

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0930334	(X3) Date Survey Completed 07/09/2019
Name of Provider or Supplier Florida Cancer Specialists & Research Institute	Street Address, City, State 836 Sunset Lake Blvd Ste 101, Venice, FL	
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
D0000	An announced CLIA validation survey was conducted at Florida Cancer Specialists & Research Institute on 07/09/2019. The laboratory was surveyed under 42 CFR Part 493 CLIA requirements. The laboratory was found out of compliance with the following condition: D6033 - 42 C.F.R. 493.1409 Condition: Laboratories performing moderate complexity testing; technical consultant
D6004	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b)</p> <p>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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapporions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with laboratory personnel, the Laboratory Director failed to ensure that Laboratory Director duties delegated to the Technical Consultant were being properly performed for 2 out of 2 years reviewed (2017-2019). Findings Included: Record review of the procedure manual revealed a "Quality Assurance (QA) Review" procedure signed and dated 06/20/13 by the Laboratory Director. The procedure documented that the laboratory would "perform a quality review at least monthly and review the results with the laboratory director for his approval." Review of the CMS-116 CLIA Application signed by the Laboratory Director on 06/20/19 showed the laboratory was performing hematocrit, hemoglobin, platelet count, red blood cell count, white blood cell count and white blood cell</p>

differential testing. Review of the Laboratory Director delegation of duties, signed and dated 06/20/13 by the Laboratory Director, showed the Technical Consultant had been designated to perform Proficiency Testing Review, Daily Quality Control Review, and Quality Assurance Manual Review on behalf of the Laboratory Director. Review of the CMS-209 Form, Laboratory Personnel Report, signed and dated on 06/20/19 by the Laboratory Director revealed 1 Technical Consultant. Record review of the Quality Assurance Manual forms titled Calibration Quality Assurance; Communication, Complaints, Problems, and Personnel - QA Tracking Sheet; Maintenance, Calibration, and Quality Control - QA Tracking Sheet; Laboratory Quality Assurance- General Form; and Proficiency Testing - QA Tracking Form revealed the Technical Consultant had not reviewed these quality assurance forms for 2 out of 2 years (2017-2019). These records were reviewed and signed by the Regional Lab Monitor (RLM). Review of the personnel record for the Regional Lab Monitor (RLM) revealed the highest level of education completed was a high school diploma. Review of the RLM Position Description, signed and dated by the RLM on 10/10/16, revealed that this position would perform quality-assurance functions to accomplish coordination, monitoring, and reporting of quality-assurance issues. Interview on 07/09/19 at 11:15 AM with the RLM confirmed that she had been reviewing all quality assurance forms since January 2017. Interview on 07/09/19 at 1:50 PM with the Laboratory Director revealed he was unaware that the RLM was reviewing and documenting the Quality Assurance Manual instead of the Technical Consultant for 2 out of 2 years (2017-2019).

D6033

TECHNICAL CONSULTANT-MODERATE COMPEXITY
CFR(s): 493.1409

The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.

This CONDITION is not met as evidenced by:
Based on record review and interview with the Regional Lab Monitor, the laboratory failed to ensure the Technical Consultant reviewed quality control and maintenance records (Refer to D6042) and evaluated the competencies of Testing Personnel (Refer to D6046) for 2 of 2 years reviewed (2017-2019).

D6042

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(4)

(b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results;

This STANDARD is not met as evidenced by:
Based on record review and interview with the Technical Consultant and Regional Lab Monitor (RLM), the Technical Consultant failed to ensure acceptable levels of analytic performance were maintained for 2 out of 2 years reviewed (2017-2019)
Findings included: Review of the procedure signed and dated by the Laboratory Director on 01/15/16 for Quality Control (QC) Review showed the "Central

Laboratory and/or the Technical Consultant" would perform a random review of the QC. Review of the undated job description for the Technical Consultant revealed the Technical Consultant was responsible for establishing a quality control program appropriate for the testing performed and establishing acceptable levels of analytic performance and ensuring that these levels were maintained throughout the testing process. Review of the Laboratory Competency Evaluation for the Technical Consultant dated 4/18/19 revealed the Technical Consultant was marked "yes" to indicate direct observation was performed for establishing QC procedures appropriate for the testing performed, establishing acceptable ranges of performance, and monitoring that performance for each test system was in place. Review of the CMS-116 CLIA Application signed by the Laboratory Director on 06/20/19 showed the laboratory was performing hematocrit, hemoglobin, platelet count, red blood cell count, white blood cell count and white blood cell differential testing. Record review of Maintenance, Calibration, and Quality Control - QA Tracking Sheets from 02/06/17 to 06/11/19 revealed that the RLM had been signing all reviews. Review of the RLM Position Description, signed and dated by the RLM on 10/10/16, revealed the qualifications for this position were Medical Lab Tech or Clinical Lab Tech license and/or certification and at least 5 years of experience in the clinical lab or a Lead Medical Assistant with over 5 years of experience in the clinical lab. The position description showed the RLM would perform quality-assurance functions to accomplish coordination, monitoring, and reporting of quality-assurance issues. Review of the "RLM - General Supervisor Competency Evaluation" dated 5/20/19 showed the RLM had been evaluated by the Technical Consultant on evaluating the Hematology QC data weekly and monthly. Interview on 07/09/19 at 11:15 AM with the RLM revealed she had been reviewing all quality control and maintenance records since January 2017. Interview on 07/09/2019 at 2:20 PM with the Technical Consultant revealed she had not reviewed quality control and maintenance logs but performed random quality control review. The Technical Consultant was unable to show documentation of the random quality control review and stated that it was not documented.

D6046

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (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.

This STANDARD is not met as evidenced by:
Based on record review and interview with the Regional Lab Monitor, the Laboratory Technical Consultant failed to perform competency evaluations on 1 out of 4 (#C, #D, #E, and #F) Testing Personnel for 2 of 2 (2017-2018) years reviewed. Findings Included: Review of the undated job description for the Technical Consultant revealed the Technical Consultant was responsible for evaluating the competency of all testing personnel on an ongoing basis. Review of the Laboratory Competency Evaluation for the Technical Consultant dated 4/4/18 and 4/18/19 revealed the Technical Consultant was marked yes for evaluating/documenting testing personnel performance semiannually for the first year and annually thereafter. Review of employee competencies for Testing Personnel #C revealed the 06/01/17 and 06/05/18 annual competency review for proper performance of hematocrit, hemoglobin, platelet count, red blood cell count, white blood cell count and white blood cell differential testing was performed by the Regional Lab Monitor (RLM). Testing Personnel #D, #E, and

#F were all new and were not yet due for competency evaluations. Record review of the RLM position description, signed and dated by the RLM on 10/10/16, showed that a Key Performance area was to assist in training clinic personnel on the use and implementation of the Quality Assurance Manual. Record review of the "General Supervisor Competency Evaluation" for the RLM, dated and signed by the Technical Consultant on 05/20/19 and 11/6/18 revealed the RLM was delegated to evaluate and document performance of all testing personnel as required. Interview on 07/09/19 at 11:15 AM with the RLM confirmed that she performed the competency evaluations. Review of the personnel record for the RLM revealed the highest level of education completed was a high school diploma.