Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0660286	01/19/2018
Name of Provider or Supplier	**Street Address, City, State**	
Liberty Dayton Regional Medical Center	1353 North Travis Street, Liberty, TX	

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	Based on the survey conducted 01-17-2018 through 01-19-2018, the laboratory was found to be out of compliance with the following conditions of 42 CFR: 493.1240 Preanalytic Systems Moderate Complexity 493.1250 Analytic Systems Moderate Complexity 493.1403 Laboratory Director Moderate Complexity 493.1409 Technical Consultant Moderate Complexity .
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: . I. Based on review of American Proficiency Institute (API) proficiency testing documentation for 2016 and 2017, confirmed by staff interview, the laboratory director (CMS form 209) failed to attest to the routine integration of 4 of 4 events in the specialty of immunohematology. Findings: 1. API proficiency testing attestation sheets for 2016 and 2017 were reviewed. Sheets for immunohematology testing for the 3rd event 2016 and the 1st, 2nd and 3rd events 2017 were signed by the laboratory technical consultant (CMS form 209). 2. In an interview at the site on 01-17-2018, the laboratory technical consultant stated that he had reviewed and signed the attestation forms listed. 3. No documentation was made available showing the delegation of the duties of technical supervisor to any other individual. The director and technical supervisor are one and the same. .
D5300	PREANALYTIC SYSTEMS CFR(s): 493.1240 Each laboratory that performs nonwaived testing must meet the applicable preanalytic

	system(s) requirements in 493.1241 and 493.1242, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the preanalytic systems and correct identified problems as specified in 493. 1249 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: . Based on surveyor observation, review of laboratory patient testing logs, laboratory policy and procedure, confirmed by staff interview, the laboratory failed to meet applicable requirements in preanalytic systems. Findings: 1. The laboratory failed to follow its own policies for acceptibility of specimens for coagulation testing. Refer to D5311. 2. The laboratory failed to provide reference lab clients with written instructions including specific information for specimen collection, preservation, storage and transport. Refer to D5317. .
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: . Based on review of laboratory policy and procedure for coaguation testing, surveyor observation and patient testing logs for 2017 and 2018, confirmed by staff interview, the laboratory failed to follow its own policy for acceptibility of specimens for coagulation testing, failing to reject 32 of 32 specimens for activated partial thromboplastin time (APTT) and 58 of 58 specimens for prothrombin time (PT) that did not meet acceptable criteria for storage temperature or time elapsed after collection. Findings: 1. Laboratory policy states: "Coagulation testing should be promptly performed on fresh, platelet poor plasma at room temperature." (Liberty Dayton Regional Medical Center Policy # 1353.04.02) A. In an interview at the site on 01-18-2018, the laboratory technical consultant stated that the laboratory began accepting patient specimens from an outside source on 05-01-2017. From that date until the time of the survey, 58 coagulation specimens from that source were tested. B. Specimens delivered from the outside source, including plasma for coagulation testing, arrived refrigerated with cold packs. In an interview at the site on 01-18-2018 the laboratory technical consultant stated all such specimens arrived refrigerated. C. Coagulation testing on specimens delivered from outside sources did not include a check for platelet poor plasma. In an interview at the site on 01-18-2018 the laboratory technical consultant stated plasma specimens for coagulation testing were not respun before testing. 2. Laboratory policy states: "If testing cannot be performed within 4 hours for APTT, platelet poor plasma should be removed from the cells and frozen at -20 Celsius (C) for up to 2 weeks." (Liberty Dayton Regional Medical Center Policy # 1353.04.02) A. In an interview at the site on 01-18-2018, the laboratory technical consultant stated that no outside source specimens for coagulation testing were respun, delivered frozen or frozen after receipt. B. Review of patient testing logs for 2017 and 2018 revealed that 32 specimens were tested for APTT more

