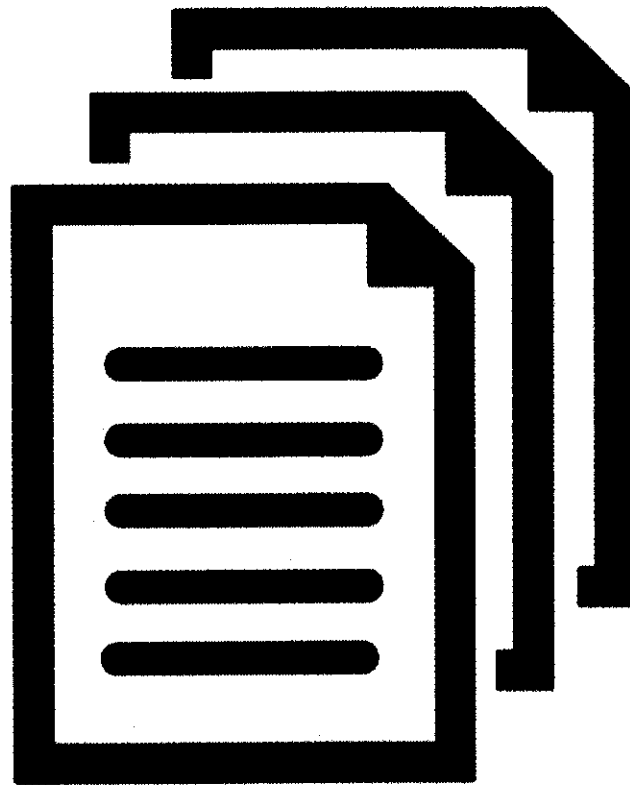


# Principles of Documentation Appendices



## **Guide to Writing a Deficiency Tag (D-Tag)**

### **Definitions (2008 POD manual)**

*Deficient Practice Statement:* A summary statement at the beginning of the evidence that sets out why the laboratory was not in compliance with a regulation.

*Finding:* A generic term used to describe each discrete item of information observed or discovered during the survey about practices of a laboratory relative to the specific requirement being cited as not being met.

### **Outline for writing a deficiency citation (D-tag)**

#### **A. Deficient Practice Statement**

1. Begin with your sources (interview, observations, record review).

*Based on \_\_\_\_\_, \_\_\_\_\_, and \_\_\_\_\_...*

- a. Whenever possible, specify what type of records, observations, or whom the interview was with (by title).
- b. Each source in listed in the DPS must be supported in the findings.

*Example: Based on interview with the technical consultant and proficiency testing (PT) record review, the laboratory director failed to ensure that the laboratory was enrolled in proficiency testing for total iron from 2013 to the date of the survey.*

2. Add what the laboratory did/did not do to cause the noncompliance.

- a. Be specific about actions lab did/did not do, but don't just restate the regulation.

*Example: Based on interview with the technical consultant and proficiency testing (PT) record review, the laboratory director failed to ensure that the laboratory was enrolled in proficiency testing for total iron from 2013 to the date of the survey.*

3. Describe extent.

*Example: The laboratory failed to perform weekly maintenance on the Coulter AcT\*2 for 6 of 20 weeks from March 2014 through September 2014.*

4. Define acronyms & identifiers.

*Example: The laboratory failed to perform Quality Control (QC) each day of testing on the Coulter AcT\*2 ...*

*Example: Based on interview with the technical consultant (TC)...*

Example: ...three of four patient final reports (014563, 145093, 145322)...

5. Include outcomes, when relevant.

Examples:

- Testing performed and reported on an unacceptable specimen
- Results are reported on the wrong patient
- Group A pRBC transfused to Group O patient due to clerical error
- Surgical specimen discarded prior to testing

Example: Based on review of specimen logs records, laboratory specimen acceptability procedures and interview with the laboratory director, the laboratory performed and reported potassium (K) results on 2 of 4 hemolyzed specimens (Specimen numbers: 07111410, 07111418)

The findings include:

1. The laboratory procedure titled "Specimen Acceptability" (CH2.1, Section 1.3) stated "...hemolyzed specimens for potassium shall be rejected due to falsely elevated results...a new specimen must be drawn..."
2. Specimen logs from July 11, 2014 showed a total of 20 specimens were received requesting potassium.
3. The specimen log showed 4 of 20 specimens had a note that they were "hemolyzed".
4. 2 of 4 hemolyzed specimens (specimen numbers 07111410, 07111418) were run and results were reported without redrawing the specimens or noting hemolysis.
5. The laboratory's normal range for K is 3.5 to 5.2 mmol/L.
6. 07111410 had a K reported as 6.2 mmol/L and 07111418 had a K reported as 5.7 mmol/L.
7. The laboratory director verified the above findings on 9/2/14 at 1:25 pm.

B. Findings (who, what, where, when, how)

1. Use very specific detail(s).

D5783

Based on review of Chemistry quality control records and procedure manual and interview with the general supervisor (HOW), the laboratory( WHO) failed to take corrective actions (WHAT) when the normal control was outside the acceptable range on five of 30 days of Potassium testing in April 2016 (WHEN). (4/2/2016, 4/7/2016, 4/11/2016, 4/18/2016, and 4/25/2016) The findings include:

1. The Chemistry procedure manual (HOW)(WHERE) stated all control values outside the acceptable range would be repeated. If the second testing of the controls were not within the acceptable range, the testing person would follow the investigative protocol and contact the supervisor.(WHAT)
2. Quality Control records (HOW)(WHERE) showed the following Potassium normal control values with no indication of any repeat testing or corrective action. (WHAT) The acceptable range for the normal control material was 3.5-3.7 mEq/L.
  - a. 4/2/2016 – 3.3 mEq/L (WHEN)
  - b. 4/7/2016 – 3.3 mEq/L (WHEN)
  - c. 4/11/2016 – 3.4 mEq/L (WHEN)
  - d. 4/18/2016- 3.4 mEq/L (WHEN)

3. The general supervisor(HOW)(WHO) reviewed the April (WHEN) Potassium control records and confirmed the out of range control values and the records did not indicate any repeat testing or corrective actions taken. (WHAT)

4. The laboratory reported 435 patient Potassium values in April 2016. (WHAT)(WHEN)

2. Use extent/universe, when possible.

Example: "...15 of 36 complete blood count (CBC) quality control (QC) values..."

3. May contain a "confirmed..." or "verified..." statement.

Example #1: The laboratory director verified the above findings on 9/2/14 at 1:25 pm.

Example #2: The technical consultant confirmed on 9/2/2014 at 2:15 pm that the laboratory did not perform calibration procedures as required for the 2 analytes.

Once the D-Tag is written can you answer the questions below?

- a. What did the laboratory fail to do? What regulation or part of a regulation did they not meet?
- b. What are your sources of evidence? Are there at least 2?
- c. What is the extent of the problem?
- d. Are identifiers included?
- e. Did you define all acronyms the first time they are used?
- f. Did you confirm the evidence? If so, did you include the confirmation in your findings?
- g. Do your findings support the DPS?
- h. Did the findings include each source listed in the DPS?
- i. Did you give any advice or directions to the lab?

### Checklist, Components Documented in a Deficiency Citation

D-Tags Reviewed	
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General				
	Yes (Y)	No (N)	N/A	Comments, include D-Tag(s) not meeting POD
Statement that requirement "Not Met"				
Applicable to the requirement cited				
Free of extraneous remarks and advice				
Written in plain language				
Deficient Practice Statement (DPS)				
Description of violation of regulation clearly stated (specific action(s), error(s), lack of action)				
Extent of deficient practice				
Source(s) of evidence				
<ul style="list-style-type: none"> <li>Observations</li> <li>Interview</li> <li>Record review</li> </ul>				
Identifier(s)				
State/Local code reference, if applicable				
Findings/Facts, if applicable				
Support DPS				
Concise, chronological, and logical order of facts				
Who				
What				
When				
Where				
How				
Outcome				
Observations: date, time, location				
Interview: date, time, identifier				
Record review: date(s), record type				
Extent				
Coding system used				
Unique identifier system used				

### **Principles of Documentation (POD) Cheat Sheet**

<b><u>Principle</u></b>	<b><u>Key Points</u></b>
1, Lab Compliance and Noncompliance	<ul style="list-style-type: none"> <li>◆ Compliance → D0000</li> <li>◆ Additional uses of D0000 as outlined in POD guidance document</li> <li>◆ Noncompliance → includes specific citations</li> </ul>
2, Using Plain Language	<ul style="list-style-type: none"> <li>◆ Written clearly, objectively in active voice and in layman's terms</li> <li>◆ Avoid words such as: seems, appears, inadequate, unnecessary</li> <li>◆ No extraneous information or advice, comments, directions, slang</li> <li>◆ Should contain only evidence to support noncompliance</li> <li>◆ Define acronyms, abbreviations 1st time used</li> <li>◆ Ensure accuracy of cited/quoted material</li> </ul>
3, Composition of a Deficiency Statement	<ul style="list-style-type: none"> <li>◆ Deficient Practice Statement:               <ul style="list-style-type: none"> <li>◦ Clearly states what lab did/did not do to cause noncompliance</li> <li>◦ Do not merely repeat the regulation</li> <li>◦ Includes: specific action(s) or lack of action(s), outcome(s) when possible, extent, sources (2 if possible) and identifiers</li> <li>◦ Name of individuals/patients should never be used</li> </ul> </li> <li>◆ Findings Statement:               <ul style="list-style-type: none"> <li>◦ Supports/illustrates lab's noncompliance</li> <li>◦ Who, what, where, when, how</li> <li>◦ Citations specific to lab, in concise and chronological or logical order</li> <li>◦ Date and time for observations</li> </ul> </li> </ul>
4, Relevance of Onsite Correction Findings	<ul style="list-style-type: none"> <li>◆ Must be documented on CMS-2567 as "NOT MET"</li> </ul>
5, Interpretive Guidelines (IG)	<ul style="list-style-type: none"> <li>◆ May not be used as a basis for citation(s)</li> <li>◆ IGs do not replace/supersede statute or regs</li> </ul>
6, Citation of State/Local Code Violation	<ul style="list-style-type: none"> <li>◆ Only used for 2 reasons, see POD guidance document</li> </ul>
7, Cross References	<ul style="list-style-type: none"> <li>◆ Applicable and provides additional strength to linked citation(s)</li> <li>◆ Must support noncompliance with requirement</li> </ul>
8, Condition Deficiencies	<ul style="list-style-type: none"> <li>◆ Includes only requirements to be corrected to achieve condition-level compliance</li> <li>◆ May stand alone as single cite or include accompanying standards</li> <li>◆ Condition statement is written as a practice statement. Findings are listed or cross-referenced</li> <li>◆ Standards supporting the out of compliance Condition must be requirements for the cited Condition</li> </ul>

## **ACTIVE / PASSIVE VOICE**

Active voice describes a sentence where the subject performs the action by the verb. Passive voice, the subject does not act, but is the object or receiver of the action. Active voice should be used in both the deficient practice statement (DPS) and the findings.

