STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CUA IDENTIFICATIONNUMBER	(X2) MULnPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	19D0694nS	A.BUILDING ___ _____ EWING ___ ___	06/14/2017

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS. CITY, STATE, ZIP CODE
HOPE MEDICAL GROUP FOR WOMEN	210 KINGS HIGHWAY SHREVEPORT, LA 71104

(X4)ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSCIDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCEDTO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
D 000	INITIAL COMMENTS ACERTIFICATION SURVEY was performed at Hope Medical Group For Women - CUA# 19D0694775 on June 14, 2017. Hope Medical Group For Women was found not in compliance with the following CONDITION LEVEL DEFICIENCIES:: 42 CFR 493.1217 CONDITION: Immunohematology 42 CFR 493.1403 CONDITION: Laboratories performing moderate complexity testing, Laboratory Director	0000	Plan of Correction: Revision of Lab Procedures Manual for all deficiencies, with Lab Director's Approval and retraining and competency assessment of lab personnel as needed.	9/21/2017
02153	493.859(a) ABO GROUP AND D(RHO) TYPING Failure to attain a score of at least 100 percent of acceptable responses for each analyte or test in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by Based on record review and interview with personnel the laboratory failed to attain a score of 100% for ABO and Rh typing resulting in an unsatisfactory score Findings 1. Review of Proficiency Testing Records 2015 through 2017 for ABO and Rh typing the laboratory failed to attain a score of 100% for the third event of 2016. The laboratory received a score of 80% resulting in an unsatisfactory score 2. Interview with personnel 4 confirmed the laboratory failed to attain a score of 100% for ABO and Rh typing for the third event of 2016	02153		
D2160	493.859(e) ABO GROUP AND D(RHO) TYPING (1) For any unsatisfactory testing event for reasons other than a failure to participate, the	D2160		

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AUG 29 2017
HEALTH STANDARDS

L [redacted] ESS GNATURE TITLE Lab Director (X6) DATE 8/24/17

Any deficiency statement ending wilh enasterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients (See instructions) Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility If deficiencies are cited, an approved plan of correction is requisite to continued program participation

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D2160	Continued From page 1 laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or unsatisfactory testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on record review and interview with personnel the laboratory failed to document corrective action for ABO and Rh typing for any unsatisfactory scores attained in proficiency testing: Findings: 1. Review of Proficiency Testing Records 2015 through 2017 for Rh typing the laboratory failed to attain a score of 100% for the third event of 2016. The laboratory received a score of 80% resulting in an unsatisfactory score. 2. Review of the Laboratory's Policy and Procedure Manual revealed the laboratory failed to establish written policies and procedure for steps to take when corrective action is need in Proficiency Testing when the laboratory attains an unsatisfactory score. 3. Interview with personnel 4 confirmed the laboratory scored an 80% for ABO and Rh typing for the third event of 2016 and confirmed the laboratory failed to document any corrective action.	D2160	Proficiency Test events and corrective actions documentation records will be kept for 2 years post date of participation. Corrective actions steps to take are written in the Proficiency Testing procedure which includes investigation and resolution.	9/21/2017
D5026 510M	493.1217 IMMUNOHEMATOLOGY If the laboratory provides services in the specialty	05026		

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D5026	Continued From page 2 of Immunohematology, the laboratory must meet the requirements specified in §§493.1230 through 493.1256, §493.1271, and §§493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on observation, record review, and interview with personnel, the laboratory failed to provide quality services for the specialty of Immunohematology. Findings: 1. The laboratory failed to establish a laboratory policy and procedure manual that contained complete policies and procedures. Refer to D54011. 2. The laboratory failed to check all suspicious and negative test results for Rh testing under the microscope as required by laboratory policy. Refer to D5401 II. 3. The laboratory failed to perform a weak D test on all donor samples that give negative or doubtful positive reactions as required by the manufacturer for eighteen (18) of eighteen (18) patients reviewed. Refer to D5411. 4. The laboratory failed to ensure that blood collection tubes are not used beyond its expiration date. Refer to D5417. 5. The laboratory's Quality Assurance monitors failed to identify and correct quality issues in Immunohematology. Refer to D5791. 6. Interview with personnel 4 on June 14, 2017 confirmed the above findings.	D5026	Rh typing procedure rewritten according to manufacturer's instruction including a complete weak D testing for suspicious and negative tests results. Requirement removed to examine results under a microscope, which was not included in manufacturer's instructions. Inventory and maintenance logs revised to included checks of all reagents and supplies G. Quality Assurance Revision of Quality Assurance plan including patient Audit monitors of test results.	9/21/2017

