Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1061284	03/25/2025
Name of Provider or Supplier	**Street Address, City, State**	
Methodist Hospital Of Dallas	2700 East Broad Street, Mansfield, 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	A validation survey was conducted. As a result of the survey, the facility was found to be out of compliance with CLIA regulations 42 CFR Part 493. CONDITION LEVEL DEFICIENCIES were found to be out of compliance: 493.1250 Analytic Systems 493.1441 Laboratory Director, high complexity
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 review of the CMS (Center for Medicare and Medicaid Services) 209 form, laboratory policies, personnel records, and staff interview, the laboratory failed to perform competency assessments for two of two Technical Consultants (TC-1, TC-2) in 2023 and 2024. Findings included: 1. Review of the laboratory's submitted CMS 209 form identified two TCs. 2. Review of the laboratory's policy titled "Quality Assurance Plan" (REF #5.3) stated: "IX. COMPETENCY TESTING AND TRAINING PROGRAMS Competency testing is required annually for all employees." 3. A review of personnel records revealed the following: TC#1: There were no documented competency assessments for the duties performed as a TC in 2024. TC#2: There were no documented competency assessments for the duties performed as a TC in 2023 and 2024. On 03/25/2025 at 11:04 a.m., the laboratory was asked to provide documentation of the competency assessments. No documentation was provided. 4. During an interview on 03/25/2025 at 11:04 a.m., the Technical Consultant-1 confirmed the laboratory failed to perform the competency assessments in 2023 and 2024.
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 the laboratory policies, manufacturer's instructions, laboratory's establishment studies, laboratory blood gas volume records, and staff interview, the laboratory failed to meet the requirements of the analytic systems as evidenced by: 1. The laboratory failed to ensure establishment studies were performed when the laboratory introduced a modified FDA (Food and Drug Administration) test into the laboratory test systems for one of one specimen type (cord blood) on the RAPIDPoint 500e blood gas analyzer. Refer to D5423.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) (b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (b)(2)(i) Accuracy. (b)(2)(ii) Precision. (b)(2)(iii) Analytical sensitivity. (b)(2)(iv) Analytical specificity to include interfering substances. (b)(2)(v) Reportable range of test results for the test system. (b)(2)(vi) Reference intervals (normal values). (b)(2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on review of the laboratory policies, manufacturer's instructions, laboratory's establishment studies, laboratory blood gas volume records, and staff interview, the laboratory failed to ensure establishment studies were performed when the laboratory introduced a modified FDA test into the laboratory test systems for one of one specimen type (cord blood) on the RAPIDPoint 500e blood gas analyzer. Findings included: 1. Review of the laboratory's policy titled "Verification of Manufacturer Performance Specification" (REF. #4.13) stated: "PURPOSE When adding or replacing an unmodified U.S. Food and Drug Administration (FDA)-approved test, method, or instrument, the laboratory will verify the manufacturer's performance specifications. POLICY The laboratory will verify all new instruments and if the situation occurs, any instrument on loan in order to establish quality control procedures. PROCEDURE A. The manufacturer will install new instrument in designated area. B. Biomed will be called to perform all safety checks and label new instrument with approval. C. A full system calibration will be performed. D. Calibration Verification Material linearity will be performed and reportable range established. E. Ten (10) Level 1 and Ten (10) Level 3 Automatic Quality Controls will be ran and used to test precision and repeatability. F. Twenty to Twenty-five (20-25) patient samples will be run on the new instrument in correlation with another

