Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D2015770	(X3) Date Survey Completed 01/11/2018
Name of Provider or Supplier Slidell Memorial Hospital Regional Cancer Center	**Street Address, City, State** 1120 Robert Boulevard, Slidell, LA	
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	A Certification Survey was conducted on January 11, 2018 at Slidell Memorial Hospital Regional Cancer Center-CLIA ID # 19D2015770. The laboratory was found in compliance with 42 CFR 493 Requirement for Laboratories; however, standard deficiencies were cited.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 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. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to ensure written policies and procedures were established to assess competency for the laboratory's Technical Consultants. Findings: 1. Review of the laboratory's CMS 209 (Laboratory Personnel Report) revealed the following personnel are listed as Technical Consultants: Personnel 2 Personnel 3 Personnel 4 Personnel 5 2. Review of the laboratory's policy and procedure manual revealed the laboratory did not have a policy for competency assessment of Technical Consultants. 3. Review of personnel records revealed the competency assessments were not performed for the duties of Technical Consultant. 4. In interview on January 11, 2018 at 10:17 am, Personnel 2 stated competency assessments for Technical Consultants were not performed.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) 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. (e) The laboratory director must-- (e)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure policies and procedures were maintained for assessing personnel competency, and whenever necessary, identify needs for remedial training or continuing education to improve skills. Findings: 1. The laboratory failed to ensure written policies and procedures were established to assess competency for the laboratory's Technical Consultants. Refer to D5209. 2. The Technical Consultants failed to ensure the procedures to assess personnel competency were complete. Refer D6046.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) 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. (e) The laboratory director must-- (e)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to provide written job descriptions for all Laboratory Personnel. Findings: 1. Review of the laboratory's policy and procedure manual and personnel records revealed the laboratory did not have written job descriptions for the following personnel: Laboratory Director Technical Consultant 2. In interview on January 11, 2018 at 10: 17 am, Personnel 2 confirmed the laboratory did not have written job descriptions for the Laboratory Director and Technical Consultant(s).
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 personnel, the Technical Consultants

	failed to ensure the procedures to assess personnel competency were complete. Findings: 1. Review of the laboratory's CMS 209 form (Laboratory Personnel Report) revealed the following personnel were listed as testing personnel: Personnel 3 Personnel 4 Personnel 5 Personnel 6 2. Review of personnel records revealed the laboratory utilized a "Sysmex XN 1000 Competency Assessment" form for personnel competency assessments; however, this form failed to include the following six (6) procedures as a minimal requirement for assessing the competency of all personnel performing laboratory testing: a) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. b) Monitoring the recording and reporting or test results. c) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventative maintenance records. d) Direct observation of performance of instrument maintenance and function checks. e) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. f) Assessment of problem solving skills. 3. In interview on January 11, 2018 at 9:56 am, Personnel 3 confirmed the competency assessment form used did not include at a minimum the six (6) procedures listed above.