

CLIA TOP 10 STANDARD DEFICIENCIES



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Top Ten Standard Deficiencies Nationwide 2009

D5791

D5411

D6021

D6094

D6003

D5291

Also Top Ten in 2023

D5413

D5217

D5401

D5439



September 2023 DATA

| NATION | | | 15,554 Laboratories |
|--------|---|------|---------------------|
| D5413 | §493.1252 Standard: Test systems, equipment, instruments, reagents, materials, and supplies | 4.4% | 677 |
| D5209 | §493.1235 Standard: Personnel competency assessment policies | 3.9% | 609 |
| D5217 | §493.1236 Standard: Evaluation of proficiency testing performance | 3.8% | 594 |
| D5401 | §493.1251 Standard: Procedure manual | 3.3% | 506 |
| D5403 | §493.1251 Standard: Procedure manual | 3.0% | 473 |
| D5417 | §493.1252 Standard: Test systems, equipment, instruments, reagents, materials, and supplies | 2.9% | 455 |
| D5429 | §493.1254 Standard: Maintenance and function checks | 2.7% | 421 |
| D5805 | §493.1291 Standard: Test report | 2.5% | 384 |
| D5421 | §493.1253 Standard: Establishment and verification of performance specifications | 2.5% | 383 |
| D5439 | §493.1255 Standard: Calibration and calibration verification procedures | 2.1% | 325 |
| | | | |