than 4 hours after collection. Collection (COLL) and result (RES) dates and times for these specimens follow. Elapsed time in hours and minutes between collection and result is indicated as ET. COLL RES ET 05/01/2017 11:27 05/02/2017 14:49 27:22 05/17/2017 11:00 05/18/2017 16:36 29:36 05/18/2017 13:30 05/19/2017 17:01 27:31 05/23/2017 09:00 05/24/2017 21:41 36:41 06/02/2017 09:00 06/03/2017 18:14 33:14 06/02/2017 10:00 06/03/2017 18:24 32:24 06/08/2017 15:05 06/09/2017 18:28 27:23 08/15/2017 15:31 08/16/2017 20:14 28:43 08/23/2017 12:50 08/24/2017 16:18 27:28 09/27/2017 13:52 09/29/2017 15:22 49:30 11/01/2017 15:00 11/02/2017 20:32 29:32 11/16/2017 17:06 11/18/2017 06:40 37:34 11/16/2017 17:08 11/18/2017 06:40 37:32 11/17/2017 10:30 11/20/2017 22:54 84:24 11/17/2017 11:50 11/20/2017 18:09 78:19 11/17/2017 14:00 11/20/2017 22:54 80:54 11/17/2017 14:50 11/20/2017 22:52 80:02 11/27/2017 16:53 11/28/2017 23:08 30:15 11/29/2017 11:23 11/30/2017 12:32 25:09 11/29/2017 13:20 11/30/2017 12:33 23:13 11/29/2017 14:16 11/30/2017 12:32 22:16 11/30/2017 09:20 12/01/2017 14:03 28:43 11/30/2017 10:00 12/01/2017 15:36 29:36 11/30/2017 10:58 12/01/2017 15:35 28:37 11/30/2017 11:20 12/01/2017 16:23 29:03 11/30/2017 11:48 12/01/2017 14:03 26:15 11/30/2017 11:58 12/01/2017 14:05 26:07 11/30/2017 15:00 12/01/2017 15:35 24:35 12/11/2017 11:48 12/12/2017 17:54 30:06 12/11/2017 15:30 12/12/2017 17:48 26:18 12/18/2017 11:30 12/19/2017 14:45 27:15 01/15/2018 16:20 01/18/2018 10:16 65:56 3. Laboratory policy states: "If testing cannot be performed within 24 hours for PT, platelet poor plasma should be removed from the cells and frozen at -20 Celsius (C) for up to 2 weeks." (Liberty Dayton Regional Medical Center Policy # 1353.04.02) A. In an interview at the site on 01-18-2018, the laboratory technical consultant stated that no outside source specimens for coagulation testing were respun, delivered frozen or frozen after receipt. B. Review of patient testing logs for 2017 and 2018 revealed that 58 specimens were tested for PT more than 24 hours after collection. Collection (COLL) and result (RES) dates and times for these specimens follow. Elapsed time in hours and minutes between collection and result is indicated as ET. COLL RES ET 05/01/2017 11:27 05/02/2017 14:49 27:22 05/17/2017 11:00 05/18/2017 16:36 29:36 05/18/2017 13:30 05/19/2017 17:01 27:31 05/23/2017 09:00 05/24/2017 21:41 36:41 05/23/2017 11:00 05/24/2017 22:10 35:10 05/24/2017 09:30 05/25/2017 18:22 32:52 05/26/2017 12:10 05/27/2017 17:25 29:15 05/30/2017 08:30 05/31/2017 18:37 34:07 05/30/2017 16:00 05/31/2017 18:37 26:37 05/31/2017 14:00 06/01/2017 17:40 27:40 05/31/2017 16:00 06/01/2017 17:10 25:10 06/01/2017 09:00 06/02/2017 17:40 32:40 06/01/2017 09:35 06/02/2017 17:40 32:05 06/01/2017 10:50 06/02/2017 17:40 30:50 06/01/2017 11:00 06/02/2017 17:40 30:40 06/01/2017 11:45 06/02/2017 17:40 29:55 06/02/2017 09:00 06/03/2017 18:14 33:14 06/02/2017 10:00 06/03/2017 18:24 32:24 06/05/2017 11:00 06/06/2017 21:12 34:12 06/05/2017 14:00 06/06/2017 20:44 30:44 06/05/2017 16:00 06/06/2017 21:13 29:13 06/06/2017 09:00 06/07/2017 14:44 29:44 06/06/2017 10:00 06/07/2017 14:43 28:43 06/06/2017 13:00 06/07/2017 14:43 25:43 06/08/2017 15:05 06/09/2017 18:28 27:23 06/12/2017 14:45 06/15/2017 16:16 73:31 07/14/2017 11:00 07/15/2017 14:19 27:19 08/01/2017 11:12 08/02/2017 15:13 28:01 08/15/2017 15:31 08/16/2017 20:14 28:43 08/23/2017 12:50 08/24/2017 16:18 27:28 08/23/2017 12:51 08/24/2017 21:53 33:02 09/27/2017 13:52 09/29/2017 15:22 49:30 10/03/2017 14:42 10/04/2017 23:03 32:21 10/11/2017 12:58 10/12/2017 16:50 27:52 11/01/2017 15:00 11/02/2017 20:32 29:32 11/16/2017 17:06 11/18/2017 06:40 37:34 11/16/2017 17:08 11/18/2017 06:40 37:32 11/17/2017 10:30 11/20/2017 22:54 84:24 11/17/2017 11:50 11/20/2017 18:09 78:19 11/17/2017 14:00 11/20/2017 22:54 80:54 11/17/2017 14:50 11/20/2017 22:52 80:02 11/27/2017 16:53 11/28/2017 23:08 30:15 11/29/2017 11:23 11/30/2017 12:32 25:09 11/29/2017 13:20 11/30/2017 12:33 23:13 11/29/2017 14:16 11/30/2017 12:32 22:16 11/30/2017 09:20 12/01/2017 14:03 28:43 11/30/2017 10:00 12/01/2017 15:36 29:36 11/30/2017 10:58 12/01/2017 15:35 28:37 11/30/2017 11:20 12/01/2017 16:23 29:03 11/30/2017 11:48 12/01/2017 14:03 26:15 11/30/2017 11:58 12/01/2017 14:05 26:07 11