### **Active voice**

In most English sentences with an action verb, the subject performs the action expressed by the verb that is the subject is doing the verb's action.

Because the subject does or "acts upon" the verb in such sentences, the sentences are said to be in the **active voice**.

Please note: Active voice is not the same as present tense. Active voice speaks to the relationship between a subject and a verb (i.e., the subject of the sentence is the actor or is acted upon) whereas tense indicates the relationship between the verb and time (e.g., current action vs past action). As soon as the surveyor exits the survey, the laboratory's actions are in the past tense.

### **Passive voice**

One can change the normal word order of many active sentences so that the subject is no longer *active*, but is, instead, being *acted upon* by the verb, that is the *subject* is acted upon.

Because the subject is being "acted upon" (or is *passive*), such sentences are said to be in the **passive voice**.

Passive voice sentences can add words which may make the reader work harder to understand the intended meaning.



**Table 1: Examples: Active Voice vs Passive Voice**

Active Voice		Passive Voice
Based on.... the technical supervisor (subject) failed to perform (verb) competency assessment...	vs	Based...It was stated (verb) by the technical supervisor (subject) that competency assessment...
Based...The technical supervisor failed to perform competency assessment for 2 of 3 testing personnel annually in 2015 and 2016.	vs	Based...It was stated by the technical supervisor that competency assessment was not performed annually on 2 of 3 testing personnel for 2015 and 2016
Based...the laboratory (subject) failed to retain (verb) documentation of performance verification for...	vs	Based...Verification of performance specification documentation (subject) was not retained (verb) by the laboratory...
Based...The laboratory failed to retain documentation of performance verification for the Siemens Advia XPT.	vs	Based...Verification of performance specification documentation for the Siemens Advia XPT was not retained by the laboratory.

Note: A sentence in active voice flows more smoothly and is easier to understand than the same sentence in passive voice.

**Table 2: Example of Deficiency Statement (DPS + Findings) Using Active Voice**

<p>Based on review of the performance specification verification documentation and interview with the general supervisor and technical supervisor, the laboratory failed to maintain any documentation that the laboratory had participated in conducting the verification of the performance specifications on the Advia XPT. Findings include:</p> <ol style="list-style-type: none"> <li>1. The general supervisor and technical supervisor stated on 6/2/16 at 11:50 am that the manufacturer performed all of the performance specification verification activities on the Advia XPT.</li> <li>2. Review of performance specification verification documentation revealed that the manufacturer had performed the studies on 5/31/16.</li> <li>3. They further stated that the laboratory staff were available to prepare quality control material and gathering patient samples for the manufacturer representative to perform the verification.</li> <li>4. The Director of Assays confirmed on 6/2/16 at 2:30 pm that the manufacturer had performed the verification of performance specifications on the Advia XPT.</li> </ol>
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**Table 3: Helpful Hints to Help With Active Voice**

➤ Active voice sentences are generally clearer, more direct, and easier to understand
➤ Emphasizes the “doer” of the action
➤ Subject = Doer
➤ Verb = “Doing” word
➤ Avoid starting a sentence in active voice and then shifting to passive voice For example, “.... the technical supervisor (subject) failed to perform (verb) competency assessment..., but it was stated by TP2 that they had competency assessment performed on their one year anniversary date.”

### **Examples for the Uses of D0000\***

**\*Please note that these are only examples, and are not the only ways to write citations at D0000. In addition, please refer to page 11 for appropriate uses of D0000.**

#### **Required Use - No Deficiencies are Cited**

- The laboratory was found to be in substantial compliance with CLIA regulations (42 CFR Part 493, effective April 24, 2003). No deficiencies were cited.
- An onsite survey conducted, (Date) found the [Name] laboratory in compliance with 42 CFR Part 493, Requirements for Laboratories.

#### **Additional Optional Uses**

##### **Indication of Survey Type**

- An announced CLIA Recertification survey was conducted at the [Laboratory Name] on [Date(s)] by the [State Agency name]. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows:

##### **Summary of Condition-Level Deficiencies**

- During a recertification survey on [Date], the laboratory was found out of compliance with the following conditions [List applicable Conditions as below]:

42 CFR §493.803 Proficiency Testing, Successful Participation  
42 CFR §493.1403, Laboratory Director, Moderate Complexity  
42 CFR §493.1409, Technical Consultant, Moderate Complexity

- A validation survey was conducted by the [insert SA] at the facility on [insert date]. The laboratory was found out of compliance with the following conditions:

[List applicable Conditions as above]

##### **PT Referral for Laboratories Performing Waived Testing**

PT Referral occurs very rarely in laboratories performing waived tests. Should PT referral be discovered at a Certificate of Waiver (CoW) or at a laboratory performing PT on waived tests, please contact your RO for guidance in citing the PT referral.

## **Additional Examples for Each Principles 2 - 6**

Disclaimer: Please note these are just examples taken from actual CMS-2567s and for Principles 3, 4, 5 and 6 are not the only way to follow the principles of documentation.

### **Principle #2: Using Plain Language**

The deficiency citation should not include advice, conclusions, extraneous comments or direction (i.e., consultation) aimed at the surveyed laboratory. The following are examples of statements which should not appear in the CMS-2567 (see verbiage in italics).

- "...Failure to include the address of the testing laboratory *limited the ability of the individual ordering the test to contact the laboratory.*" (CONCLUSION)
- "The LD confirmed the procedures in the SOP and the QA plan were currently in use by the laboratory. *They should have been signed off by the director when he took the position.*" (ADVICE)
- "...failed to review and evaluate the instrument calculated routine chemistry ratios using an alternative method (*manual calculation, electronic calculation*) since October 2016." (ADVICE)
- "Review of the urine culture policy...failed to contain step-by-step procedures on how to interpret the results of the test on each type of media. *For example how many colonies are seen on EMB, PEA, and BAP and how is that reported?.*" (CONSULTATION)
- "Based on quality assessment records reviewed, lack of documentation, and interview with the testing person, the laboratory failed to...The laboratory tested approximately 10 specimens per year using Potassium Hydroxide (KOH) *to dissolve skin and nail cells for the detection of the presence or absence of fungal elements.* Findings include:  
...The testing person also stated the laboratory did not perform or document they verified KOH test accuracy *to perform, identify, and record the presence or absence of fungal elements using KOH to digest extraneous cells* at least twice a year." (EXTRANEOUS)
- "...it was determined that the laboratory failed to implement a mechanism, *such as a chart audit (instrument printout result compared to the transcribed entry into eClinical EMR)* to ensure the accuracy of manual recording and transcribing of patient results..." (ADVICE)
- "Based on the review of 2014-2017 quality control records, manufacturer's instructions, shipping invoices and observation of laboratory supplies, the laboratory failed to verify the acceptable criteria for new lots of chemistry quality control materials prior to use. *This deficient practice could result in the laboratory unable to identify quality control failures as they occur.*"

### **Principle #3: Composition of a Deficiency Citation**

A deficiency citation consists of (A) a regulatory reference, (B) a deficient practice statement and (C) relevant findings. Please note that regulatory text is in italics.

#### **EXAMPLE 1 - LACKED EXTENT AND IDENTIFIERS, REGULATORY REFERENCE**

D2015 493.801(b)(5)(6) TESTING OF PROFICIENCY SAMPLES

*The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.*

#### **Original Citation**

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory did not process the proficiency testing (PT) samples in the same manner as the patients. Findings:

1. The PT records from 2016 (3 events) did not include the initials of the testing person on the instrument printout.
2. The testing personnel are required to initial the instrument print outs, therefore, they should be initialing the instrument printouts for the PT samples

**Comment:** The deficient practice statement lacked an extent and identifiers along with it merely repeated the regulation. In the corrected deficiency, we have added an extent and the identifiers - 3 PT events in 2016. It could also be written as 3 of 3 PT events in 2016. Since the extent is 3 of 3, we know the identifiers are Events 1, 2 and 3 without writing them.

To provide more information about what the lab did not do, we added to the regulatory words that lab did not process PT samples like patients by saying how the instrument printouts for PT samples were not initialed by the testing person.

Principle 3 speaks to not merely repeating the regulation in the DPS and also the need to describe the extent of the deficiency and the identifying (identifiers) of the documents reviewed to cause the deficiency.

Possible Rewrite

Based on Proficiency testing (PT) record review, instrument printouts, and interview with the testing person, the laboratory did not process 3 of 3 Hematology proficiency testing (PT) events in 2016 in the same manner as patients as instrument printouts were not initialed by testing personnel to show which personnel performed the testing. Findings:

1. The Hematology PT records for 2016 (all 3 events) did not include the initials of the testing person. Instrument printouts for patient testing showed the testing persons initials.
2. Testing person #1 stated the practice of the laboratory was that each testing person initialed the instrument printouts as they reviewed the results. Testing person #1 also confirmed that the instrument printouts for the 2016 PT events showed no initials by the testing personnel.

**EXAMPLE 2 - LACKED EXTENT AND IDENTIFIERS**

**D5801 493.1291(a) TEST REPORT**

*The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (1) Results reported from calculated data. (2) Results and patient-specific data electronically reported to network or interfaced systems. (3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations.*

This STANDARD is not met as evidenced by:

Based on record review and staff interview it was determined that the final results recorded on the test log sheet were different from the results found in the Electronic Medical Record (EMR) in the specialty of Bacteriology. Findings include:

1. Record review of the EMR final report in patient charts revealed that test results for bacterial cultures were inconsistent and unmatched on the following patient test reports.
  - a. Medical record number 31005
  - b. Medical record number 46852
  - c. Medical record number 62558
2. Interview with the general supervisor on 2/11/15 at 11:10 am confirmed that discrepancies exist between the EMR final report in the patient's chart and the laboratory log sheet.
3. The laboratory performs 8,027 tests in the specialty of Bacteriology annually.