RANK VS REGIONS

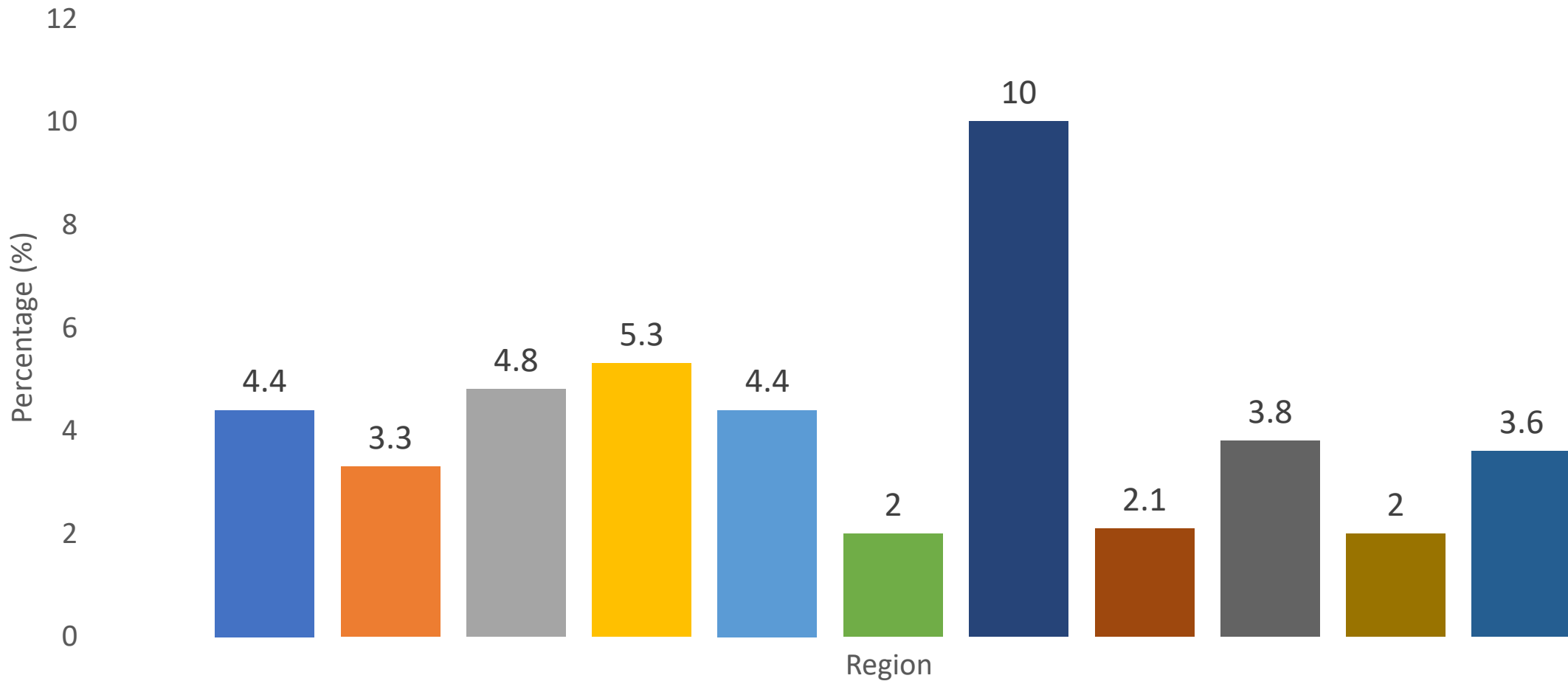
| Tags | Nation | Region 1 | Region 2 | Region 3 | Region 4 | Region 5 | Region 6 | Region 7 | Region 8 | Region 9 | Region 10 |
|-------|--------|----------|---------------|--------------|---------------------|----------|----------|-------------|----------|---------------|-----------|
| | | Boston | New York City | Philadelphia | Atlanta | Chicago | Dallas | Kansas City | Denver | San Francisco | Seattle |
| D5413 | 4.4 | 3.3 | 4.8 | 5.3 | 4.4 | 2 | 10 | 2.1 | 3.8 | 2 | 3.6 |
| D5209 | 3.9 | 3 | 3.7 | 9 | 2.8 | 4.1 | 6.5 | 0.3 | 6.6 | 1.7 | 5 |
| D5217 | 3.8 | 1.9 | 2 | 6.8 | 3.2 | 5 | 6 | 1.4 | 3.4 | 4.6 | 3.6 |
| D5401 | 3.3 | 2.2 | 4.6 | 3 | 1.6 | 2 | 9.6 | 2.6 | 3.8 | 1.9 | 1.9 |
| D5403 | 3 | 5 | 2.6 | 5.7 | 2.7 | 3.7 | 4.5 | 1.2 | 4.2 | 0.8 | 1.7 |
| D5417 | 2.9 | 0.8 | 3.1 | 4.3 | 2.3 | 3.1 | 5.9 | 1.2 | 4 | 1.6 | 2.9 |
| D5429 | 2.7 | 2.5 | 1.3 | 7.3 | 1.7 | 2.6 | 7.3 | 0.7 | 0.8 | 1.2 | 4.3 |
| D5805 | 2.5 | 2.8 | 1.8 | 3 | 1.7 | 2.9 | 6.6 | 1.7 | 2.1 | 1.3 | 1.4 |
| D5421 | 2.5 | 2 | 1.6 | 3.4 | 1.1 | 2.5 | 7.4 | 3.7 | 3.5 | 1 | 1.2 |
| D5439 | 2.1 | 1.6 | 1.6 | 2.4 | 2.2 | 1.9 | 3.9 | 1.8 | 2.5 | 0.8 | 2.4 |
| | | | | | Regional percentage | | | | | | |

D5413—Most Popular

CLIA D5413 standard deficiency tag is widely used by State Agency and Federal surveyors. It is based on the regulation 42 C.F.R. §493.1252 Standard: Test systems, equipment, instruments, reagents, materials, and supplies. This regulation requires that the laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions if provided. These conditions must be monitored and documented and, if applicable, include the following:

- (b)(1) Water quality,
- (b)(2) Temperature,
- (b)(3) Humidity, and
- (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