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D5401	Continued From page 3	05401		
D5401	**493.1251(a) PROCEDURE MANUAL**	05401	Citation addressed in Lab Procedures Manual: Lab Manual revised and written to include all test performed, indicated in Table of Contents including policy and procedures. Lab Manual available to all Lab testing personnel by copy in laboratory.	9/21/2017
510M	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: I. **Based** on **review** of the laboratory's policy and procedure manual and interview with personnel, the laboratory failed to establish a laboratory policy and procedure manual that contained complete policies and procedures. Findings: 1. Review of the laboratory policy and procedure manual revealed the laboratory failed to have policies and procedures for: Proficiency Testing (PT): a) Ordering and ensuring that you are enrolled for Proficiency Testing. b) VVhat to do when you receive samples from the PT Provider. c) How to handle the samples; who will test, when to test, how do you assure no inter and intra laboratory communication takes place d) How to record results to send into the PT Provider to be scored. e) VVhat records to maintain. f) How to evaluate when you receive your scores from the PT Provider. g) what steps to take if corrective action is needed. A policy and procedure that addresses weak Anti-D testing to include (but not inclusive): when to perform , how to perform, what quality control is needed			

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05401	Continued From page 4 2. Interview with personnel 4 on June 14, 2017 confirmed the laboratory failed to have detailed written policies and procedures that addressed the items listed above. II. Based on observation, record review and interview with personnel, the laboratory failed to check all suspicious and negative test results for Rh testing under the microscope as required by laboratory policy. Findings: 1. Review of the Laboratory's Policy and Procedure Manual revealed under Rh testing, Interpretation: "check all suspicious and negative test results under the microscope. Record results on the green sheet and lab log. If negative, record the result in red on the green sheet and lab log." 2. Observation during tour of the laboratory on June 14, 2017 revealed the laboratory failed to have a microscope. 3. Review of a random selection of patient test records from November 1, 2016 through June 13, 2017 revealed the laboratory failed to document microscopic review for the following eighteen (18) patients documented with a negative Rh: On June 13, 2017: Patients 9 and 10. On May 11, 2017: Patients 11 -13. On April 8, 2017: Patients 3, and 14 -18. On February 9, 2017: Patients 19 - 21. On January 4, 2017: Patient 22. On December 8, 2016: Patient 23. On November 1, 2016: Patients 24 and 25. 4. Interview with personnel 4 on June 14, 2017 confirmed the laboratory does not have a	D5401	Removal of lab requirement to check results under microscopic, which was not included in the manufacturer's instructions. Test performance includes a macroscopic result reading. Lab error of test requirement.	9/21/2017

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D5401	Continued From page 5 microscope and confirmed the laboratory failed to follow laboratory procedure for microscopic review for all suspicious or negative Rh tests performed.	D5401		
D5411 510M	493.1252(a) TEST SYSTEMS EQUIPMENT INSTRUMENTS.REAGENT Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under §493.1253 This STANDARD is not met as evidenced by Based on record review and interview with personnel the laboratory failed to perform a weak D test on all donor samples that give negative or doubtful positive reactions as required by the manufacturer for eighteen (18) of eighteen (18) patients reviewed: Findings 1. Review of the Immucor Blood Group Reagent Anti-D package insert revealed under "Tube Test 5. A weak D test should be performed on all donor samples that give negative or doubtful positive reactions. (Proceed to weak D Test)." 2. Review of the Laboratory's Policy and Procedure Manual revealed only an initial screen for Anti-D and does not require the laboratory to perform a weak D test. Further review of the Laboratory's Policy and Procedure Manual revealed copies of package inserts from Immucor for ABO and Rh typing. 3. Review of a random selection of patient test records from November 1, 2016 through June 13.	D5411	Citation addressed in Lab Procedures Manual; Rh typing and weak D testing procedure rewritten according to manufacturer's instructions stated in Immucor Blood Group Insert.	9/21/2017