Comment: The original deficiency lacked an extent, identifiers and also did not use active voice in finding #3. The extent of 3 Medical records was added to the practice statement along with the identifying Medical record numbers. This information was in the findings in the original deficiency but needs to be in the DPS according to Principle 3. Also note finding #3 was reworded to active voice where the subject (general supervisor) confirms information. We also added the discrepancies noted between the log sheet and EMR to show the seriousness of the deficiency.



Possible Rewrite

Based on review of Bacteriology culture records and Electronic Medical Record (EMR) final reports and interview with the general supervisor, it was determined that the final results recorded for 3 patients on the test log sheet were different from the results found in the EMR in the specialty of Bacteriology. (Medical record (MR) numbers 31005, 46852, and 62558) Findings include:

1. Record review of the EMR final report in patient charts revealed that test results for bacterial cultures were inconsistent and unmatched on the following patient test reports.
  - a. MR number 31005 - Log sheet stated >100,000 E. coli. EMR final report stated no pathogens found.
  - b. MR number 46852 - Log sheet stated large amount Group A Streptococcus. EMR stated no pathogens found.
  - c. MR number 62558 - Log sheet stated large amount Group B Streptococcus. EMR stated large amount of Group A Streptococcus.
2. The general supervisor confirmed on 2/11/17 at 11:10 am these discrepancies existed between the EMR final report in the patient's chart and the laboratory log sheet.
3. The laboratory performs 8,027 tests in the specialty of Bacteriology annually.

**EXAMPLE 3 - LACKED REFERENCE TO REGULATION**

**D6128 493.1451(b)(9) TECHNICAL SUPERVISOR RESPONSIBILITIES**

*The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation.*

This STANDARD is not met as evidenced by:

Based on personnel records review and laboratory testing personnel interview at 11:00 a.m. on 6/9/15, it was determined that the laboratory director failed to establish written procedures to monitor and ensure the competency evaluations of the testing personnel since 2013.

Comment: This original deficiency is not fitted to the regulation where it is written. The regulation is about Technical Supervisor responsibilities but the deficiency is about the failure of the laboratory director. Also the regulation speaks to competency of testing personnel, not the clinical consultant. The corrected version changed to the technical supervisor to fit the regulation and also the interview with the technical supervisor. When determining whether a technical supervisor (or other personnel) fulfilled their responsibilities, it is best to interview the technical supervisor.

**Suggested Rewrite**

Based on review of personnel records and the personnel manual, and testing personnel interview, it was determined the technical supervisor failed to establish written procedures to monitor and ensure the competency of 5 of 5 testing persons since 2015. (Testing persons #1-5) The findings include:

1. No competency evaluations were found in the personnel records and no competency procedures were found in the personnel manual.
2. The testing personnel confirmed during an interview 04/05/2017, that the technical supervisor had not performed competency assessments and there was no procedure developed.

**EXAMPLE 4 - LACKED FINDINGS**

**D6053 493.1413(b)(9) TECHNICAL CONSULTANT RESPONSIBILITIES**

*The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.*

This STANDARD is not met as evidenced by:

Based on surveyor's review of the personnel records, laboratory records and an interview with the technical supervisor, the technical consultant failed to follow the laboratory's competency policy and perform the semi-annual evaluation for three of five testing personnel during the first year of patient testing in calendar year 2016.

Comment: The original deficiency included a DPS with sources, who was deficient, the lack of action that caused the deficient practice related to the regulation, and an extent. It lacked identifiers for the testing persons listed. The original deficiency lacked any findings to provide the information that was learned from the sources and also the information that showed how the laboratory was deficient. The rewritten deficiency has added the identifiers to the practice statement and also the findings providing what was learned from the record review and the interview.

**Possible Rewrite**

Based on surveyor's review of the personnel records, laboratory policy and procedures and an interview with the technical consultant, the technical consultant failed to follow the laboratory's competency policy and perform the semi-annual evaluation for the three of five testing personnel during the first year of patient testing in calendar year 2016. (Testing persons 3, 4 and 5) The findings include:

1. The laboratory policy and procedures related to competency stated each new testing person would be evaluated semi-annually during their first year of employment.
2. Personnel and laboratory records showed no competency evaluations performed in calendar year 2016 for Testing persons 3, 4, and 5 who started working for this laboratory 12/2/2016.
3. The technical supervisor stated during an interview on 1/31/2017 that no semi-annual evaluations were performed on the three testing personnel.

**EXAMPLE 5 - LACKED FINDINGS FOR ALL SOURCES AND ADEQUATE INFORMATION**

D5401 493.1251(a) PROCEDURE MANUAL

*A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.*

This STANDARD is not met as evidenced by:

Based on the surveyor's review of the written laboratory procedure manual, observation of a staining procedure posted on the wall in the MOHS laboratory, and an interview with the testing person, the laboratory failed to have one functioning staining procedure or provide instruction when to two differing procedures. Findings:

The staining procedure in the MOHS laboratory did not correspond with the staining procedure in the laboratory procedure manual.

Comment: The original deficiency lacked findings related to what was learned from the sources: the interview, the procedures, when the interview was held, when the procedure on the wall was observed and differences between the procedures.

Possible Rewrite

Based on the surveyor's review of the written laboratory procedure manual, observation of staining procedures posted on the wall in the MOHS laboratory, and an interview with the testing person, the laboratory failed to have one functioning staining procedure or provide instruction when to use the two differing procedures. Findings:

1. The written laboratory procedure manual included a procedure for staining tissue from a MOHs procedure.
2. A written staining procedure posted on the wall in the MOHS laboratory was observed at 2PM, 10/4/16. This staining procedure in the MOHS laboratory did not correspond with the staining procedure in the laboratory procedure manual. No instruction was noted to indicate when to use either procedure.
3. The testing person (who conducts the MOHs staining procedures) stated she uses the procedure on the wall as that one was used in her training. She also stated she was not aware that the procedure in the manual was different but noted the differences in staining times when shown.

**EXAMPLE 6 - ADDITIONAL SOURCE, NEEDED FINDINGS, LACKED EXTENT & IDENTIFIERS**

D5405 493.1251(c) PROCEDURE MANUAL

*Manufacturer's test system instructions or operator manuals may be used, when applicable, to meet the requirements of paragraphs (b)(1) through (b)(12) of this section. Any of the items under paragraphs (b)(1) through (b)(12) of this section not provided by the manufacturer must be provided by the laboratory.*

This STANDARD is not met as evidenced by:

Based on review of records, observation and laboratory general supervisor interview on 12/2/14 at 10:40 A.M., it was determined that the laboratory failed to follow the manufacturer's instructions for performing RPR (rapid plasma reagent) quality control procedures. The findings include:

- a. The manufacturer establishes that three levels of control material of different reactivity (reactive, non-reactive and weakly reactive) must be included each day of testing.
- b. Syphilis serology quality control records were reviewed since 1/2014.
- c. Since 11/3/14, the laboratory did not include nor document the three levels of control material of different reactivity (reactive, non-reactive and weakly reactive).
- d. The laboratory reported and processed 22 RPR patient samples from 11/3/14 to 12/1/14.

Comment: The original deficiency included the sources of review of records, observation and general supervisor interview. There was no observation noted in the findings, so that source was deleted. The review of records was expanded to include the types of records reviewed as noted in the findings – manufacturer's procedures and quality control records. The extent of the deficiency was added - 4 of 4 days, along with the dates to give identifier the specific dates when quality control was not documented.

A finding was added to provide what was learned from the review of the quality control records. This finding replaced finding b. in the original deficiency and the information of the time period reviewed was removed. In the deficiency, the timeframe reviewed gave no valuable information. We also added in finding c. to include what was learned from the interview with the general supervisor. In reviewing the deficiency, the sources in the DPS also have specific information of what was learned from each source in the findings.

**Possible Rewrite**

Based on review of quality control records, manufacturer quality control procedures and laboratory general supervisor interview, the laboratory failed to follow the manufacturer's instructions for documenting the RPR (rapid plasma reagent) quality control values for 4 of 4 days of testing reviewed. (11/8/16, 11/15/16, 11/22/16, and 11/29/16) The findings include:

- a. The manufacturer establishes that three levels of control material of different reactivity (reactive, non-reactive and weakly reactive) must be included each day of testing.
- b. Review of the RPR quality control records showed no entries for the three levels of control for the four testing days in November 2016. (11/8/16, 11/15/16, 11/22/16, and 11/29/16)
- c. The general supervisor stated during an interview 12/6/2016 at 10am that she was not aware the controls had not been documented as done.
- d. The laboratory reported and processed 22 RPR patient samples from 11/3/14 to 12/1/14.

**EXAMPLE 7 - ADDITIONAL SOURCES, LACKED EXTENT & IDENTIFIERS**

D5413 493.1252(b) TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT

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

This STANDARD is not met as evidenced by:

Based on observations, quality control records, procedures manual review and laboratory director interview on 10/21/2014 at 10:48 AM, it was determined that the laboratory failed to monitor and document the laboratory's room temperature and relative humidity. The findings include:

1. The laboratory procedures manual establishes that the laboratory must monitor and document the bacteriology area room temperature (18°C - 30° C) and relative humidity (30% - 80%) daily.
2. The laboratory director confirmed that the laboratory did not monitor nor document the room temperature and relative humidity readings since January 9, 2014.

Comment: The original deficiency included observation as one of the sources but there is no information related to what was learned from an observation. The observation was removed from the rewritten deficiency. The original deficiency lacked any extent of the deficiency practice or any identifying information related to the extent. Both were added in the rewritten version. A finding was added to show what was learned from the review of the quality control records. The date and time of the interview with the director was moved from the DPS to the finding speaking of what was learned in the interview.

**Possible Rewrite**

Based on quality control records and procedure manual review and laboratory director interview, it was determined that the laboratory failed to monitor and document the laboratory's room temperature and relative humidity daily from January 9, 2016 thru October 21, 2016 . (285 days)

The findings include:

1. The laboratory procedure manual established that the laboratory must monitor and document the bacteriology area room temperature (18°C - 30° C) and relative humidity (30% - 80%) daily.
2. Bacteriology quality control records showed no documentation for temperature or humidity since January 9, 2016.
3. The laboratory director confirmed during an interview October 21, 2016 at 10am that the laboratory did not monitor nor document the room temperature and relative humidity readings since January 9, 2016.



