

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D1003010	(X3) Date Survey Completed 09/21/2023
Name of Provider or Supplier Downriver Medical Associates	Street Address, City, State 2300 Biddle Avenue Suite 100, Wyandotte, MI	
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
D5400	<p>ANALYTIC SYSTEMS CFR(s): 493.1250</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: . Based on record review and interviews, the laboratory failed to perform calibration verification at least once every 6 months for its Abbott iSTAT Chem 8 test system (refer to D5439) and failed to ensure control results for its Abbott iSTAT glucose testing met test system requirements (refer to D5481).</p>
D5439	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b)</p> <p>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</p>

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 record review and interview with the Technical Consultant, the laboratory failed to perform calibration verification at least once every 6 months for its Abbott iSTAT Chem 8 test system for 1 (September 2022 to September 2023) of 1 year reviewed. Findings include: 1. A review of the laboratory's verification of performance specifications for its Abbott iSTAT Chem 8 test system revealed calibration verification was performed in September 2022. 2. A review of the laboratory's patient testing logs revealed patient testing started on 5/11/23. 3. The surveyor requested calibration verification documentation since September 2022 on 9/21/23 at 9:33 am and it was not made available. 4. An interview on 9/21/23 at 9:33 am with the Technical Consultant confirmed calibration verification had not been performed at least once every 6 months for the Abbott iSTAT Chem 8 testing system.

D5481

CONTROL PROCEDURES

CFR(s): 493.1256(f)(g)

(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

. Based on record review and interview with the Technical Consultant, the laboratory failed to ensure control results for its Abbott iSTAT glucose testing met test system requirements for 1 (June 2023) of 5 months reviewed. Findings include: 1. A review of the laboratory's control records revealed the Tri-control Level 3 lot# 321157 had an acceptable range of 28 to 46 mg/dL. 2. A review of the Abbott iSTAT quality control documentation for testing performed on 6/1/23 revealed a result of "**** mg/dL" for the Level 3 lot# 321157 control glucose reading. 3. An interview on 9/21/23 at 10:20 am with the Technical Consultant confirmed the laboratory had reported patients when glucose controls had not been acceptable and 9 patients had been performed and reported before controls had passed on 7/3/23.

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 record review and lack of documentation, the Technical Consultant was

not qualified to perform duties for the laboratory's routine chemistry testing (refer 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 possess qualifications that are equivalent to those required for such certification; 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 one year of laboratory training or experience, or both in non-waived 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) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service.

This STANDARD is not met as evidenced by:

. Based on record review and a lack of documentation, the Technical Consultant was not qualified to perform duties for the laboratory's routine chemistry testing for 5 (May 2023 to September 2023) of 5 months the laboratory has been testing in the routine chemistry specialty. Findings include: 1. A review of the Technical Consultant's documentation revealed a lack of at least two years' training or experience in non-waived routine chemistry testing. 2. The surveyor requested documentation of at least two years' training or experience in non-waived routine chemistry testing on 9/21/23 at 9:33 am and it was not made available. 3. The laboratory was given an additional 7 days to provide the missing documentation and it was not provided.