Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D2015770	(X3) Date Survey Completed 12/12/2019
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 performed on December 12, 2019 at Slidell Memorial Hospital Regional Cancer Center, CLIA ID # 19D2015770. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level 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 policies were followed for competency assessments of one (1) of two (2) Technical Consultants reviewed. Findings: 1. Review of the personnel records for two (2) Technical Consultants revealed the laboratory's utilizes a "Competency-Laboratory Supervisor Technical Consultant/General Supervisor" form for documentation of assessment of their duties. 2. Further review of the competency form for Technical Consultant 2 revealed the Laboratory Director did not perform the assessment. 3. In interview on December 12, 2019, Technical Consultant 1 stated he performed the competency assessment for Technical Consultant 2, not the Laboratory Director.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.

	This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to ensure the Laboratory Director reviewed the performance evaluation for proficiency testing results for Reticulocytes for two (2) of four (4) events reviewed. Findings: 1. Review of the laboratory's "Proficiency Testing" policy revealed "The scored results are reviewed by the section supervisor, the Department Director, and the Pathologist." 2. Review of the College of American Pathologists (CAP) proficiency testing records for 2018 and 2019 revealed the laboratory did not have documentation of review of the results by the Laboratory Director for the following two (2) events: 2018 Reticulocytes RT4-B 2019 Reticulocytes RT4-B 3. Further review of the identified two (2) events revealed Testing Personnel 1 signed the evaluation forms on the following dates: 2018 Reticulocytes RT4-B signed by Testing Personnel 1 "11/13/18" 2019 Reticulocytes RT4-B signed by Testing Personnel 1 "10/16/19" 4. On December 12, 2019 at approximately 11:00 am, Surveyor stated to Technical Consultant 1 the 2019 Reticulocyte second event results were not reviewed by the Laboratory Director. In interview at approximately 11:54 am, Technical Consultant 1 stated the results for the second event were reprinted and the Laboratory Director reviewed. The documents presented to surveyor were signed and dated by the Laboratory Director on "12/12/19, " the date of the survey. 5. In further interview on December 12, 2019, Technical Consultant 1 confirmed the Laboratory Director did not review the results prior to the survey.
D6005	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(c) 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. (c) The laboratory director must be accessible to the laboratory to provide onsite, telephone or electronic consultation as needed. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to delegate, in writing, the responsibilities of Technical Consultant for one (1) of two (2) Technical Consultants reviewed. Findings: 1. Review of the laboratory's CMS 209 form (Laboratory Personnel Report) revealed Technical Consultant 1 and Technical Consultant 2 are listed as the Technical Consultants. 2. Review of personnel records for Technical Consultant 2 revealed the laboratory did not have documentation of the Laboratory Director delegating the tasks and responsibilities of Technical Consultant. 3. In interview on December 10, 2019 at 9:55 am, Technical Consultant 1 confirmed the laboratory did not have documentation of Technical Consultant responsibilities delegated by the Laboratory Directory for Technical Consultant 2.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(4)(iii) Ensure that all proficiency testing reports received are

	reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. Refer to D5211.
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 for assessing personnel competency were maintained. Findings: 1. The laboratory failed to ensure policies were followed for competency assessments of one (1) of two (2) Technical Consultants reviewed. Refer to D5209. 2. The Technical Consultants failed to evaluate competency semi-annually for one (1) of five (5) testing personnel reviewed. D6053. 3. The Technical Consultants failed to evaluate competency annually for four (4) of five (5) testing personnel reviewed. Refer to D6054.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) 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 record review and interview with personnel, the Technical Consultants failed to evaluate competency semi-annually for one (1) of five (5) testing personnel reviewed. Findings: 1. Review of the laboratory's "Competency Assessment" policy revealed "In order to comply with guidelines established by CLIA'88, CAP and other regulatory agencies, laboratory personnel must be evaluated during their initial training, and orientation in a section. A follow-up assessment will occur in 6 months and annually thereafter to document competency in all procedures performed." 2. In interview on December 12, 2019 at 9:42 am, Testing Personnel 1 stated Testing Personnel 5 was hired in February 2019. 3. In interview on December 12, 2019 at 12:

	14 pm, Technical Consultant 2 stated Testing Personnel 5 began working at their facility in April 2019, the February date was her hire date at the main hospital. 4. Review of testing personnel records for Testing Personnel 5 revealed the laboratory did not have documentation of performance of a semi-annual competency assessments, due October 2019. 5. In further interview on December 12, 2019 at 12: 14 pm, Technical Consultant 2 stated she did not have a semi-annual competency assessment for Testing Personnel 5.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Technical Consultants failed to evaluate competency annually for four (4) of five (5) testing personnel reviewed. Findings: 1. Review of the laboratory's "Competency Assessment" policy revealed "In order to comply with guidelines established by CLIA'88, CAP and other regulatory agencies, laboratory personnel must be evaluated during their initial training, and orientation in a section. A follow-up assessment will occur in 6 months and annually thereafter to document competency in all procedures performed." 2. Review of testing personnel records revealed the laboratory did not have 2018 annual competency assessments for the following testing personnel: Testing Personnel 1: 2018 competency assessment was not performed by Technical Consultants Testing Personnel 2 Testing Personnel 3 Testing Personnel 4 3. In interview on December 12, 2019 at 11:54 am, Technical Consultant 2 stated she did not the 2018 competency assessments for the identified testing personnel.