STATEMENT OFDEFICIENCIES ANOPLANOF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATIONNUMBER	(X2) MULTIPLECONSTRUCTION	X3) DATE SURVEY COMPLETED
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05411	Continued From page 6 2017 revealed the laboratory failed to perform a weak D test for the following eighteen (18) patients: On June 13, 2017: Patients 9 and 10. On May 11, 2017: Patients 11 -13. OnApril 8, 2017: Patients 3, and 14 - 18. On February 9, 2017: Patients 19 - 21. On January 4, 2017: Patient 22. On December 8, 2016: Patient 23. On November 1, 2016: Patients 24 and 25. 4. Interview with personnel 4 on June 14, 2017 confirmed the laboratory only performs the initial screen for Anti-D and does not perform a weak D test. Personnel 4 also revealed she was unaware of thepackage inserts requirement to perform a weak D test when a negative or doubtful positive Anti-D test is obtained for a patient. Personnel 4 confirmed the patients cited above failed to have a weak D test performed.	D5411		
D5417 510M	493.1252(d) TEST SYSTEMS, EQUIPMENT, INSTRUMENTS. REAGENT Reagents, solutions, culture media. control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by Based on observation, and interview with personnel the laboratory failed to ensure that blood collection tubes are not used beyond its expiration date Findings: 1. Observation by the surveyor on June 14 2017 revealed the laboratory maintained the following expired items that were found in place for patient	D5417	Citation addressed in Lab Procedures Manual; D: Responsibility of Testing Personnel E: Lab Requirements Revision of frequency of inventory checks and maintenance logs documentation of all reagents and supplies.	9/21/2017

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Q5417	Continued From page 7 testing: Six (6) BD Vacutainer K2EDTA 7.2 mg (purple top) blood collection tubes - lot number 5175946 with an expiration date of 2016/11. Six (6) BO Vacutainer K2EDTA 7.2 mg (purple top) blood collection tubes- lot number 5210787 with an expiration date of 2016/12. 2. Interview with personnel 3 on May 17, 2017 confirmed by observation the expired items were in place for patient testing and were expired.	D5417		
05791 510M	493.1289(a)(c) ANALYTIC SYSTEMS QUALITY **ASSESSMENT** (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in §§493.1251 through 493.1283. (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 Assurance monitors failed to identify and correct quality issues in Immunohematology. Findings: 1. A review of patient test records and quality control records indicated problems found in Immunohematology as follows: a) The laboratory failed to establish a laboratory policy and procedure manual that contained complete policies and procedures. Refer to	D5791	Citation addressed in Lab Procedures Manual: Section Quality Control Control Acceptability Criteria Rh typing and weak D testing D. Requirements of Testing Personnel E. Lab Requirements G. Quality Assurance	9/21/2017

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D5791	Continued From page 8 D5401I. b) The laboratory failed to check all suspicious and negative test results for Rh testing under the microscope as required by laboratory policy. Refer to 05401II. c) The laboratory failed to perform a weak D test on all donor samples that give negative or doubtful positive reactions as required by the manufacturer for eighteen (18) of eighteen (18) patients reviewed. Refer to D5411. d) The laboratory failed to ensure that blood collection tubes are not used beyond its expiration date. Refer to D5417. 2. Review of the Laboratory's Policy and Procedure Manual revealed the laboratory had a generalized Quality Assurance Plan; however the policy failed to include policies and procedures that addressed items in Hematology. Further review of the Laboratory's Policy and Procedure Manual revealed the laboratory also failed to include monitors throughout Hematology Systems in the laboratory. 3. Interview with personnel 4 on June 14, 2017 confirmed the laboratory Quality Assurance Plan failed to identify and correct the problems cited above	05791		
06000	493.1403 MODERATE COMPLEXITY LABORATORY DIRECTOR The laboratory must have a director who meets the qualification requirements of §493.1405 of this subpart and provides overall management and direction in accordance with §493.1407 of	D6000	Citation addressed in Lab Procedures Manual: B: Personnel Requirements Section Laboratory Director C. Responsibilities of Lab Director	9/21/2017