## **Principle #4: Relevance of Onsite Correction of Findings**

### **EXAMPLE 1- SERIOUS FINDINGS**

D6025 - §493.1407(e)(7) STANDARD LABORATORY DIRECTOR RESPONSIBILITIES

*The laboratory director must ensure that patient test results are reported only when the system is functioning properly.*

This STANDARD is not met as evidenced by:

Based on observation of the laboratory refrigerator and storage areas, review of the laboratory test volume records, test requisitions, testing records and test reports, and interview with the testing person and laboratory director, the laboratory director failed to ensure that A1c reagents, calibration materials and control materials were available to conduct hemoglobin A1C testing on the (name) chemistry analyzer. The findings include:

- a. The testing person stated during the entrance interview (1PM, 7/12/2017) that the laboratory conducted all tests listed on the test volume document provided to the surveyor.
- b. Observation of the laboratory refrigerator at 3PM on 7/12/2017 revealed no A1C reagents, calibration materials or control materials.
- c. Review of test requisitions and reports for June 2017 showed 24 A1C tests requested and results reported.
- d. Review of testing records for the A1C analyzer showed no testing records for June 2017 and showed the last test records for the instrument to be October 2016. No records of calibration were available.
- e. When asked about the lack of reagents, calibration materials and control materials, the testing person stated that "Yes, we are out of reagents but we are waiting for a new shipment".
- f. When asked when the laboratory ran out of A1c reagents, the testing person said, I cannot remember but the reagents had been on back order for quite some time." No reagent shipment records were available for review.
- g. When asked about testing records for the A1c results reported during the June 2017 including the previous day, the testing person gave no response.
- h. The laboratory director was contacted via telephone to report the findings prior to the exit conference at 2PM, 7/13/2017. He stated he was not aware of any problems associated with the A1c testing, shipments of reagents or lack of testing. He stated he would be visiting with the testing person immediately.

**Comment:** This deficiency covers several areas the surveyor would review and follow when serious and questionable information is discovered. Note we have used all three sources including two interviews, several different records reviewed and observations of more than one location. In many situations this information may be expanded with more specific information. This could be decided to be a deficiency with Immediate Jeopardy.

**EXAMPLE 2 - CORRECTED ONSITE**

**D5205 - §493.1233 COMPLAINT INVESTIGATIONS**

*The laboratory must have a system in place to ensure that it documents all complaints and problems reported to the laboratory. The laboratory must conduct investigations of complaints, when appropriate.*

This STANDARD is not met as evidenced by:

Based on record review and technical consultant interview, the laboratory did not have a system in place describing how the laboratory will document, investigate, track and resolve complaints including laboratory related problems it receives. Findings:

1. The technical consultant confirmed the lab did not address complaints and lab related problems including having a policy and procedure.
2. The technical consultant said that he was unaware of the requirement and had not conducted any investigations.

Comment: This deficiency was corrected onsite when the technical consultant provided a new policy and procedure for documenting complaints. Considering, the staff had not been trained on the new policy and no investigations had been completed, the deficiency was not really corrected. A quick fix during they survey is just that, a quick fix. It does not address the systemic problem that caused the deficiency. In this case, the lack of awareness to respond and investigate problems and complaints throughout the laboratory.

### **Principle #5: Interpretive Guidelines**

The deficiency citation explains how the laboratory fails to comply with the regulatory requirements, not how it fails to comply with the guidelines for the interpretation of those requirements. Guidelines are not regulatory requirements rather interpretations of regulatory requirements. Deficiencies should only be cited for noncompliance with regulatory requirements.

#### **D5445 §493.1256 CONTROL PROCEDURES**

*Unless CMS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must (1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at §§493.1278. (2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section.*

This STANDARD is not as evidenced by:

Based on review of urinalysis microscopic procedures, urinalysis quality control records and interview with the testing person, the laboratory failed to have any control procedures including photomicrographs or charts of all possible urine sediment components. The findings include:

1. The manual urinalysis microscopic procedures did not include any instruction about quality control including reference materials such as photomicrographs or charts of all possible urine sediment components.
2. The testing person stated that the laboratory had no instruction for controls for manual urine microscopic testing and had no reference materials to aid testing personnel in identifying sediment components.

**Comment:** This deficiency is written using information from the guidelines giving the laboratory the option to use the photomicrographs or charts of all possible urine sediment components as a control procedure. See 5449.

### **Principle #6: Citation of State or Local Code Violation**

The laboratory's failure to comply with State or local laws or regulations is not documented in the Form CMS-2567 except when the Federal regulation requires compliance with State or local laws. When the authority having jurisdiction for that State or local law has made a decision of noncompliance which has resulted in an adverse action which has been sustained through the hearing process (such as removal of the license to operate), the Form CMS-2567 should note that the laboratory no longer has a State license.

#### **EXAMPLE 1 - CURRENT STATE LICENSE REQUIRED**

This could be used for any of the personnel D-Tags that require State licensure.

- Based on review of personnel records and interview with the laboratory director, the laboratory failed to ensure that 1 of 1 testing personnel held a current XX State license to perform laboratory testing from mm/dd/yy to mm/dd/yy. Section YYY of State requirement requires laboratory testing to be performed by a licensed ZZZ.
- Based on review of personnel records and interview with the clinical consultant, the laboratory failed to ensure the clinical consultant, hired 18 months prior to the survey (January 11, 2016) held a license to practice medicine in the State where the laboratory was located. The findings include:
  - a. Personnel records indicated the clinical consultant held a license to practice medicine in the State where he resides (Kansas) and not in the State of the laboratory (Nebraska).
  - b. The clinical consultant confirmed he is licensed to practice medicine in Kansas where he lives and not in Nebraska where the laboratory was located.

#### **EXAMPLE 2 - STATE/LOCAL ADVERSE ACTION**

Typically this would be used for noncompliance with 42 CFR 493.1101(c).

D3009 §493.1101(c) Standard: Facilities

*The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements.*

- Based on evidence in the attached notice of determination of noncompliance, the laboratory did not meet (State or local) Law/Regulation #XXX. The State of (State) took adverse action against the laboratory. See attached.

EXAMPLE 3 – NOT FOLLOWING LOCAL LAWS - DEFICIENCY SHOULD NOT BE WRITTEN.

D3011 §493.1101(d) Standard: Facilities

*Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials.*

Based on review of laboratory fire drill records related to fire safety and interview with the laboratory directory and fire department personnel, the laboratory failed to ensure they followed the local fire safety practices. The findings include:

1. Local fire practices required a monthly fire drill for all businesses. The laboratory had no records to show these fire drills were taking place.
2. The laboratory director stated he was unaware of this requirement and the laboratory had not conducted any fire drills.
3. Fire department personnel visited the laboratory during the survey to remind the laboratory of this requirement.

Comment: Although there are local laws requiring fire drills, it is the responsibility of the local authorities, not CLIA to monitor the laboratory and take action should it be necessary. If the surveyor noted safety issues in the future, it may be appropriate to notify the local authorities as noted in D3011.

Uses of D8100

D8100      493.1771      INSPECTION REQUIREMENTS

*Each laboratory issued a CLIA certificate must meet the requirements in §493.1773 and the specific requirements for its certificate type, as specified in §§493.1775 through 493.1780. All CUA-exempt laboratories must comply with the inspection requirements in §§493.1773 and 493.1780, when applicable.*

D8101      493.1773(a)      BASIC INSPECTION REQUIREMENTS FOR ALL LABORATORIES ISSUED A CLIA CERTIFICATE AND CLIA-EXEMPT LABORATORIES

*(a) A laboratory issued a certificate must permit CMS or a CMS agent to conduct an inspection to assess the laboratory's compliance with the requirements of this part. A CLIA-exempt laboratory and a laboratory that requests, or is issued a certificate of accreditation, must permit CMS or a CMS agent to conduct validation and complaint inspections.*

D8103      493.1773(d)      REQUIREMENT TO PROVIDE INFORMATION AND DATA

*A laboratory must provide, upon request, all information and data needed by CMS or a CMS agent to make a determination of the laboratory's compliance with the applicable requirements of this part.*

D8201      493.1775(b)      INSPECTION OF COW OR PPMP LABS

*If necessary, CMS or a CMS agent may conduct an inspection of a laboratory issued a certificate of waiver or a certificate for provider-performed microscopy procedures at anytime during the laboratory's hours of operation to do the following:*  
*(1) Determine if the laboratory is operated and testing is performed in a manner that does not constitute an imminent and serious risk to public health.*  
*(2) Evaluate a complaint from the public.*  
*(3) Determine whether the laboratory is performing tests beyond the scope of the certificate held by the laboratory.*  
*(4) Collect information regarding the appropriateness of tests specified as waived tests or provider-performed microscopy procedures.*

D8301      493.1777(a)      INSPECTION OF LABORATORIES THAT HAVE REQUESTED OR HAVE BEEN ISSUED A CERTIFICATE OF COMPLIANCE

*(a) Initial inspection. (a)(1) A laboratory issued a registration certificate must permit an initial inspection to assess the laboratory's compliance with the requirements of this part before CMS issues a certificate of compliance.*  
*(a)(2) The inspection may occur at any time during the laboratory's hours of operation.*



**CoW, TESTING OUTSIDE OF CERTIFICATE**

**Example 1**

D8100 This CONDITION is not met as evidenced by:  
Based on interview with the Manager of Ears, Ears, Ears Otolaryngology and the Chief of Ambulatory Operations at 3:00 pm on 6/26/17 and review of a patient result log book, it was determined that the laboratory was performing testing outside of the scope of their Certificate of Waiver (CoW). Refer to D8201.

D8201 This STANDARD is not met as evidenced by:  
Based on interview with the Manager of Ears, Ears, Ears Otolaryngology and the Chief of Ambulatory Operations at 3:00 pm on 6/26/17 and review of a patient result log book, it was determined the laboratory was performing Tzanck smear testing. Findings:

1. The laboratory was issued a CoW on 10/28/15.
2. Review of the patient result log book for June 2016 and May 2017 revealed that the laboratory performed and reported results for Tzanck smears for ten patients:

<u>Date</u>	<u>Patient ID</u>
6/2/16	06021604
6/3/16	06031615
6/11/16	06111609
6/28/16	06281609
5/8/17	05081704
5/8/17	05081718
5/15/17	05151712
5/23/17	05231703
5/26/17	05251716
5/29/17	05291707

3. Interviews with the Manager and Chief of Ambulatory Operations at 3:00 pm on 6/26/17 confirmed that the laboratory was performing Tzanck smears.
4. Refer to D1000.