	established ABG analyzer. G. The laboratory director will approve validation /verification studies for all new instruments and new lab tests. H. After all results are deemed satisfactory and approved, the new instrument will be placed into patient use." Review of the laboratory's policy titled "REFERENCE INTERVALS FOR ARTERIAL BLOOD GAS/ELECTROLYTE RESULTS" (REF. #3.15) stated: "II. RECOMMENDED PROCEDURE WHO IS RESPONSIBLE/ EFFECT IF NOT CARRIED OUT The Medical directors are responsible for setting these intervals and should be carried out by the Respiratory Therapists. REFERENCE INTERVALS ... 6. Neonatal Cord Blood Analyte Reference Interval pH 7.35-7.3 PCO2 (mmHg) 35-60 PO2 (mmHg) 5-40 BE (mmol/L) -2-2" 2. A review of the RAPIDPoint 500e System Operator's Guide page 2-8 revealed the following: "System Operation Sample Collection Devices ... Sample Type Arterial, venous, mixed venous blood, or Pleural Fluid Collection Device Syringe Sample Type Capillary Collection Device Capillary tube" The manufacturer's operator's guide did NOT specify cord blood as an approved specimen type for the RAPIDPoint 500e analyzer. The laboratory modified the FDA approved test system to include blood gas analysis on cord blood specimens. 3. A review of the laboratory's verification studies on the RAPIDPoint 500e analyzers revealed the following: In April 2023 verification studies were performed on RAPIDPoint 500e Serial # 61284 (located in the NICU) and Serial #55755 (located in ICU). In May 2024 verification studies were performed on RAPIDPoint 500e Serial # 64936 (located in the ER) and Serial #64922 (located in Neurotrauma ICU). Further review of the studies revealed the laboratory failed to document performance of establishment studies on cord blood for the modified FDA-approved test system that included the following: a) accuracy b) precision c) reportable range d) sensitivity e) specificity/interfering substances f) sample stability g) verification of patient normal ranges 4. On 3/25/25 at 11:59 a.m., the laboratory was asked to provide documentation of performing the required studies for cord blood. No documentation was provided. 5. A review of laboratory blood gas volume records revealed the laboratory performed blood gas analysis on 171 cord blood specimens in 2023 and 161 cord blood specimens in 2024. 6. During an interview on 03/25/2025 at 12:15 pm, the Technical Consultant, after a review of records confirmed the laboratory did not perform establishment studies on the RAPIDPoint 500e for cord blood specimen types. Word Key: FDA- Food and Drug Administration REF- reference PCO2- partial pressure of carbon dioxide PO2- partial pressure of oxygen BE- base excess mmHg- millimeters of mercury mmol/L- millimoles per liter NICU- neonatal intensive care unit ICU- intensive care unit ER- emergency room
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on review of the CMS 209 form, laboratory personnel records, laboratory policies, manufacturer's instructions, laboratory's establishment studies, laboratory blood gas volume records, and staff interview, the laboratory director failed to have documentation to qualify as a laboratory director overseeing high complexity testing (refer to D6078) and failed to provide oversight for high complexity testing (refer to D6086).

D6078	LABORATORY DIRECTOR QUALIFICATIONS CFR(s): 493.1443 The laboratory director must be qualified to manage and direct the laboratory personnel and performance of high complexity tests and must be eligible to be an operator of a laboratory within the requirements of subpart R. (a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if such licensing is required; and (b) The laboratory director must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology; or (b)(2)(i) Be a doctor of medicine, a doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have at least 2 years of experience directing or supervising high complexity testing; and (b)(2)(iii) Have at least 20 CE credit hours in laboratory practice that cover the director responsibilities defined in 493.1445; or (b)(3)(i)(A) Hold an earned doctoral degree in a chemical, biological, clinical or medical laboratory science or medical technology from an accredited institution; or (b)(3)(i)(B) Hold an earned doctoral degree; and (b)(3)(i)(B)(1) Have at least 16 semester hours of doctoral level coursework in biology, chemistry, medical technology (MT), clinical laboratory science (CLS), or medical laboratory science (MLS); or (b)(3)(i)(B)(2) An approved thesis or research project in biology/chemistry/MT/CLS/MLS related to laboratory testing for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings; and (b)(3)(ii) Be certified and continue to be certified by a board approved by HHS; and (b)(3)(iii) Have at least 2 years of: (b)(3)(iii)(A) Laboratory training or experience, or both; and (b)(3)(iii)(B) Laboratory experience directing or supervising high complexity testing; and (b)(3)(iv) Have at least 20 CE credit hours in laboratory practice that cover the director responsibilities defined in 493.1445; or (b)(4) Notwithstanding any other provision of this section, an individual is considered qualified as a laboratory director of high complexity testing under this section if they were qualified and serving as a laboratory director of high complexity testing in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024. (b)(5) For the subspecialty of oral pathology, be certified by the American Board of Oral Pathology, American Board of Pathology, or the American Osteopathic Board of Pathology. This STANDARD is not met as evidenced by: Based on review of the CMS 209 form and laboratory personnel records, the laboratory director did not meet the qualifications of director for the modified high complexity testing performed at the facility. Findings included: 1. The laboratory modified the RAPIDPoint 500e blood gas analyzer by introducing an unacceptable specimen type (cord blood). Refer to D5423. 2. When the laboratory introduced a modified FDA test into the laboratory test systems, the system becomes high complexity. 3. A review of the CMS 209 form and personnel records for the Laboratory Director on the date of the survey did not include supporting information that the Laboratory Directory was certified in anatomic or clinical pathology; or had at least one year of laboratory training during medical residency; or have at least 2 years of experience directing or supervising high complexity testing. Key: CMS- Centers for Medicare and Medicaid Services FDA - Food and Drug Administration

D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and This STANDARD is not met as evidenced by: Based on review of the laboratory policies, manufacturer's instructions, laboratory's establishment studies, laboratory blood gas volume records, and staff interview, the Laboratory Director failed to ensure verification studies were complete prior to reporting test results. Refer to D5423.