D5413



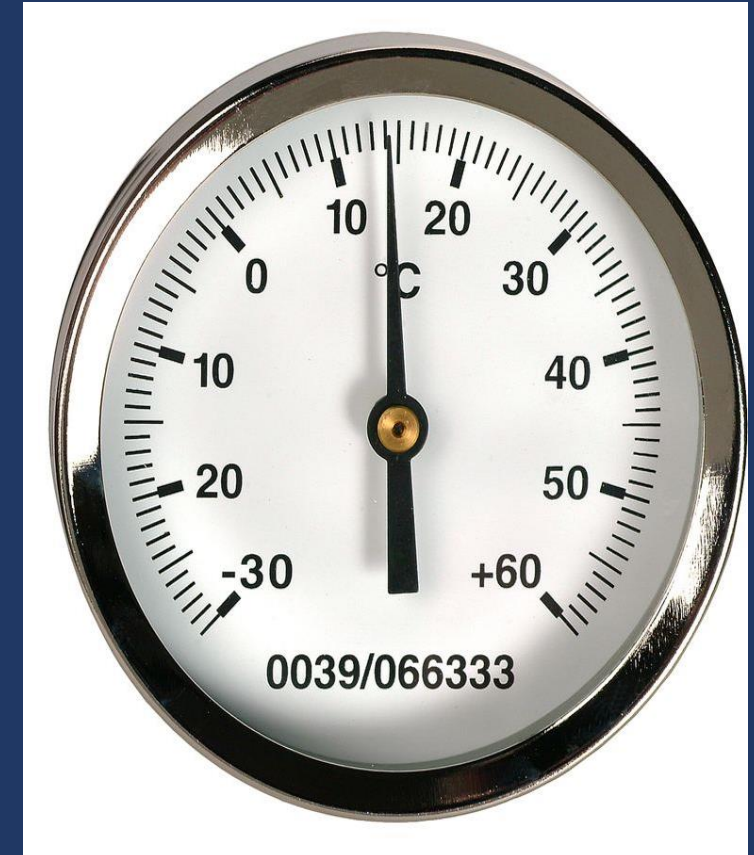
- Nation
- Region 1
- Region 2
- Region 3
- Region 4
- Region 5
- Region 6
- Region 7
- Region 8
- Region 9
- Region 10

Common Reasons for D5413 Citation

- Laboratories failing to document room temperature and humidity when required by the manufacturer. This monitoring ensures proper test performance.
- Laboratories failing to store reagents at the correct refrigerator or freezer temperature range as required by the manufacturer. Reagents and controls must be stored correctly to prevent deterioration or incorrect results.

Additional Reasons for D5413 Citation

- Temporary Testing Sites failing to monitor and document temperatures to protect instruments, reagents, and controls from extreme temperature fluctuations. Extreme fluctuations can cause incorrect test results.
- Laboratories failing to ensure the usage of the appropriate water quality as required for each instrument, kit, or test system. Correct water quality minimizes contamination of test results.

