

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0659053	(X3) Date Survey Completed 01/17/2018
Name of Provider or Supplier Dci Laboratory, Llc	Street Address, City, State 2917 Foster Creighton Drive, Nashville, TN	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of testing personnel competency assessments, the laboratory's policy titled Quality Assurance Program-Analytical Areas, and interview with the quality assurance manager, the laboratory's policy for competency assessment failed to include all required competency assessment elements. The required elements include: direct observation of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing; monitoring the recording and reporting of test results; review of intermediate test results or worksheets, quality control records, proficiency testing results and preventative maintenance records; direct observation of instrument maintenance and function checks; assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and assessment of problem solving skills. The findings include: 1. Observation of the hematology section of the laboratory on January 17, 2018 at 9:30 am revealed the following non-waived test systems in use for patient testing: Siemens Advia 2120i for complete blood count (CBC), Biorad D100 for hemoglobin A1C, Stago Compact for Coagulation, and a microscope. 2. Review of the 2017 testing personnel competency assessments for the hematology section of the laboratory revealed that problem solving was not included as part of testing personnel competency assessments as follows: testing personnel number 1: not included for Siemens Advia 2120i, microscopy; testing personnel number 2-not included for Stago Compact, microscopy; testing personnel number 3-not included for the Stago compact, microscopy; testing personnel number 4: not included for the Siemens Advia</p>

2120i, microscopy. 3. Review of the laboratory's policy titled "Quality Assurance Program--Analytical Areas," section H titled "Employee Competency" revealed that problem solving was not included as part of testing personnel competency assessment. 4. Interview with the quality assurance manager on January 17, 2018 at 2:45 pm confirmed that the laboratory's competency assessment policy did not include problem solving as part of assessing testing personnel competency and the laboratory failed to establish policies that include all required elements for testing personnel competency assessment. _____

D5401

PROCEDURE MANUAL
CFR(s): 493.1251(a)

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 review of the laboratory's College of American Pathologists (CAP) proficiency testing (PT) records, the policy titled Quality Assurance Program--Analytical Areas, and interview with the hematology supervisor, the hematology section of the laboratory failed to follow procedure for proficiency testing for 3 of 3 proficiency testing events in 2017. The findings include: 1. Review of the laboratory's CAP PT records revealed that blood cell identification was performed by multiple testing personnel as follows: 2017 FH4-A-testing personnel numbers 1, 3, and 4; 2017 FH4-B testing personnel numbers 1, 3, and 4; 2017 FH4-C testing personnel numbers 1, 2, 3, and 4. 2. Review of the laboratory's policy titled Quality Assurance Program--Analytical Areas revealed the following statement under section G.2.d. "Proficiency testing samples may be used for competency testing of department employees after the PT results are reported to the appropriate state/agency." 3. Interview with the hematology supervisor on January 17, 2018 at 2:15 pm revealed that multiple testing personnel provide a response for the blood cell identification for competency testing purposes prior to the result submission. The hematology supervisor confirmed the laboratory failed to follow the laboratory's policy when multiple testing personnel performed PT samples for blood cell identification before the laboratory's PT results were submitted, not after.