

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D1035686	(X3) Date Survey Completed 06/30/2026
Name of Provider or Supplier Onecore Health	Street Address, City, State 100 Ne 85th Street, Oklahoma City, OK	
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	The validation survey was performed on 06/30/2026. The laboratory was found out of compliance with the following CLIA Condition: 493.1409; D6033: Technical Consultant
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) (b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on a review of records, Form CMS-209, and interview with the chief nursing officer and clinical educator, the laboratory failed to ensure proficiency testing (PT) samples were tested by personnel who routinely performed patient testing for four of four chemistry core events reviewed in 2025 and 2026. Findings include: (1) On 06/30/2026 at 12:45 pm, the chief nursing officer and clinical educator stated the laboratory performed the following testing on the iSTAT 1 analyzer: (a) pH, pCO₂, pO₂, and Lactate using the CG4+ cartridge; (b) pH, pCO₂, pO₂, Sodium, Potassium, Ionized Calcium, Glucose, Hemoglobin, and Hematocrit using the CG8+ cartridge. (2) Interview with the clinical educator on 06/30/2026 at 01:00 pm and review of Form CMS-209 confirmed that five persons performed the above patient testing during 2025 and to date in 2026; (3) A review of PT records for the first, second, and third 2025 events and the first 2026 event identified that four of four events had been tested by testing person #8; (4) The findings were reviewed with the chief nursing officer and clinical educator. Both stated on 06/30/2026 at 01:45 pm, the PT specimens for the four events had been tested by one testing person.
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2)

(a)(2) Function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturers established limits before patient testing is conducted. (b) 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 do the following:

This STANDARD is not met as evidenced by:

Based on a review of records, manufacturer's instructions, and interview with the chief nursing officer and clinical educator, the laboratory failed to perform function checks every six months as defined by the manufacturer of the iSTAT 1 analyzer during the review period of January 2025 through the current date. Findings include: (1) On 06/30/2026 at 12:45 pm, the chief nursing officer and clinical educator stated the laboratory performed the following testing on the iSTAT 1 analyzer: (a) pH, pCO₂, pO₂, and Lactate using the CG4+ cartridge; (b) pH, pCO₂, pO₂, Sodium, Potassium, Ionized Calcium, Glucose, Hemoglobin, and Hematocrit using the CG8+ cartridge. (2) A review of the manufacturer's manual titled, "Procedure Manual for the iSTAT 1 System" on page 12 under "Every 6 Month Procedures" stated, "Verify thermal probe reading as described below"; (3) A review of records from January 2025 through the current date identified no evidence the thermal probe checks had been performed after 10/29/2025; (4) The findings were reviewed with the chief nursing officer who stated on 06/30/2026 at 02:55 pm, the thermal probe checks had not been performed every six months.

D5775

COMPARISON OF TEST RESULTS
CFR(s): 493.1281(a)(c)

(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites.

This STANDARD is not met as evidenced by:

Based on a review of records and interview with the the chief nursing officer and clinical educator, the laboratory failed to have a system that evaluated and defined the relationship between blood gas testing performed using two types of iSTAT 1 test cartridges at least twice annually during the review period of January 2025 through the current date. Findings include: (1) On 06/30/2026 at 12:45 pm, the chief nursing officer and clinical educator stated the laboratory performed the following testing on the iSTAT 1 analyzer (serial number 404777): (a) pH, pCO₂, and pO₂ using the CG4+ cartridge; (b) pH, pCO₂, andn pO₂ using the CG8+ cartridge. (2) Interview with the chief nursing officer on 06/30/2026 at 03:05 pm, confirmed the laboratory did not have a method to evaluate the relationship between the test results using the two cartridge types and it had not been performed during the review period.

D6033

TECHNICAL CONSULTANT-MODERATE COMPLEXITY
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 a review of records and interview with the chief nursing officer and clinical educator, the technical consultant failed to provide technical supervision in accordance with 493.1413 of this subpart for five of five competency evaluations performed in 2026. Findings include: (1) The technical consultant failed to ensure the individual who performed the duties and responsibilities of the technical consultant, met the qualifications. Refer to D6035.

D6035

TECHNICAL CONSULTANT QUALIFICATIONS

CFR(s): 493.1411

(a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant 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, 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 1 year of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i)(A) Hold an earned doctoral or master's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(3)(i)(B) Meet either requirements in 493.1405(b)(3)(i)(B) or (b)(4)(i)(B) or (C); AND (b)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i)(A) Have earned a bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(4)(i)(B) Meet 493.1405(b)(5)(i)(B); and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(5)(i) Have earned an associate degree in medical laboratory technology, medical laboratory science, or clinical laboratory science; and (b)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. (b)(6) For blood gas analysis, the individual must- (b)(6)(i) Be qualified under paragraph (b)(1), (2), (3) or (4) of this section; or (b)(6)(ii)(A) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; and (b)(6)(ii)(B) Have at least 2 years of laboratory training or experience, or both, in blood gas analysis; or (b)(7) Notwithstanding any other provision of this section, an individual is considered qualified as a technical consultant under this section if they were qualified and serving as a technical consultant for moderate complexity testing in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024.

This STANDARD is not met as evidenced by:

Based on a review of records and interview with the clinical educator, the laboratory failed to ensure the individual who performed the duties and responsibilities of the technical consultant, met the qualifications for five of five competency evaluations reviewed during 2026. Findings include: (1) A review of records for five persons performing moderate complexity testing during 2025 and to date in 2026 identified the 2026 annual competencies for five of five testing persons had been performed by an individual who did not meet the regulatory requirements of a technical consultant as follows: (a) Testing Person #4 - Performed on 04/26/2026 (b) Testing Person #5 - Performed on 05/04/2026 (c) Testing Person #7 - Performed on 04/29/2026 (d) Testing Person #8 - Performed on 04/29/2026 (e) Testing Person #9 - Performed on 04/29/2026 (2) The records were reviewed with the clinical educator who stated on 06/30/2026 at 02:40 pm, the evaluations had been performed by an individual who did not meet the regulatory qualifications of a technical consultant.