Example 2

- D8100      This CONDITION is not met as evidenced by:  
Through observation and interview, it was determined the laboratory failed to meet the requirements for its Certificate of Waiver as it was performing provider-performed microscopy testing. Cross refer to D8201.
- D8201      This STANDARD is not met as evidenced by:  
Through observation and interview, it was determined the laboratory was performing microscopic wet prep examinations, KOH examinations, and urine microscopic examinations which are non-waived tests. Findings follow:  
A. The surveyor observed a microscope on the counter in the laboratory area.  
B. In an interview on 3/27/13 at 11:30, the Testing Person confirmed the physicians were performing microscopic wet prep examinations, KOH examinations, and urine microscopic examinations. Refer to D1000.

**PPM, TESTING OUTSIDE OF CERTIFICATE**

**Example 1**

- D8100      This CONDITION is not met as evidenced by:  
Based on receipt of a complaint concerning tests performed beyond the scope of the PPMP certificate currently held by the laboratory, and a subsequent onsite inspection, it was determined that the laboratory was not in compliance with the specific requirements for the certificate type issued. See D8201.
- D8201      This STANDARD is not met as evidenced by:  
Based on receipt of a complaint concerning tests performed beyond the scope of the certificate held by the laboratory, a subsequent onsite investigation, and interview with the director and testing personnel, it was determined that the laboratory, was performing non-waived tests that were classified beyond the scope of the current Provider-Performed Microscopy Procedure (PPMP) certificate held. Findings included:
- a. At the time of the investigation, the laboratory held a valid PPMP certificate which permitted performance of all tests classified as CLIA Waived and the following lists of provider performed microscopy procedures:
  - b. An unannounced on site investigation was conducted on 7/25/2017.
  - c. The following moderate complexity test kits and materials were available for use:
    - 1) Nova Diagnostics Biokit HSV-2 (Herpes) Rapid Test Lot Number 02975, Expiration 2/2014
    - 2) Diagnostics Direct Syphilis Health Check (Anti-Treponemal EIA) Lot Number 08111, Expiration 11/2013
  - d. The laboratory director stated that the tests identified in above were currently in use and confirmed that patient testing began for both HSV-2 and Syphilis in 2015, but the laboratory was unaware that these tests were beyond the scope of the PPMP certificate type.
  - e. For the period reviewed, covering tests performed from 3/2015 through 7/2017, approximately 1,500 patients were tested for HSV-2 and Syphilis.

## Appendix G

### Example 2

D8100 This CONDITION is not met as evidenced by:  
Based on surveyor observation, review of laboratory records and acknowledged by interview, the laboratory failed to restrict the tests performed to the testing allowed under a Certificate of Provider-Performed Microscopy Procedures (PPMP). (Refer to D8201)

D8201 This STANDARD is not met as evidenced by:  
Based on surveyor observation, review of laboratory records and acknowledged by interview, the laboratory failed to restrict the tests performed to the testing allowed under a Certificate of Provider-Performed Microscopy Procedures (PPMP) for the time period of 05/23/2016 to 02/22/2017.  
Findings include:

1. A review of patient testing logs available for review revealed the facility performed moderate complexity testing serum pregnancy tests. Records revealed that two (2) serum pregnancy tests (Serum Human Chorionic Gonadotropin (HCG)) were performed in October 2016.
2. A review of Clinitek Status test reports available for review revealed that microscopic urine examinations were done by testing personnel who were not a physician, midlevel practitioner or dentist. Records revealed that 10 urine microscopic tests were documented in October and December 2016.
3. An interview of the owner on 02/22/2017 at 1220 hours confirmed that medical technologists performed serum pregnancy tests and urine microscopies. He stated they were unaware that their CLIA certificate did not authorize them to perform the microscopic urine examination and serum pregnancy tests.

Please refer to patient alias lists.

**REFUSAL OF ACCESS, DOCUMENTS, STAFF**

**Example 1, Access**

- D8100      This CONDITION is not met as evidenced by:  
Based on interview with the laboratory director and the laboratory's attorney, the laboratory failed to permit the [##] State Agency ([##] SA) access to the laboratory to perform an initial survey. Refer to D8101
- D8101      This STANDARD is not met as evidenced by:  
Based on interview with the technical supervisor (TS) and the laboratory's attorney, the laboratory failed to allow the [Add State] State Agency (## SA) access to the laboratory to perform an initial survey on July 9, 2017. Findings include:
- a. The [##] SA surveyor arrived at the laboratory for an announced survey on 7/9/17 at 9:00 am.
  - b. The laboratory's hours of operation were Monday-Friday from 8:30 am through 5:00 pm.
  - c. The TS stated through a closed door that "the laboratory director is unavailable for the survey, you need to contact our attorney".
  - d. The attorney was contacted and stated that "the laboratory director was ill and unavailable for the survey scheduled today" and "would contact the State Agency when she was available".
  - e. The [##] SA surveyor explained to the attorney that the laboratory director did not need to be present; that they had the authority to perform a survey at any time during the laboratory's operating hours to determine compliance; and if refused, would need to inform the Regional Office of the refusal to permit the survey.
  - f. The laboratory's attorney refused to allow the [##] SA surveyors to perform the initial survey.

Example 2, Documents

- D8100      This CONDITION is not met as evidenced by:  
Based on interview with the laboratory director and the technical consultant, the laboratory refused to provide personnel qualification documentation, establishment of performance specification documentation and quality control (QC) data. Refer to D8103
- D8103      This STANDARD is not met as evidenced by:  
Based on interview with the laboratory director (LD) and the technical consultant (TC), the laboratory refused to provide personnel qualification documentation for five of five laboratory personnel as well as documentation of establishment of performance specification and quality control (QC) for an FDA-modified toxicology test. Findings include:
1. The surveyor requested personnel qualification documentation for three testing personnel, one laboratory director and one technical consultant.
  2. The laboratory was performing toxicology testing on the [insert instrument].
  3. The laboratory modified the test system by testing a non-FDA approved or cleared specimen type (serum).
  4. The surveyor requested documentation for establishment of performance specifications and QC for [insert instrument].
  5. The LD and TC both refused to allow the surveyor to review the requested documentation on 6/19/18 at 10:35 am as the owner instructed them that it was proprietary information and they did not need to show the surveyor the documentation.



## **Examples – Lack of Documentation**

### **Example 1**

D6046 §493.1413(b)(8) TECHNICAL CONSULTANT RESPONSIBILITIES

*(b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. The procedures for evaluation of the competency of the staff must include, but are not limited to—*

This STANDARD is not met as evidenced by:

Based on lack of documentation and interview with the technical consultant, the laboratory failed to document competency assessment (CA) for four of four testing personnel (TP). Findings include:

1. The procedure, "Competency Assessment, v. 2.0" was reviewed.
2. Section 2.4 stated that CA should be "evaluated and documented at 6 months during the first year of employment and annually thereafter."
3. TP #1 and #2 were hired on 9/5/15, TP #3 was hired 1/3/16 and TP#4 was hired 4/25/16.
4. No documentation was found that CA was performed from September 2014 through the date of the survey.
5. The TC confirmed on 11/18/17 at 2:05 pm that CA had not been performed or documented.

### **Example 2**

D3033 493.1105(a)(3)(i) RETENTION REQUIREMENTS

*In addition, the laboratory must retain records of test system performance specifications that the laboratory establishes or verifies under §493.1253 for the period of time the laboratory uses the test system but no less than 2 years.*

This STANDARD is not met as evidenced by:

Based on the review of shipping invoices, patient reports, interviews with laboratory staff and a manufacturer representative, and lack of documentation, the laboratory failed to maintain documentation of verification studies for the ACE Alera chemistry analyzer and the TOSOH A1Aimmunoassay analyzer.

Findings are:

1. Record review of shipping records indicated that the ACE Alera and TOSOH AIA were installed in October 2016.
2. The technical consultant, TC#1, stated during a phone interview on 7/12/17 at 9:45 am that the records were located at the back of the instrument manuals.
3. No verification records were found during the survey.

## **Examples – DPS and Findings Do Not Match**

### **Example #1**

D5481 §493.1256(f)(g) CONTROL PROCEDURES

*(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results.*

*§493.1256(g) The laboratory must document all control procedures performed.*

Based on review of the laboratory's instrument printouts, quality control (QC) records, and interviews with the Office Manager (OM) and Technical Consultant (TC), the laboratory failed to retain failed QC instrument printouts from 2016 and 2017 for the complete blood count (CBC) testing performed. Findings Include:

1. Review of the laboratory's 2015 Beckman Coulter AcTDiff instrument printouts did not find any failed or unacceptable QC printouts.
2. The Surveyor requested the laboratory's 2016 and 2017 instrument printouts for all QC testing performed on the Beckman Coulter AcTDiff instrument. The OM stated the failed or unacceptable QC records are trashed or erased in the analyzer and the actual instrument printouts are shredded.
3. The TC confirmed on 3/16/2017 at 5 pm that the laboratory did retain all instrument printouts for at least 2 years, but was unable to provide the requested documentation.

*Comments: In this example the DPS cites a different time frame than Finding #1 which leaves the reader confused about what documents were missing, if any. Finding #3 directly conflicts with the DPS as the TC stated that the lab did retain the instrument printouts.*

### **Example #2**

D5791 493.1289(a) ANALYTIC SYSTEMS QUALITY ASSESSMENT

*(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified at §§493.1251 through 493.1283.*

This STANDARD is not met as evidenced by:

Based on review of quality assessment (QA) and QA documentation, and interview with the laboratory director, the laboratory failed to follow the QA procedure for 2017. Findings include:

1. The laboratory's quality control (QC) procedure, Quality Control (QC-001), stated in section 4.3 that "QC must be run each day of patient testing and acceptable prior to release of patient test results".
2. Two levels of Bio-Rad controls were used each day of patient testing on the Siemens XPT.
3. Review of the QC data from April 2017, July 2017, and October 2017 revealed the following number of days QC was unacceptable:

## Appendix I

- a. Glucose, Level 1: 20 of 60 days
  - b. Glucose, Level 2: 12 of 60 days
  - c. Calcium, Level 1: 8 of 60 days
  - d. Total Protein, Level 2: 13 of 60 days
  - e. Creatinine, Level 1: 11 of 60 days
  - f. Creatinine, Level 2: 7 of 60 days
4. The laboratory director confirmed the above findings on 12/15/17 at 3:45 pm.

*Comments: The DPS speaks to QA; however, the findings speak to QC.*

## Examples – Repeating Regulations in DPS

The statement of deficient practice must not merely repeat the regulation, but should state specifically what the facility did that was wrong or failed to do in relation to the regulation and let the reader know what to look for in the findings. Many D-Tags have multiple regulatory requirements. It is important that the DPS speak to the specific portion of the regulation(s) that the laboratory failed to meet.