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06000	Continued From page 9 this subpart. This CONDITION is not met as evidenced by: Based on observation, record review and interview with personnel, the Laboratory Director failed to provide overall management and direction for the laboratory. Findings: 1. The Laboratory Director failed to ensure laboratory personnel performed testing as required for accurate and reliable results. Refer to D6014. 2. The Laboratory Director failed to ensure that a quality assessment (QA) program was established and maintained to assure the quality of laboratory services provided. Refer to D 6021. 3. 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 D6031.	06000		
D6014	493.1407(e)(3)(iii) LABORATORY DIRECTOR RESPONSIBILITIES 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.	06014	Citation addressed in Lab Procedure Manual: C. Responsibilities of Lab Director Section Control Acceptability Criteria G: Quality Assurance	9/21/2017

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06014	Continued From page 10 This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure laboratory personnel performed testing as required for accurate and reliable results. Findings: 1. The laboratory failed to check all suspicious and negative test results for Rh testing under the microscope as required by laboratory policy. Refer to D5401 II. 2. The laboratory failed to perform a **weak** D test on all donor samples that give negative or doubtful positive reactions as required by the manufacturer for eighteen (18) of eighteen (18) patients reviewed. Refer to 05411. 3. The laboratory failed to ensure that blood collection tubes are not used beyond its expiration date. Refer to D5417	06014		
06021	493.1407(e)(5) LABORATORY DIRECTOR RESPONSIBILITIES 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 quality assessment programs are established and maintained to assure the quality of laboratory services provided, This STANDARD is not met as evidenced by Based on observation, record review and	06021	Citation addressed in Lab Procedures Manual: B. Personnel Requirements C. Responsibility of Lab Director D. Responsibility of Testing Personnel G. Quality Assurance	9/21/2017

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D6021	Continued From page 11 interview with laboratory personnel, the Laboratory Director failed to ensure that a quality assessment (QA) program was established and maintained to assure the quality of laboratory services provided. Findings: 1. A review of patient test records and quality control records indicated problems as follows: a) The laboratory failed to establish a laboratory policy and procedure manual that contained complete policies and procedures. Refer to D54011. b) The laboratory failed to check all suspicious and negative test results for Rh testing under the microscope as required by laboratory policy. Refer to D5401 11. c) The laboratory failed to perform a weak D test on all donor samples that give negative or doubtful positive reactions as required by the manufacturer for eighteen (18) of eighteen (18) patients reviewed. Refer to D5411. d) The laboratory failed to ensure that blood collection tubes are not used beyond its expiration date. Refer to D5417. 2. Review of the Laboratory's Policy and Procedure Manual revealed the laboratory had a generalized Quality Assurance Plan: however the policy failed to include policies and procedures that addressed items in Hematology. Further review of the Laboratory's Policy and Procedure Manual revealed the laboratory also failed to include monitors throughout Hematology Systems in the laboratory.	D6021		

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D6021	Continued From page 12 3. Interview with personnel 4 on June 14, 2017 confirmed the laboratory Quality Assurance Plan failed to identify and correct the problems cited above.	D6021		
D6031	493.1407(e)(13) LABORATORY DIRECTOR RESPONSIBILITIES 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. Findings: 1. Review of the laboratory policy and procedure manual revealed the laboratory failed to have policies and procedures for: Proficiency Testing (PT): a) Ordering and ensuring that you are enrolled for Proficiency Testing. b) What to do when you receive samples from the PT Provider. c) How to handle the samples; who will test, when to test, how do you assure no inter and intra laboratory communication takes place d) How to record results to send into the PT	06031	Citation addressed in Lab Procedures Manual: C. Responsibility of Lab Director F. Proficiency Testing Section Rh typing and weak D testing	9/21/2017

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06031	Continued From page 13 Provider to be scored. e) What records to maintain. f) How to evaluate when you receive your scores from the PT Provider. g) what steps to take if corrective action is needed. A policy and procedure that addresses weak Anti-0 testing to include (but not inclusive): when to perform• how to perform. what quality control is needed 2. Interview with personnel 4 on June 14, 2017 confirmed the laboratory failed to have detailed written policies and procedures that addressed the items listed above.	06031		