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D5317	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(d) If the laboratory accepts a referral specimen, written instructions must be available to the laboratory's clients and must include, as appropriate, the information specified in paragraphs (a)(1) through (a)(7) of this section. This STANDARD is not met as evidenced by: . Based on review of laboratory policy and procedure, confirmed by staff interview, the laboratory failed to provide reference lab clients with written instructions that included specific information for specimen collection, preservation, storage and transport. Findings: 1. During review of laboratory policy and procedure, a copy of written instructions for reference lab clients was requested. The document supplied consisted of procedures for receipt of specimens from outside sources and did not include information on storage or transport temperature for blood specimens, or for specimen stability times. 2. In an interview at the site on 01-18-2018, the laboratory technical consultant stated that no written instructions on specimen collection, preservation, storage or transport had been supplied to reference lab clients. .
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: . Based on review of laboratory documentation and staff interview, the laboratory failed to correct identified problems in coagulation testing. Refer to 5403. Based on surveyor observation, review of laboratory documenation and staff interview, the laboratory failed to correct identified problems in blood storage. Refer to D5555. .
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in

	493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: . I. Based on review of laboratory documentation from 2016, 2017 and 2018 for testing on the ACL Elite coagulation analyzer, confirmed by staff interview, the laboratory failed to follow its own policy to establish a normal patient mean for each lot of thromboplastin. Findings: 1. The laboratory procedure manual states: "Reference intervals should be established or verified, as appropriate, whenever there is a change in: - Instrumentation and/or methodology - lot number of reagent - Sample collection tubes - At least once a year." (Liberty Dayton Regional Medical Center Policy #1353.04.04) 2. Documentation of lot changes for RecombiPlasTin 2G, a thromboplastin reagent used for coagulation testing on the ACL Elite analyzer, was requested. No normal patient testing was documented. 3. Documentation of normal patient mean establishment was requested. None could be provided. In an interview at the site on 01-19-2018, the laboratory technical consultant stated that no normal patient mean studies had been performed at lot change. II. Based on review of laboratory documentation from 2016, 2017 and 2018 for testing on the ACL Elite coagulation analyzer, confirmed by staff interview, the laboratory failed to follow its own policy to verify 4 out of 5 new lots of QC (quality controls). 1. Lot change documentation for coagulation controls was requested. Documents provided showed repetitive testing on 11-14-17 and 11-15-2017 using level 1 and level 3 controls, lot 579852. The laboratory technical consultant stated no documentation was available for the following QC lots: Lot N0254860 Level 1 start 02-29-2016 Lot N0556523 Level 3 start 02-29-2016 Lot N105672 Level 1 start 03-14-2017 Lot N116627 Level 1 start 03-14-2017 .
D5537	ROUTINE CHEMISTRY CFR(s): 493.1267(b)(d) For blood gas analyses, the laboratory must perform the following: (b) Test one sample of control material each 8 hours of testing using a combination of control materials that include both low and high values on each day of testing. (d) Document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: . Based on review of blood gas analysis quality control documentation for the OptiMedical OPTI CCA-TS2 analyzer for 2016, 2017 and 2018, patient records and staff interview, the laboratory failed to perform external quality controls at the frequency required by regulation. Findings: 1. Blood gas analysis quality control documentation was reviewed. Results for liquid controls were found indicating the controls were routinely run twice a month and at lot change intervals. 2. In an interview at the site on 01-19-2018, testing person 11 (CMS form 209) stated it was standing laboratory practice to perform electronic controls on a daily basis and external liquid controls twice a month. This was confirmed by the laboratory technical

