Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D0982695	02/21/2020
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 performed on February 21, 2020 at Newco Women's Medical Center, CLIA ID # 19D0982695. 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: I. Based on record review and interview with personnel, the laboratory failed to establish complete competency assessment policies for physicians performing laboratory testing. Findings: 1. In interview on February 21, 2020, Testing Personnel 1 stated the physicians in the office perform wet preps and fern tests. 2. Review of the laboratory's CMS-209 form (Laboratory Personnel Report) revealed eight (8) physicians listed as testing personnel. 3. Review of the laboratory's personnel records for the eight (8) physicians revealed the laboratory did not include the following six (6) procedures as a minimal requirement for assessing the competency of the physicians 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. 4. In interview on February 21, 2020, Testing Personnel 1 confirmed the

	laboratory did not have documentation of competency assessments for the physicians performing wet prep and fern tests. II. Based on record review and interview with personnel, the laboratory failed to ensure written policies and procedures to address competency for one (1) of two (2) Technical Consultants were complete. Findings: 1. Review of the laboratory's CMS-209 (Laboratory Personnel Report) revealed the Laboratory Director serves as the Technical Consultant. 2. Review of the laboratory's quality control and proficiency test records revealed Testing Personnel 1 also serves as the Technical Consultant. 3. Review of the laboratory's policies and procedures revealed the laboratory did not include competency assessment criteria or frequency of performance for personal serving as Technical Consultant. 4. In interview on February 21, 2020 at 10:05 am, Testing Personnel 1 confirmed the Laboratory Director did not perform an assessment for her duties as Technical Consultant. Testing Personnel 1 stated she was unaware of the duties of a Technical Consultant.
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: ***Repeat deficiency from survey conducted March 20, 2018.*** 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 "Proficiency Testing Procedure" revealed "Any result that is deemed unacceptable or unsuccessful must be investigated using the 'Unsuccessful/Unacceptable PT Checklist.' This form provides guidance in conducting an investigation of an unacceptable or unsuccessful PT result." 2. Review of the laboratory's 2019 American Proficiency Institute (API) results PT results revealed the laboratory received the following unacceptable results: 2nd Event Hematology/Coagulation: White Blood Cell Differential 80%: Granulocytes 80%, Lymphocytes 60% a) Sample HEM-08 for Granulocytes and Lymphocytes: "Unacceptable" b) Sample HEM-09 for Lymphocytes: "Unacceptable" 3. Further review of the laboratory's 2019 PT records revealed the laboratory did not perform an assessment for the identified unacceptable PT results. 4. In interview on February 21, 2020 at 11:30 am, Testing Personnel 1 and Testing Personnel 2 stated they were unsure of what was done about the identified PT results. Testing Personnel 1 and Testing Personnel 2 further stated the previous employee handled the PT results before Testing Personnel 1 was hired in November 2019.
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 follow their established quality control (QC) procedure for LIM broth. Findings: 1. Review of the laboratory's "Additional QC Procedures For Meridian Illumigene Group B

	Strep Assay, LIM Broth" procedure revealed the laboratory is to perform the following procedures for each new lot and/shipment of broth and document: a) "QC for Sterility" b) "QC for Ability to Produce Growth" c) "Visual Inspection" 2. Further review of the identified procedure revealed the results for the QC procedures would be recorded on the "LIM Broth QC Log." 3. Review of the laboratory's documents for Group B streptococcus testing revealed the laboratory did not have documentation of QC for new lots and/or shipments for LIM broth. 4. In interview on February 17, 2020 at 12:03 pm, Testing Personnel 1 and Testing Personnel 2 stated they were unaware of the LIM Broth QC log book and QC procedure. Testing Personnel 1 confirmed the laboratory did not perform QC on new lot and/or shipment of LIM broth. 5. Review of the laboratory's test menu revealed the laboratory performs 1,675 Group B streptococcus tests annually.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on observation, record review and interview with personnel, the laboratory failed to monitor the temperature where supplies are stored. Findings: 1. Observation by surveyor during laboratory tour on February 21, 2020 revealed the laboratory stored the following supplies on a shelf in the bathroom without monitoring the temperature: a) Acid Reagent, Lot # 901654, Quantity: one (1) bottle b) Base Reagent, Lot # 867014, Quantity: one (1) bottle c) Wash 1,Lot #877362, Quantity: two (2) bottles 2. Review of the manufacturer storage requirements for the identified items revealed the following: a) Acid Reagent, storage temperature 2-25 degrees Celsius b) Base Reagent, storage temperature 2-25 degrees Celsius c) Wash 1, storage temperature 2-25 degrees Celsius 3. In interview on February 21, 2020 at 9:19 am, Testing Personnel 1 stated the temperature of the bathroom, where supplies are stored, is not monitored.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by:

	Based on record review and interview with personnel, the laboratory failed to perform temperature checks in 2019 on the thermal cyclers utilized for molecular testing. Findings: 1. Review of the laboratory's maintenance records revealed "Thermal Cycler Temperature Validation Record" forms for the laboratory's Eppendorf Mastercycler, Serial Number 5333Z0959146 and 5333ZN358788. The temperature validations were performed March 15, 2018. 2. Further review of the laboratory's maintenance records revealed the temperature validatios were not performed in 2019. 3. In interview on February 21, 2020 at 3:27 pm, Testing Personnel 1 stated she did not find documentation of the temperature validations being performed in 2019. Testing Personnel 1 stated it can no longer be done in-house because the supplies are not offered.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the laboratory failed to perform calibration procedures on the Cell-Dyn 1800 utilized for Complete Blood Count (CBC) testing every six (6) months. Findings: 1. Observation by surveyor during the laboratory tour on February 21, 2020 revealed the laboratory utilized a Cell-Dyn 1800 instrument for CBC testing. 2. Review of the "Cell-Dyn 1800 System Operator's Manual" under "Calibration Procedures" revealed the following: "Criteria must be established for calibration verification. Criteria to include: a) when there is a reformulation of a vendor's reagent or when switching to a different reagent vendor b) when indicated by quality control data c) following major maintenance or service d) when directed by Abbott communications e) at least every 6 months" 3. Review of the laboratory's records revealed the laboratory did not have documentation of calibration verification performance in 2018 or 2019. 4. In interview on February 21, 2020, Testing Personnel 1 stated calibrations have not been performed since she has been at the laboratory (hire date November 2019). Testing Personnel 1 confirmed the laboratory did not have documentation of calibration verifications at least every six (6) months for 2018 or 2019.

D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to take corrective action when quality control (QC) values were unacceptable for Complete Blood Count (CBC) testing per laboratory policy. Findings: 1. Review of the laboratory's "Quality Control" policy revealed the following: a)" Cell-Dyn Hematology Analyzer: Three levels of controls (low, normal, and high) are to be performed each day patients are run, before testing, every 8 hours. The controls must be evaluated and acceptable before patient samples can be processed." b) "The following steps should be performed until the situation is corrected: b1) Repeat control . If control is out upon repeat, continue through steps b2) Check reagents for proper dating and/or deterioration b3) Check instrument to make sure it is properly functioning b4) Try another aliquot of control b5) Call manufacturer for technical assistance b6) Notify Technical Supervisor b7) Document all corrective action on the corrective action form" 2. Review of the laboratory's CBC QC records for December 2018, July 2019, and January 2020 revealed QC was unacceptable for the following dates: a) December 17, 2018: Normal Control: RBC reported 4.5 M/uL (acceptable range 4.0-4.5); Flag "Outside 2SD" b) July 1, 2019 High Control: MCV reported 92.6 fL (acceptable range 89.0-92.0); Flag "Outside 2SD" 3. Further review of the laboratory's CBC QC records revealed the laboratory did not perform corrective actions for the identified dates. 4. Review of patient logs for the identified dates revealed the following patients were reported without corrective action: a) December 17, 2018: Total of seventeen (17) patients reported Patient 206892 Patient 206898 Patient 206901 Patient 206907 Patient 206925 b) July 1, 2019: Total of seven (7) patients reported Patient 228480 Patient 229491 Patient 229493 Patient 229496 Patient 229541 5. In interview on February 17, 2020, Testing Personnel 1 confirmed the identified patients were reported without corrective action for unacceptable QC.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the laboratory's quality assessment monitors failed to correct issues identified with the analytic system. Findings: 1. Review of the laboratory's "Monthly Quality Assessment

