

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D0940311	(X3) Date Survey Completed 08/15/2018
Name of Provider or Supplier Pardee Cancer Center	Street Address, City, State 805 6th Avenue West, Suite 100, Hendersonville, NC	
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 review of personnel records, review of laboratory policy and procedures, and technical consultant (TC) interview 08/15/18, the laboratory failed to establish competency procedures that meet the regulations as stated in section 493.1413 (b)(8) of the 42 CFR Part 493 Requirements for Laboratories and are specific for the tasks performed by each testing personnel and technical consultant. Section 493.1413 (b)(8) states: " The procedures for evaluation of the competency of the staff (testing personnel) must include, but are not limited to.... Direct observations 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 preventive maintenance records; Direct observation of performance 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; Review of personnel records revealed laboratory policy "Hendersonville Hematology and Oncology Laboratory Process Competency", a list of laboratory functions that are circled either acceptable or unacceptable for testing personnel competency. The policy fails to document observation of specimen handling, processing and testing, it fails to document what was monitored for the recording and reporting of test results, it fails to document a review of test results, quality control records, and preventive maintenance records; fails to document observation of</p>

instrument maintenance and function checks and fails to demonstrate an assessment of problem solving skills as required for testing personnel competency assessment. Review of laboratory records revealed documentation testing personnel were reviewed for proficiency testing results. Review of personnel records revealed 16 of 18 testing personnel competency assessments were circled "acceptable" for laboratory function "8. Performs instrument calibrations". During interview with TC at approximately 12:00 p.m., the TC stated he is the only personnel that performs calibrations. The laboratory's competency policy fails to evaluate the specific tasks performed by each testing personnel and the technical consultant. Review of personnel records and laboratory policies revealed the laboratory failed to establish a competency assessment policy for the tasks performed by the technical consultant. Interview with TC at approximately 12:00 p.m. confirmed the laboratory failed to establish a competency assessment policy for the technical consultant. He stated he did not realize it was required.

D5775

COMPARISON OF TEST RESULTS
CFR(s): 493.1281(a)(c)

(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.

This STANDARD is not met as evidenced by:
Based on review of laboratory records, review of laboratory procedures and interview with technical consultant (TC) 08/15/18, the laboratory failed to establish procedures for instrument comparison studies and failed to perform instrument comparisons at least twice a year. The laboratory performs complete blood count (CBC) testing on 2 Act Diff 2 hematology analyzers. Review of laboratory records revealed the laboratory had performed comparison studies in January 2017. The laboratory failed to perform instrument comparisons at least twice a year from January 2017 until time of survey August 2018, a period of approximately 20 months. Review of laboratory procedures failed to reveal a procedure defining the criteria used for evaluating instrument comparison studies between the 2 hematology analyzers. Interview with TC at approximately 1:00 p.m. confirmed the laboratory did not have a procedure for defining the criteria used for evaluating instrument comparison studies and the laboratory failed to perform comparison studies twice a year as required.