### Example 1

D6000            §493.1407   Standard; Laboratory director responsibilities.

*The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations.*

This CONDITION is not met as evidenced by:

Based on review of documentation and interview with the technical consultant, the laboratory director failed to fulfill his responsibility for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations.

*Comments: It is unclear from the DPS what specific requirements the laboratory director did not fulfill. The citation should have included specific "failed to..." statements with cross references or a more specific DPS with findings that cross refer to the appropriate standard(s).*

*Example meeting POD:*

*Based on review of documentation and interview with the technical consultant on 5/13/17 at 3:30 pm, the laboratory director failed to ensure that a quality control (QC) program for chemistry was established (see D6020) and failed to ensure remedial actions were taken when QC was unacceptable for complete blood counts (CBCs) (D6025).*

OR

*Based on review of documentation and interview with the technical consultant on 5/13/17 at 3:30 pm, the laboratory director failed to ensure that a quality control (QC) program was established and failed to ensure remedial actions were taken when hematology QC was unacceptable. Findings include:*

- 1. The laboratory director failed to ensure that a quality control (QC) program for chemistry was established (see D6020).*
- 2. The laboratory director failed to ensure remedial actions were taken when QC was unacceptable for complete blood counts (CBCs) (D6025).*



Example 2

D5793 §493.1289 Standard: Analytic systems quality assessment.

*(b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of postanalytic systems quality assessment reviews with appropriate staff.*

This STANDARD is not met as evidenced by:

Based on review of quality assessment (QA) documents and interview with laboratory director, the laboratory failed to include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff.

*Comments: It is unclear from the DPS what specific requirements of analytic quality assessment were not met. The citation should have included a more specific "failed to..." statement.*

*Example meeting POD:*

*Based on laboratory personnel interviews and WBC differential flow cytometer performance report record review on February 17, 2016, the laboratory failed to have an analytic systems quality assessment mechanism that included a review of the effectiveness of flow cytometer corrective actions taken to resolve problems. Findings include:*

- a. For patient capillary specimens, it was the practice of the laboratory to use flow cytometry instrumentation to perform and report patient WBC differentials.*
- b. On August 23, 2015, in which the flow cytometer was used to perform and report patient WBC differentials, laboratory "Cytometer Performance Reports" indicated that at 09:30 the flow cytometer performance check failed. The performance check was repeated and again failed at 10:18. At 12:49, laboratory documentation indicated that the flow cytometer performance check passed.*
- c. The laboratory maintained no documentation to indicate that the actions taken on August 23, 2015 to "pass" the flow cytometer performance check had been reviewed for the effectiveness of the actions under the laboratory's quality assessment mechanism.*

### **Examples – Writing Condition Statements**

Please Note: Below are examples of the same condition-level deficiency writing in several ways (i.e., narrative or with findings). This illustrates the different ways that condition-level deficiencies may be written according to the POD.

**D5024 493.1215 HEMATOLOGY**

*If the laboratory provides services in the specialty of Hematology, the laboratory must meet the requirements specified in §§493.1230 through 493.1256, §493.1269, and §§493.1281 through 493.1299.*

**D5024 This CONDITION is not met as evidenced by:**

Based on record review and interview with the laboratory director and technical supervisor, the laboratory failed to have a procedure manual which included the corrective action to take when complete blood counts (CBC) calibration and quality control (QC) results failed to meet the laboratory's criteria for acceptability (see D5403); document CBC calibrations (see D5437); failed to verify stated values of commercially assayed CBC controls (see D5469); failed to ensure QC for PT/INR was acceptable prior to reporting patient test results (see D5481); failed to follow corrective action policies and procedures as necessary to maintain the laboratory operation for testing patient CBC specimens in a manner that ensured accurate and reliable patient test results and reports (see D5779); failed to have an analytic systems quality assessment mechanism that included a review of the effectiveness of the laboratory's corrective actions for CBCs (see D5779); and failed to ensure that the calculated International Normalized Ratio (INR) results were accurate prior to reporting final patient results (see D5801).

OR

Based on the number and severity of the deficiencies cited herein, the Condition: Hematology was not met. The laboratory failed to have a procedure manual which included the corrective action to take when complete blood counts (CBC) calibration and quality control (QC) results failed to meet the laboratory's criteria for acceptability (see D5403); document CBC calibrations (see D5437); verify stated values of commercially assayed CBC controls (see D5469); ensure QC for PT/INR was acceptable prior to reporting patient test results (see D5481); follow corrective action policies and procedures as necessary to maintain the laboratory operation for testing patient CBC specimens in a manner that ensured accurate and reliable patient test results and reports (see D5779); have an analytic systems quality assessment mechanism that included a review of the effectiveness of the laboratory's corrective actions for CBCs (see D5779); and ensure that the calculated International Normalized Ratio (INR) results were accurate prior to reporting final patient results (see D5801).

OR

## Appendix K

Based on the number and severity of the deficiencies cited herein, the Condition: Hematology was not met...Findings include:

1. The laboratory failed to have a procedure manual which included the corrective action to take when complete blood counts (CBC) calibration and quality control (QC) results failed to meet the laboratory's criteria for acceptability (see D5403).
2. The laboratory failed to document CBC calibrations (see D5437); verify stated values of commercially assayed CBC controls (see D5469).

**Examples – Multiple Citations Cited Under Same Regulation**

**EXAMPLE 1**

**D5791 493.1289(a) ANALYTIC SYSTEMS QUALITY ASSESSMENT**

*The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in §§493.1251 through 493.1283.*

This STANDARD is not met as evidenced by:

1. Based on surveyor review of the Quality Control (QC) Records, Procedure Manual (PM) and interview with the Laboratory Director (LD), the laboratory failed to monitor that the New QC verification procedures were followed for 4 of 4 lots of New QC materials from January 5, 2016 thru May 10, 2017. (Lot #s 46X31, 56X32, 66X33, 76X34.) The findings include:
  - a) The procedure manual included a procedure on how to verify new lots of QC materials.
  - b) Quality control record reviews showed the laboratory did not perform and document the verification of the 4 new lots received for Hematology Quality Control materials before putting in use as per their procedure. Lot numbers 46X31, 56X32, 66X33, and 76X34.
  - c) The LD confirmed on 10/23/16 at 1:30 PM that the procedure for verifying new lots of QC materials was not followed.
2. Based on surveyor review of calibration records, manufacturer's Instructions and interview with the Laboratory Director (LD), the laboratory failed to monitor hematology calibration to ensure the laboratory followed the manufacturer's instructions for times of "Needed" calibration. "Needed" calibrations were noted and not completed on 8/25/2016, 10/14/2016 and 1/5/2017. The findings include:
  - a) Calibration records showed calibration performed on 8/25/14 with a "Platelets" status 'Needed'. The laboratory did not follow the manufacturer's procedure to adjust the calibration factor.
  - b) Calibration records for 10/14/2016 and 1/5/2017 showed the laboratory had not reprinted the calibration after adjusting the calibration factor.
  - c) The LD confirmed on 10/23/14 at 1:00 PM that the calibration procedures were not followed.

**Comment:** This regulation addresses the analytic systems and relates to all specialties of testing. A surveyor may have deficiencies at this tag with no similarity hence writing different deficient practice statements with findings is probable. Note that the two deficient practice statements are about monitoring practices but are both very different in substance. One is monitoring the verification of new lots of QC materials and the other monitoring that calibration is completed as needed according to manufacturer's instruction.



**EXAMPLE 2**

**D5413 493.1252(b) TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENTS**

*(b) 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:*

*(1) Water quality.*

*(2) Temperature.*

*(3) Humidity.*

*(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.*

This STANDARD is not met as evidenced by:

1. Based on observation and document review, the laboratory failed to define ten of ten freezer temperature ranges that were consistent with the manufacturer's instructions for freezers which stored reference materials and patient specimens. Findings include:
  - a. A tour of the laboratory on 11/15/2016 at 10:35 am where the freezers were kept showed that the freezer doors were labeled with the laboratory's acceptable temperature ranges.
  - b. Four of four -80 C freezers were marked with a temperature range of -60 to -90C.
  - c. Six of six -20 C freezers were marked with a temperature range of -17 to -25C.
  - d. Review of two manufacturer instructions for samples stored in the -80 C freezers required that the samples be kept at "at least -80 C."
  - e. Review of three manufacturer instructions for samples stored in the -20 C freezers required that the samples be kept at "at least -20 C."
  - f. The Technical Supervisor confirmed on 11/15/2016 at 11 am that the freezers were labeled with the above ranges and that the ranges did not meet manufacturer instructions.
2. Based on review of the procedure, manufacturer package insert (PI), interview with the general supervisor and observation, the laboratory failed to follow the manufacturer's instructions for expiration date of Innovin (thromboplastin) used for Prothrombin Time/International Normalized Ratio (PT/INR) testing. Findings include:
  - a. Dade Innovin (thromboplastin) lot number 539280 was put into use by the laboratory at the end of March 2016.
  - b. The general supervisor stated that the PIs were usually white.
  - c. The PI for lot number 539280 was pink.
  - d. Review of the PI revealed an "important note" that this specific lot number was only stable for 2 days instead of 10 days after reconstitution when stored at 2-8 C.
  - e. The current vial of Innovin reagent was observed in the 2-8 C refrigerator with a 5 day expiration date on 11/16/2016 at 2:15 pm.
  - f. PT SOP-1001, Version A, "Measuring Prothrombin Time" stated on page 6, section 4.2 that "the package insert for a new lot must be reviewed for any changes before use."
  - g. The general supervisor confirmed on 11/16/2016 that the change in storage and stability of the Innovin reagent had not been identified from March 2016 through November 2016.

## Appendix L

Comment: This regulation addresses the test system, equipment, instruments, and reagents. A surveyor may have deficiencies at this tag with no similarity hence writing different deficient practice statements with findings is probable. Note that the two deficient practice statements are about defining freezer temperatures and appropriate expiration date of reagents and are both very different in substance.

