting Test Volumes

As part of the 2025 New York State Clinical Laboratory Permit re-application process, **all laboratories holding a permit** are required to submit volumes of non-waived clinical laboratory tests performed at your laboratory between January 1 and December 31 of the previous year.

Please do not include the following in your volume report:

- Waived tests
- Tests performed under a Limited Service Registration
- Tests performed by the laboratory's reference laboratory
- Tests performed as part of quality control, quality assurance, or proficiency testing
- Tests performed on non-human specimens

The guidelines below are provided to assist in the proper reporting for these volumes. Laboratories are required to submit test volume data to ensure that the federal Centers for Medicare and Medicaid Services has a reliable means of calculating national workload statistics.

General:

- Each measured, individual analyte (e.g. creatinine, FISH probe) in a panel of tests is counted separately.
  - "Individual analyte" would be each analyte (billable or otherwise) tested, therefore there will be numerous "analytes" per patient.
- Calculations should not be included in test volume counting (e.g., A/G ratio, MCH and T7).
- For methods requiring testing in duplicate, count as only one test per specimen.

Specific areas of testing:

- For **allergen testing,** each allergen should be counted as one test.

- For **andrology**, sperm counts performed in conjunction with the processing of donor semen that are not reported to a physician or the donor, and are part of the internal quality control policy to ensure an adequate number of sperm in each ejaculate to warrant cryopreservation and distribution to clients, should not be counted.

- For **cellular immunology**, each measured individual analyte is counted separately.

- For **chemistry** profiles, each individual analyte is counted separately.

- For **complete blood counts**, each measured individual analyte that is ordered and reported is counted separately. Differentials are counted as one test.

- For **cytogenetics**, the number of tests is determined by the number of specimen types processed on each patient; e.g., a bone marrow and a venous blood specimen received on one patient is counted as two tests. Additionally, each element of a panel of tests would be counted individually, e.g. each FISH probe would be counted individually. If the laboratory performs both karyotyping and FISH, the karyotype would be counted as one test and each FISH probe would be counted as one test. Microarray testing should be counted as one test per chip.

- For **cytology**, each slide (not case) is counted as one test for both Pap smears and non-gynecologic cytology.

- Testing for **genetics** should be counted as one test per each reportable result.

- For **histocompatibility**, each HLA typing (including disease associated antigens), HLA antibody screen or HLA crossmatch is counted as one test.

- For **histopathology**, each block (not slide) is counted as one test. Autopsy services are not included. For those laboratories that perform special stains on histology slides, the test volume is determined by adding the number of special stains performed on the slides to the total number of specimen blocks prepared by the laboratory.

    - If technical component testing is billed separately from professional component testing, each component for each block/special stain is counted separately.

- For **immunohematology**, each ABO, Rh, antibody screen, crossmatch or antibody identification is counted as one test. This includes testing of units to confirm blood type grouping prior to transfusion. Electronic cross-matching is not to be counted as a test.

- For **microbiology**, nucleic acid panels are counted as one test per organism. Susceptibility testing is counted as one test per group of antibiotics used to determine susceptibility for one organism. Cultures are counted as one per specimen regardless of the extent of the identification, number of organisms isolated and the number of test/procedures required for identification.

- For **urinalysis**, microscopic and macroscopic examinations count as one test. Macroscopic (dipsticks) are counted as one test regardless of the number of reagent pads on the strip.

- For **wet mounts**, each slide is counted as one test.