Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D0982695	03/20/2018
Name of Provider or Supplier	**Street Address, City, State**	
Women's Medical Center, The	515 Westbank Expressway, Gretna, 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 March 20, 2018 at Newco Women's Medical Center-CLIA ID # 19D0982695. The laboratory was found in compliance with 42 CFR 493 Requirement for Laboratories; however, standard deficiencies were cited.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to perform an assessment for unacceptable proficiency test (PT) results. Findings: 1. Review of the laboratory's 2017 American Proficiency Institute (API) PT results revealed the laboratory received the following unacceptable results: 1st Event Chemistry Core: Sample CH-03 for HCG- 80% 3rd Event Hematology/Coagulation: Sample HEM-13 for Lymphocytes-80% 2. Review of the laboratory's PT records revealed the laboratory did not perform an assessment for the identified unacceptable PT results. 3. In interview on March 20, 2018 at 1:55 pm, Personnel 2 stated an assessment was not performed for unacceptable PT results. Personnel 2 further stated she thought since the overall scores were above 80% nothing further needed to be done.
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 record review and interview with personnel, the laboratory failed to establish complete policies and procedures. Findings: 1. Review of the laboratory's policy and procedure manual revealed the laboratory did not establish complete policies for the following: a) Performance specification: detailed procedures for performing accuracy and precision (day-to-day, run-to-run, and within-run variation, as well as operator variance) studies, acceptability criteria for studies, and actions to take when data from the studies fail to meet acceptability criteria 2. In interview on March 20, 2018 at 4:00 pm, Personnel 2 confirmed the laboratory did not have a policy for performance specification studies.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: I. Based on observation, record review, and interview with personnel, the laboratory failed to have complete verification studies for Syphilis testing. Findings: 1. Observation by surveyor during laboratory tour on March 20, 2018 revealed the laboratory utilizes the Siemens Centaur XP instrument for Syphilis testing. 2. In interview on March 20, 2018 at 1:30 pm, Personnel 2 stated the Syphilis test was added to the Centaur in May 2017. 3. Review of the laboratory's policy and procedure manual revealed the laboratory did not have written policies and procedures for performance specifications that included: written detailed instructions on how testing personnel would verify the accuracy, precision (day-to day, run-to-run, within-run, and operator variance),and reportable and reference ranges as well as acceptability criteria for the verification of the performance specifications. 4. Review of the laboratory's performance verification study documents revealed the following information was not included: *Precision to include day-to-day, run-to-run, within-run, and operator variance *Acceptability criteria and Laboratory Director approval /signature of performance verification studies 5. In interview on March 20, 2018 at 4: 00 pm, Personnel 2 confirmed the laboratory did not have complete precision studies performed. Personnel 2 stated the laboratory performed a patient comparative study with CPL reference laboratory on May 25, 2017. 6. Review of the laboratory's Task 1 and 3 forms revealed the laboratory performs 3,078 Syphilis tests annually. II. Based on observation, record review, and interview with personnel, the laboratory failed to have complete verification studies for HIV testing. Findings: 1. Observation by surveyor during laboratory tour on March 20, 2018 revealed the laboratory utilizes the Siemens Centaur XP instrument for HIV testing. 2. In interview on March 20, 2018 at 1:30 pm, Personnel 2 stated the assay for HIV changed in May 2017. 3. Review of the laboratory's policy and procedure manual revealed the laboratory did not have written policies and procedures for performance specifications that included: written detailed instructions on how testing personnel would verify the accuracy, precision (day-to day, run-to-run, within-run, and operator variance),and reportable and reference

	ranges as well as acceptability criteria for the verification of the performance specifications. 4. Review of the laboratory's performance verification study documents revealed the following information was not included: *Precision to include day-to-day, run-to-run, within-run, and operator variance *Acceptability criteria and Laboratory Director approval/signature of performance verification studies 5. In interview on March 20, 2018 at 4:00 pm, Personnel 2 confirmed the laboratory did not have complete precision studies performed. Personnel 2 stated the laboratory performed a patient comparative study with CPL reference laboratory on May 25, 2017. 6. Review of the laboratory's Task 1 and 3 forms revealed the laboratory performs 3,614 HIV tests annually.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) 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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on observation, record review, and interview with laboratory personnel, the Laboratory Director failed to ensure that complete verification procedures were performed. Refer to D5421 I and D5421 II.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) 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)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure the laboratory followed the corrective action plan for unacceptable proficiency testing results. Refer to D5221.
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: **REPEAT DEFICIENCY from Survey Date September 6, 2016** Based on record review and interview with personnel, the Laboratory Director failed to ensure policies and procedures were established for assessing personnel competency, and whenever necessary, identify needs for remedial training or continuing education to improve skills. Findings: 1. Review of the laboratory's CMS-209 form (Laboratory Personnel Report) revealed Personnel 2 and Personnel 3 serve as Testing Personnel. 2. Review of personnel records revealed the laboratory utilizes a "Laboratory Testing Personnel Evaluation" form that includes: direct observation of test performance, monitoring the recording/reporting of test results, review of test records, instrument maintenance /function checks, Proficiency testing/blind testing, and evaluation of problem solving skills. 3. Review of competency records revealed evaluations were completed December 4, 2017 for Personnel 2 and Personnel 3; however, the form was not test specific. 4. Further review of Personnel 3's competency assessment form revealed the Laboratory Director who also serves as the Technical Consultant, did not perform the assessment. 5. In interview on March 20, 2018 at 1:20 pm, Personnel 2 confirmed the laboratory did not utilize competency assessment forms that are test specific. Personnel 2 confirmed she assessed Personnel 3's competency, not the Laboratory Director.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) 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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based on record review and interview with laboratory personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel responsible for any aspect of the testing process. Refer to D5401.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must 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: **REPEAT DEFICIENCY from Survey Date September 6, 2016** Based on record review and interview with personnel, the Laboratory Director failed to ensure policies and procedures were established for assessing personnel competency, and whenever necessary, identify needs for remedial training or continuing education to improve skills. Findings: 1. Review of the laboratory's CMS-209 form (Laboratory Personnel Report) revealed Personnel 2 serves as Testing Personnel for high complexity testing. 2. Review of personnel records revealed the laboratory utilizes a "Laboratory Testing Personnel Evaluation" form that includes: direct observation of test performance, monitoring the recording/reporting of test results, review of test records, instrument maintenance/function checks, Proficiency testing/blind testing, and evaluation of problem solving skills. 3. Review of Personnel 2's competency records revealed an evaluation was completed December 4, 2017 for Personnel 2; however, the form was not test specific. 4. In interview on March 20, 2018 at 1:20 pm, Personnel 2 confirmed the laboratory did not utilize competency assessment forms that are test specific.