	consultant, who stated the practice had been in place since 2007. In the period from 02-01-2017 to 01-18-2018, 519 blood gas tests were performed. Documentation of an Individual Quality Control Plan for blood gas analysis was requested. No such documentation could be made available. .
D5555	IMMUNOHEMATOLOGY CFR(s): 493.1271(c)(f) (c) Blood and blood products storage. Blood and Blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: . Based on surveyor observation and review of laboratory refrigerator temperature records for 53 of 53 days between November 2017 and January 2018, confirmed by staff interview, the laboratory failed to store blood in a refrigerator equipped with an audible alarm system. Findings: 1. During a visual inspection of the laboratory, the surveyor observed that there were no blood units in the blood storage refrigerator. Blood storage refrigerator chart recorder discs for 2017 and 2018 were requested. Discs were made available covering the period up to 11-27-2017. 2. In an interview at the site on 01-19-2018, the laboratory technical consultant stated that the blood storage refrigerator had begun to malfunction in November 2017 and blood storage had been transferred to the adjacent laboratory refrigerator. Beginning on 11-27-2017 the temperature of the laboratory refrigerator was monitored every two hours. Manual temperature charts covering the period 11-27-2018 to 01-19-2018 were provided. 3. The laboratory refrigerator used for storage of blood was not equipped with an audible alarm system. .
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 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 this subpart. This CONDITION is not met as evidenced by: . Based on surveyor observation, review of laboratory policies and procedures, review of patient testing logs, competency verification documentation and range verification documentation, confirmed by staff interview, the laboratory director failed to provide overall management and direction of the laboratory. Refer to D6004, D6022 and D6032. .
D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b) 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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: . I. Based on review of competency verification for respiratory department testing personnel, confirmed by staff interview, the laboratory director failed to ensure the technical consultant verified competency for 8 of 8 respiratory technicians performing blood gas analysis. Refer to D6046. II. Based on surveyor observation, review of patient testing logs and laboratory policy and procedure, confirmed by staff interview, the laboratory director failed to ensure compliance with applicable regulations. A. The laboratory director failed to ensure that the laboratory followed its own policy for acceptibility of specimens for coagulation testing. Refer to D5311. B. The laboratory director failed to ensure that the laboratory provided reference lab clients with written instructions that included specific information for specimen collection, preservation, storage and transport. Refer to D5317. C. The laboratory director failed to ensure that respiratory technicians performed external quality controls at the frequency required by regulation. Refer to D5537. D. The laboratory director failed to ensure that the laboratory followed its own policy for range establishment at reagent lot change for coagulation testing. Refer to D5411. E. The laboratory director failed to ensure that the laboratory stored blood units in a refrigerator equipped with an audible alarm. Refer to D5555. .
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 surveyor observation, review of patient testing logs and laboratory policy and procedure, the laboratory director failed to ensure that the laboratory quality assessment program identified failures in quality that occurred in coagulation testing. Refer to D 5311. .
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 review of laboratory policies and procedures, confirmed by staff interview, the laboratory director failed to specify in writing the duties of the laboratory technical consultant. Refer to D2009 item 3. .
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: . Based on surveyor observation, review of laboratory documentation and staff interview, the technical consultant failed to provide technical oversight to the laboratory. Refer to D6042 and D6046. .
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: . Based on review of quality control documentation, confirmed by staff interview, the technical consultant failed to establish an appropriate quality control program for blood gas testing using the Opti-CCA analyzer. Refer to D5537. .
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 review of laboratory personnel competency verification documentation, confirmed by staff interview, the technical consultant failed to evaluate the competency of 8 of 8 respiratory technicians performing blood gas analysis. Findings: 1. Competency verification documentation was requested for all testing personnel. Materials offered did not include evidence of competency verification using the

	required criteria for testing personnel 11, 12, 13, 14, 15, 16, 17 and 18, all respiratory technologists performing blood gas analysis. 2. In an interview at the site on 01-19-2018, the laboratory technical consultant stated that he had not evaluated respiratory technicians for competency and was not aware it was his responsibility to do so. .