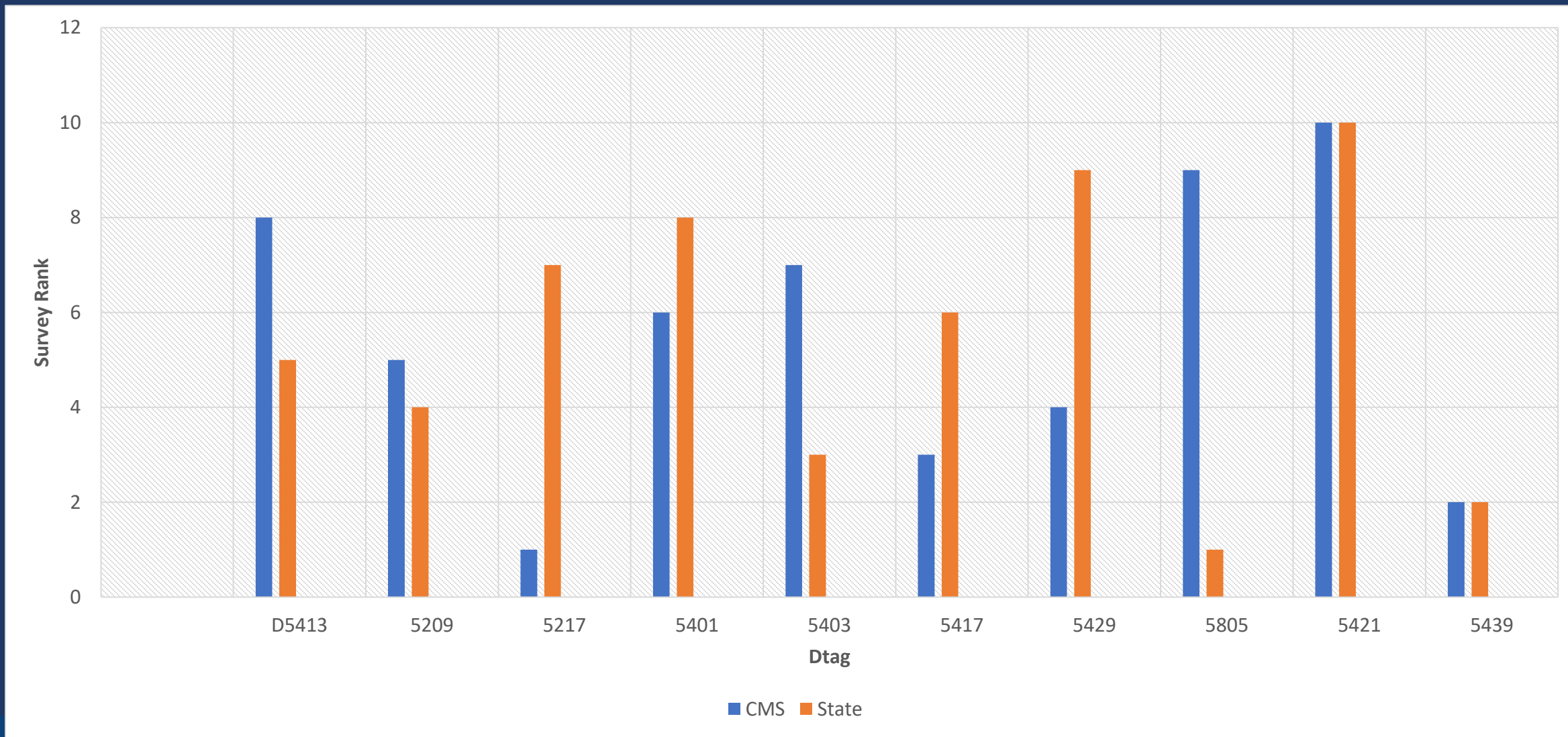


Why is D5413 frequently used?

Tag D5413 is cited frequently since it is easily found during the survey process. Review of temperature, humidity, and storage requirement documentation is performed during a survey. Not only is D5413 frequently cited, but it is also easily fixed by laboratories. Documentation of temperature, humidity, correct storage of reagents, and ensuring correct water quality is easy to implement by laboratories.

It is important to remember that correct monitoring and documentation of room temperature, humidity, storage of reagents according to the manufacturer's requirements, and ensuring appropriate water quality maintains accurate and reliable test system operation and provides accurate patient test results.

Surveyor Ranking for Potential Outcome



TOP SURVEYOR RANKING OF DEFICIENCIES BASED ON OUTCOME

#1 D5421-HIGHEST RANK FOR PATIENT OUTCOME

Failure to verify the reference interval (normal values).

#2 D5805-SECOND HIGHEST FOR PATIENT OUTCOME CMS—LOWEST FOR THE STATE AGENCY

Failure to include the address of the laboratory where the test was performed.

Failure to include identification number and/or specimen source.

SURVEYOR RANKING OF DEFICIENCIES BASED ON OUTCOME

- D5217—LOWEST RANK FOR PATIENT OUTCOME-CMS

Failure to verify the accuracy of non-regulated analytes twice annually.

- D5413 and D5209—MIDDLE OF THE GROUP BUT THE TOP 2 DTAGS CITED

D5209-Failure to establish policies and assess employees in the positions of Technical Consultant, Clinical Consultant, Technical Supervisor, and General Supervisor.

Questions??