	Checklist" revealed the following processes are monitored: a) Quality Control: a1) All QC documents (quantitative and qualitative) reviewed a2) All calibration documents reviewed a3) All maintenance documents reviewed a4) Corrective actions reviewed for all QC problems to ensure resolutions and discontinuance b) Proficiency Testing (PT) b1) All PT results reviewed b2) All failed PT was evaluated in accordance with the written PT procedure c) Communications c1) All suggestions and complaints have been retrieved from the boxes c2) The laboratory liaison and director have communicated all issues of concern 2. Observation during laboratory tour and review of the laboratory's policy and procedure manual, quality control records, and patient test records revealed the laboratory's monitors did not identify the following issues: a) The laboratory failed to follow their established quality control (QC) procedure for LIM broth. Refer to D5401. b) The laboratory failed to monitor the temperature where supplies are stored. Refer to D5413. c) The laboratory failed to perform temperature checks in 2019 on the thermal cyclers utilized for molecular testing. Refer to D5435. d) The laboratory failed to perform calibration procedures on the Cell-Dyn 1800 utilized for Complete Blood Count (CBC) testing every six (6) months. Refer to D5439. e) The laboratory failed to take corrective action when quality control (QC) values were unacceptable for Complete Blood Count (CBC) testing per laboratory policy. Refer to D5783.
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 to Testing Personnel 1. Findings: 1. Review of personnel records for Testing Personnel 1 revealed the laboratory did not have documentation of the Laboratory Director delegating the tasks and responsibilities of Technical Consultant to her. 2. Review of the laboratory's proficiency testing records and quality control records revealed Testing Personnel 1 signed the reviews of quality control records and the evaluations for the 2019 Immunology/Immunohematology 3rd Event and 2019 Hematology /Coagulation 3rd Event. 3. Review of the laboratory's "Proficiency Testing Procedure" revealed "The technical consultant, or laboratory director reviews and documents the review of the PT provider's analysis of the results." 3. In interview on February 21, 2020, Testing Personnel 1 confirmed the Laboratory Director did not delegate the responsibilities of Technical Consultant to her.
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(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)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel were performing test methods as required. Refer to D5413.
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: ***Repeat deficiency from survey conducted March 20, 2018.*** 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.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure that a quality control program was maintained to assure quality laboratory services were provided. Refer to D5401.
D6022	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur.

	This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure that a quality assessment (QA) program was maintained to assure the quality of laboratory services provided and to identify failures as they occur. Refer to D5793.
D6023	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(6) 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)(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system; This STANDARD is not met as evidenced by: Based on record review, and interview with personnel, the Laboratory Director failed to ensure that the laboratory performed the required maintenance to ensure acceptable levels of analytical performance. Findings: 1. The laboratory failed to perform temperature checks in 2019 on the thermal cyclers utilized for molecular testing. Refer to D5435. 2. The laboratory failed to perform calibration procedures on the Cell-Dyn 1800 utilized for Complete Blood Count (CBC) testing every six (6) months. Refer to D5439.
D6024	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(7) 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)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified, This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure corrective actions were taken and documented when deviations from laboratory's quality control limits occurred. Refer to D5783.
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. Refer to D5209 I and D5209 II.