**EXAMPLE 3**

D5805 493.1291(c) TEST REPORT

*The test report must indicate the following: (1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (2) The name and address of the laboratory location where the test was performed. (3) The test report date. (4) The test performed. (5) Specimen source, when appropriate. (6) The test result and, if applicable, the units of measurement or interpretation, or both. (7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.*

This STANDARD is not met as evidenced by:

**A. Name and Address of the Laboratory where tests performed and reported:**

Based on electronic medical record (EMR) review and interview with the general supervisor, the laboratory failed to ensure 2 of 2 laboratory test results documented in the EMR did not contain the required information as to the name and address of the laboratory location where the test was performed. (EMR #s 1690 and 2122) Findings include:

1. EMR record review of the following patient test reports from the Sheridan EMR on 2/11/17 revealed that the laboratory failed to inscribe the name and address of the facility where testing took place.
  - a. Test report for MR# 1690
  - b. Test report for MR# 2122
2. The general supervisor stated in an interview on 2/11/17 at 12:15 pm the name and address of the laboratory had been left out of the EMR database.
3. The laboratory performs 64,247 tests annually.

**B. Incorrect reference ranges and units of measurement (UOM):**

Based on EMR record review and general supervisor interview, the laboratory failed to ensure the reference ranges and units of measurements (UOM) from the analyzer printout and the Electronic Medical Record (EMR) match on 2 of 2 records reviewed. (EMR #s 1690 and 2122) Findings include:

1. Review of the final CBC test reports from EMR and the Horiba hematology analyzer on 2/11/17 revealed that the reference ranges and UOM's for CBC parameters were inconsistent and unmatched on the following patient test reports.
  - a. Test report for EMR# 1690
  - b. Test report for EMR# 2122
2. The general supervisor stated in an interview on 2/11/17 at 12:20 pm that discrepancies exist between the EMR final report and the Horiba instrument printout. The general supervisor also stated that EMR reference ranges and UOM's for CBC parameters were overlooked following last computer system upgrade.
3. Laboratory performs 10,044 CBC's annually.

**Comment:** This regulation has several different requirements therefore a surveyor may have more than one deficiency at this tag requiring the more organization. More than one DPS with findings may be the best route to organizing the information for more clarity as noted in this example. One deficiency is related to the name and address of the testing location on reports and the other deficiency related to the reference ranges and units of measure not matching between the EMR and instrument. Note the surveyor has organized the two different deficiencies into two practice statements, each with findings. Each deficiency has a separated DPS and findings that can stand alone.

### Cross Referencing

#### Example 1

**D6021** §493.1407(e)(5) Standard; Laboratory director responsibilities

*Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and*

This STANDARD is not met as evidenced by:

Based on lack of quality assessment (QA) documentation, the laboratory director failed to ensure that General Laboratory System QA program was established and maintained to ensure the quality of laboratory services provided for Chemistry testing. **Refer to D5291.**

**D5291** §493.1239(a) General Laboratory Systems Quality Assessment

*The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at §§493.1231 through 493.1236.*

This STANDARD is not met as evidenced by:

Based on lack of Quality Assessment (QA) documentation and interview with the facility personnel, the laboratory failed to establish written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the general laboratory systems for the specialty of chemistry. Findings include:

1. No QA policies for the general lab system (GLS) were presented for review during the survey, including but not limited to, policies and procedures specific to proficiency testing and personnel competency.
2. The laboratory provided documentation of a blank form titled "I-stat Audit Tool", however there was no documentation to indicate the laboratory completed the form.
3. The "I-State Audit Tool" did not include proficiency testing or competency assessment.
4. The facility personnel confirmed that the laboratory did not have an established QA policy.
5. The laboratory performed approximately of 600 blood gas annually.

**Example 2**

**D5791** §493.1289(a) Analytic systems quality assessment

*The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in §§493.1251 through 493.1283.*

STANDARD is not met as evidenced by:

Based on laboratory personnel interviews and complete blood count (CBC) quality control and calibration record review, the laboratory failed to have an analytic systems quality assessment mechanism that included a review of procedures to include actions to be taken when calibration and quality control results fail, ensure calibration documentation is maintained, and ensure the verification of commercially assayed quality control materials. Finding include:

- a. The laboratory's Siemens Advia 2120i and Advia XPT procedures failed to include the corrective actions to be taken when calibration or quality control results failed to meet the laboratory's criteria for acceptability. **See D5403.**
- b. The laboratory's quality assessment mechanism failed to ensure that all CBC calibration documentation was maintained. **See D5437.**
- c. The laboratory's quality assessment mechanism failed to ensure that the stated values of commercially assayed CBC and chemistry quality control materials were verified. **See D5469.**

**D5403** Procedure Manual

§493.1251 Procedure manual

*(b) The procedure manual must include the following when applicable to the test procedure:*

*(b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in §493.1242.*

This STANDARD is not met as evidenced by:

1. Based on interviews with laboratory testing personnel and review of the laboratory's hematology Advia 2120i procedure manual, the laboratory failed to have a procedure manual that included the corrective action to take when calibration or quality control results failed to meet the laboratory's criteria for acceptability. Findings include:
  - a. It was the practice of the laboratory to test patient venous complete blood counts (CBC) specimens using a Siemens Advia 2120i instrument.
  - b. In the laboratory's procedure titled "SOP Advia 2120i Operation and Maintenance," there was no written protocol for the corrective action to be taken when calibration or quality control failed to meet the laboratory's criteria for acceptability.
  - c. Between February 1, 2016 and September 28, 2016, the laboratory performed and reported 5,395 patient CBC test results using the Advia 2120i.
  - d. Review of calibration and control logs showed out of range controls were approached differently by each of the testing personnel and there was no consistent approach.



Some out of range controls were repeated, others were logged as only control out this week, and others documented as within three standard deviations.

- e. e. Testing person # 1 stated the practice by testing personnel was to address the control failures but no consistent approach was decided or written. Testing person #1 also confirmed there was no written procedure for corrective action to take when controls or calibration failed.
2. Based on review of the quality control (QC) procedure for the Siemens Advia XPT and interview with the testing personnel, the laboratory failed to have control procedures prior to beginning patient testing on 2/6/2016. Findings include:
    - a. SOP-C100, Revision A, "Advia XPT System Daily QC Procedure" revealed an effective date of 10/15/2016.
    - b. A chart provided by the laboratory indicated that eight of twenty analytes run on the above system were put into use for patient testing prior to 10/15/2016. The initial use dates of the eight analytes ranged from 2/6/2015 through 5/9/2016.
    - c. Testing personnel confirmed there was no approved control procedure prior to 10/15/2016.

**D5437**      §493.1255      Calibration and Calibration Verification

- (a) Perform and document calibration procedures -*
- (a)(1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer;*
- (a)(2) Using the criteria verified or established by the laboratory as specified in §493.1253(b)(3)--*
- (a)(2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and*
- (a)(2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and*
- (a)(3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.*

This STANDARD is not met as evidenced by:

Based on laboratory personnel interviews and complete blood count (CBC) calibration documentation record reviews, the laboratory failed to document two of two CBC instrument calibrations performed using the Drew 3 instruments, and failed to document calibrations performed on two of two Advia 2120i.

1. Based on laboratory personnel interviews and complete blood counts (CBC) calibration documentation record reviews on September 23, 2015, the laboratory failed to document all CBC instrument calibrations performed using the Drew 3 instruments. Findings included:
  - a. It was the practice of the laboratory to test patient capillary CBC specimens using two Drew 3 instruments the laboratory designated as "Drew #2" and "Drew #3." On September 28, 2016, information recorded on "Drew #2" indicated that the "Drew #2" was calibrated on August 24, 2016, and information recorded on "Drew #3" indicated that the "Drew #3" was calibrated on August 31, 2016.

- b. The laboratory maintained no documentation of the August 24, 2016 and August 31, 2016 calibrations of the laboratory's two Drew 3 CBC instruments.
  - c. According to laboratory personnel, between August 24, 2016 and September 28, 2016, the laboratory performed and reported 523 patient CBC specimens using the two Drew 3 instruments.
2. Based on laboratory personnel interviews and complete blood count (CBC) calibration documentation record reviews, the laboratory failed to document CBC instrument calibrations performed using two of two Advia 2120i instruments from the date of installation, 10/5/14 through 9/28/16. Findings included:
  - a. It was the practice of the laboratory to test patient venous CBC specimens using two Siemens Advia 2120i instruments, designated as #1 and #2.
  - b. For Advia 2120i #1, the laboratory maintained no documentation of any calibrations prior to May 21, 2016. For Advia 2120i #2, the laboratory maintained no documentation of any calibrations performed.
  - c. Between October 2014 and May 21, 2016, the laboratory performed and reported 2,005 patient CBC test results using the Advia 2120i #1. From 10/5/14 to 9/28/16, the laboratory performed and reported 1,067 patient CBC test results using the Advia 2120i #2.

**D5469**      §493.1256(d)(10)      Control Procedures

*Establish or verify the criteria for acceptability of all control materials.*  
*(d)(10)(i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available.*  
*(d)(10)(ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory.*  
*(d)(10)(iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters.*

This STANDARD is not met as evidenced by:

1. Based on interview with the laboratory personnel and review of Complete Blood Count (CBC) records, the laboratory failed to verify the stated values of the commercially assayed CBC quality control materials in use from June 27, 2016 thru the date of the survey. Findings include:
  - a. It was the practice of the laboratory to use commercially assayed CBC quality control materials to monitor patient CBC testing using two Drew 3 instruments.
  - b. Laboratory CBC quality control records indicated that on June 27, 2016 the laboratory changed the lot of quality control material from lot number TD048 to TD051.
  - c. The laboratory maintained no documentation to indicate that the stated values of CBC quality control material lot number TD051 had been verified by the laboratory.
  - d. According to laboratory personnel, between June 27, 2016 and September 28, 2016, the laboratory used one of the Drew 3 instruments on 30 different days to perform and report patient CBC specimens, and used the other Drew 3 instrument on 87 different days to perform and report patient CBC specimens.

2. Based on interview with the general supervisor and review of chemistry quality control (QC) records, the laboratory failed to verify the stated values of the commercially assayed QC materials used on the Advia 1800 and Advia XPT from June 2016 thru the survey date.

Findings include:

- a. The general supervisor stated that when a new lot number of QC was started, the QC ranges were entered into the chemistry analyzers (Advia 1800 and Advia XPT) from the manufacturer's package insert just prior to use.
- b. The general supervisor further stated that the new lot number of QC was run on time prior to patient testing.
- c. QC records show that MultiQual lot number 45660 was put into use in 2015 and discontinued in August 2016.
- d. The general supervisor confirmed on 9/28/16 at 9:40 am that manufacturer's QC ranges for new lot numbers of chemistry controls were not verified.



Examples, PT Desk Review Citations

**D2016 (mandatory citation) + specialty/subspecialty specific D-Tag must be cited. Laboratory Director D-Tag is optional.**

**D2016 493.803(a)(b)(c) SUCCESSFUL PARTICIPATION**

*(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA.*

*(b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part.*

*(c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists:*

*(1) There is immediate jeopardy to patient health and safety.*

*(2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance.*

*(3) The laboratory has a poor compliance history.*

**Initial Unsuccessful**

**Example 1**

**D2016** This CONDITION is not met as evidenced by:

Based on an off-site desk review of the laboratory's 2016 and 2017 Medical Laboratory evaluation (MLE) proficiency testing (PT) records and an email and telephone interview with the laboratory coordinator on April 11, 2017, it was determined that the laboratory failed to attain a score of at least eighty (80) percent of acceptable responses for Hematology Cell Identification in two (2) out of three (3) Hematology testing events resulting in unsuccessful PT performance. See 2130

**D2130 493.851(f) HEMATOLOGY**

*Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance.*

**D2130** This STANDARD is not met as evidenced by:

Based on an off-site desk review of the laboratory's 2016 and 2017 Medical Laboratory Evaluation (MLE) proficiency testing (PT) records, and an email and telephone interview with the laboratory coordinator on April 11, 2017 it was determined that the laboratory failed to attain a score of at least eighty (80) percent of acceptable responses for White Blood Cell (WBC) Differential Identification in two (2) out of three (3) Hematology testing events. Findings include:

1. Desk review of the laboratory's 2016 and 2017 MLE PT records revealed WBC Differential Identification scores of less than eighty percent for the following Hematology events:

## Appendix N

2016 MLE M2 -score of 60%,

2017 MLE M1- score of 60%

2. In an email and telephone interview with the laboratory coordinator on 4/11/17, it was confirmed that the laboratory was unsuccessful in the PT events listed above.

### Example 2

D2016 This CONDITION is not met as evidenced by:

Based on review of 2016 hematology proficiency testing (PT) results reported to the CLIA database by the PT provider and phone interview with the technical supervisor, the laboratory failed to successfully participate in PT. See D-tag 2130, unsatisfactory performance for the same analyte in two consecutive hematology PT testing events. Refer to D2130.

D2130 493.851(f) HEMATOLOGY

*Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance.*

D2130 This STANDARD is not met as evidenced by:

Based on review of 2016 hematology proficiency test (PT) performance reported to the CLIA data base by the PT provider and phone interview with the technical supervisor, the laboratory failed to achieve satisfactory performance for the fibrinogen analyte in two consecutive testing events. Findings:

1. The laboratory obtained an unsatisfactory score of 0 percent for the fibrinogen analyte in the first testing event of 2016.
2. The laboratory obtained an unsatisfactory score of 20 percent for the fibrinogen in the second testing event of 2016.
3. Phone interview with the technical supervisor on September 19, 2016 at 12:30 PM confirmed the laboratory failed to achieve satisfactory performance for the fibrinogen analyte in the first and second PT events for 2016.

### Example 3

D2016 This CONDITION is not met as evidenced by:

Based on proficiency testing desk review, the laboratory failed to successfully participate in proficiency testing for the analyte Free Thyroxine (Free TY). Refer to D2107.

D2107 493.843(f) ENDOCRINOLOGY

*Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.*

D2107 This STANDARD is not met as evidenced by:

Based on proficiency testing (PT) desk review and the laboratory's graded PT results from American Proficiency Institute (API), the laboratory failed to achieve successful performance for the analyte, Free Thyroxine (Free TY), in two out of three testing events. Findings:

Analyte	Year	Event	Score
Free TY	2017	1	60%
Free TY	2017	2	20%

**Non-Initial (or Subsequent) Unsuccessful**

**Example 1**

D2016 This CONDITION is not met as evidenced by:  
Based on review of the Proficiency Testing (PT) data report (Report 155) report and graded results from, American Proficiency Institute (API), the laboratory failed to successfully participate in a Cell Identification. The laboratory had unsatisfactory scores for the 1st event of 2014, the 2nd event of 2014 and 3<sup>rd</sup> event 2014. See D2130.

D2130 493.851(f) HEMATOLOGY  
*Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance.*

D2130 This STANDARD is not met as evidenced by:  
Based on a review of the Proficiency Testing (PT) data report (CASPER Report 155) and graded results from the proficiency testing organization American Proficiency Institute (API), the laboratory failed to successfully participate in Cell Identification. The laboratory had unsatisfactory scores for the 1st event of 2014, the 2nd event of 2014 and 3rd event 2014 for the analyte listed above. Findings include:

1. API 2014 Event 1 for Cell Identification the score was 53% and was unsatisfactory.
2. API 2014 Event 2 for Cell Identification the score was 67% and was unsatisfactory.
3. API 2014 Event 3 for Cell Identification the score was 27% and was unsatisfactory.

**Example 2**

D2016 This CONDITION is not met as evidenced by:  
Based on review of 2016 and 2017 hematology proficiency testing (PT) results reported to the CLIA database by the PT provider and phone interview with the technical supervisor, the laboratory failed to successfully participate in PT. Refer to D2130

D2130 493.851(f) HEMATOLOGY  
*Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance.*

D2130 This STANDARD is not met as evidenced by:  
Based on review of 2016 and 2017 hematology proficiency test (PT) results reported to the CLIA database by the PT provider and phone interview with the technical supervisor, the laboratory failed to achieve satisfactory performance for the fibrinogen analyte in two consecutive testing events. Findings:

1. The laboratory obtained an unsatisfactory score of 0 percent for the fibrinogen analyte in the first testing event of 2016.

2. The laboratory obtained an unsatisfactory score of 20 percent for the fibrinogen analyte in the second testing event of 2016.
3. The laboratory obtained an unsatisfactory score of 40 percent for the fibrinogen analyte in the first testing event of 2017.
4. Phone interview with the technical supervisor on May 15, 2017 at 2:00 PM confirmed the laboratory failed to achieve satisfactory performance for the fibrinogen analyte in the first and second testing PT events for 2016 and first testing event of 2017.

Example 3

D2016 This CONDITION is not met as evidenced by:

Based on proficiency testing desk review, the laboratory repeatedly failed to successfully participate in proficiency testing for the subspecialty of Bacteriology. Refer to D2028

D2028 *493.823(e) BACTERIOLOGY*

*Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.*

D2028 This STANDARD is not met as evidenced by:

Based on review of data from proficiency testing (PT) reports and the laboratory's PT results from American Association of Bioanalysts (AAB), the laboratory failed to achieve satisfactory performance in the subspecialty of Bacteriology and has sustained a subsequent occurrence of unsuccessful participation in PT. Findings:

Subspecialty	Year	Event	Score
Bacteriology	2016	1	20
Bacteriology	2016	2	60
Bacteriology	2016	3	60

## **Frequently Asked Questions (FAQs), POD**

Q1. Can D0000 be used for anything else besides compliance, if no D-Tag is available or if there are new regulations which don't have a D-Tag assigned yet?

A1. Due to our continued improvement and practical application of the principles of documentation, CLIA policy also allows for the following additional uses of D0000:

- Indication of survey type
- Summary of condition-level deficiencies
- Documentation of PT referral for Certificate of Waiver or PT referral for waived tests being performed under other certificate types

D0000 should not be used for the following:

- List of acronyms used in Form CMS-2567
- Indication of surveyor or names
- Narrative to describe the survey and a summary of noncompliance issues

Q2. Is it ok if the laboratory needs additional paper to respond? Is "see attached" acceptable for an AOC or POC?

A2. It is perfectly acceptable for a laboratory to refer to additional documents when responding to the CMS-2567, especially if their response cannot fit on the CMS-2567 or if they choose to respond with "see attached" in the correction column, as long as it is clearly indicated what and where those documents are found in their submission. **The CMS-2567 must always include: laboratory director or representative signature, title, and date.**

Q3. What is the difference between "extent" and "universe"?

A3. Extent is the prevalence or frequency of a deficient practice. Universe is one way to describe extent. Universe is defined as the total number of individuals, records, observations, objects, related to the laboratory practice or patients at risk as a result of a deficient practice, and is used as the denominator when determining the extent of a deficient practice. Both extent and universe should be reflected in a numerical format, if at all possible.

Extent and universe are very important in order to accurately reflect the degree of a specific deficient practice. It is up to the surveyor to determine the relevant universe.

Q4. If the laboratory director and technical consultant or technical supervisor is the same person, can we say "laboratory director/technical consultant (or supervisor)" in all of the personnel D-Tags?

- A4. It is important when citing personnel D-tags that your deficient practice statement and/or findings only reference the specific position (e.g., laboratory director (LD), technical consultant (TC), technical supervisor (TS), etc.) that is being cited on the CMS-2567. Many laboratories, especially POLs, will have one person filling more than one position – LD/clinical consultant/TC. You may also find that the LD of a high complexity laboratory is also acting as the TS. However, if the regulatory reference speaks to non-compliance with a LD responsibility, the D-tag citation on the CMS-2567 should only contain a reference to the LD. This is true for all personnel citations. The CMS-209 will reflect that one person is fulfilling more than one position.
- Q5. Why do we have to use POD?
- A5. PODs provide a consistent framework on how to document a laboratory's compliance or noncompliance. Many styles of writing are acceptable and style is a matter of personal preference. Just remember to follow the POD while injecting your own personal style.
- Q6. Why do we need to review the CMS-2567 before we send it to the laboratory?
- A6. The CMS-2567 is the record of the survey and the key element in supporting, or not supporting, a determination of compliance. It is important that this document be legally defensible. In addition, this document is used by the laboratory to analyze and correct its deficient practice(s). So, it is very important that you proofread the CMS-2567 after it is written, and before it is sent to the laboratory, to ensure that the principles of documentation are being followed and that it makes sense. This is especially true if you are copying and pasting information into the CMS-2567. Some examples of items to check are:
- Spelling and grammar
  - Transposed numbers in D-tags cross references (e.g., D5217 not D5127)
  - Cross referenced D-tags are actually cited on the CMS-2567
  - DPS/findings speak to the citation (e.g., QC tag with DPS/findings speaking about QA)
  - Findings support the DPS (e.g., lab cited for QC problems with BUN and glucose in the DPS and only BUN in addressed in the findings, lab cited for not monitoring temperature and humidity in DPS and findings speak about temperature and centrifuge rpms)
  - No advice or directions
  - Acronyms are defined the first time they are used
  - Write in complete sentences