

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 41D0892960	(X3) Date Survey Completed 06/29/2022
Name of Provider or Supplier Atmed Treatment Center	Street Address, City, State 1524 Atwood Avenue, Johnston, RI	
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
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>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</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to test proficiency testing (PT) samples in the same manner as routine patient samples in the specialties of Chemistry and Hematology. Findings include: 1. Record review on 6/8/2022 of the laboratory's American Associates of Bioanalytists (AAB) 2020, 2021 and 2022 Hematology/Coagulation and Chemistry Cardiac Markers PT records revealed technical consultant (TC) 1 performed the proficiency testing for all of the Hematology/Coagulation and Chemistry Cardiac Markers PT events. 2. Interview with TC 1 on 6/8/2022 at 11:35 AM confirmed the above findings. 3. The laboratory performs 180 Chemistry and 18,000 Hematology tests annually.</p>
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during</p>

the PT event.

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the laboratory director (LD) failed to attest that proficiency testing samples were performed in the same manner as patient specimens. Findings include: 1. Record review on 6/8/2022 of the 2020 American Associates of Bioanalytists (AAB) Chemistry Cardiac Markers events 2 and 3 attestation pages revealed the pages were not signed by the LD. 2. Record review on 6/8/2022 of the 2020 AAB Hematology/Coagulation event 2 attestation page revealed the page was not signed by the LD. 3. Record review on 6/8/2022 of the 2021 AAB Chemistry Cardiac Markers events 1,2 and 3 attestation pages revealed the pages were not signed by the LD. 4. Record review on 6/8/2022 of the 2021 AAB Hematology /Coagulation events 1,2 and 3 attestation pages revealed the pages were not signed by the LD. 5. Record review on 6/8/2022 of the 2022 AAB Chemistry Cardiac Markers events 1 and 2 attestation pages revealed the pages were not signed by the LD. 6. Record review on 6/8/2022 of the 2022 AAB Hematology/Coagulation events 1 attestation pages revealed the pages were not signed by the LD. 7. Interview with technical consultant 1 on 6/8/2022 at 11:30 AM confirmed the above findings.

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 record review and staff interview, the laboratory director (LD) failed to have a policy in place to assess the competency of all laboratory personnel. Findings Include: 1. Record review of the laboratory's procedure manual on 6/8/2022 revealed the laboratory did not have a policy in place to assess the competency of the technical consultant (TC). 2. Record review of the laboratory's 2020 and 2021's competency records on 6/8/2022 revealed the laboratory failed to document competency for 2 of 2 TC's based on their CLIA responsibilities. 3. Staff Interview on 6/8/2022 at 10:30 AM with TC1 and TC2 confirmed the above findings.

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 surveyor observation, record review and staff interview, the laboratory failed to monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1251 through 493.1283 for each specialty and

subspecialty of testing performed. The cumulative effect of this lack of oversight resulted in the laboratory's inability to ensure accuracy and reliability of patient test results in the specialty of Hematology and Chemistry. Refer to D5403, D5415, D5445, and D5783.

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:

Based on record review and staff interview the laboratory procedure manual failed to include normal ranges in the specialty of Chemistry. Findings include: 1. Record review of the laboratory procedure manual on 6/8/2022 revealed a lack of reference ranges for Troponin, Creatine Kinase Muscle Brain (CKMB) and Myoglobin. 2. Staff interview with technical consultant 1 on 6/8/2022 at 12:30 confirmed the procedure manual did not contain reference ranges for Troponin, CKMB and Myoglobin. 3. The laboratory performs 180 Chemistry annually.

D5415

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT

CFR(s): 493.1252(c)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:

Based on surveyor observation, record review, and staff interview the laboratory failed to label reagents with the appropriate expiration dates in the specialty of Hematology. Findings include: 1. Surveyor observation of the laboratory refrigerator on 6/8/2022 at 12:45 PM revealed the following reagents were stored in the refrigerator: a. One tube of abnormally high CBC 4C-ES control lot #087600 exp. 7/18 /2022. b. One tube of abnormally low CBC 4C-ES control lot #067600 exp. 7/18

/2022. c. One tube of normal CBC 4C-ES control lot #087600 exp. 7/18/2022. d. The above reagents did not have an open date or new expiration date recorded on the tubes. 2. Record review on 6/8/2022 of the Coulter 4C-ES Cell Control 'Table of Expected Results' states, "35 open vial days." 3. Staff interview on 6/8/2022 at 12:45 PM with technical consultant 1 confirmed the above findings. 4. The laboratory performs 18,000 Hematology tests annually.

D5445

CONTROL PROCEDURES
CFR(s): 493.1256(d)(1)(2)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--
(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on record review and staff interview the laboratory failed to run daily quality controls (QC) in the specialty of Chemistry. Findings Include: 1. Record review on 6/8/2022 of the laboratory's 2020 and 2021 Traige QC records for Troponin, Creatine Kinase Muscle Brain, and Myoglobin revealed QC was only performed when a new box was opened and monthly. 2. Staff interview on 6/8/2022 at 12:30 PM with technical consultant 1 confirmed the above findings. 3. The laboratory performs 180 Chemistry tests annually.

D5783

CORRECTIVE ACTIONS
CFR(s): 493.1282(b)(2)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.

This STANDARD is not met as evidenced by:
Based on record review and staff interview the laboratory failed to document corrective action and evaluate if patient results were affected when white blood count (WBC) quality control (QC) was out of range in the specialty of Hematology. Findings Include: 1. Record review on 6/8/2022 of the laboratory's 2020 and 2021 QC 'WBC/Diff Control review' records revealed: a. On 2/9/2021 at 8:25 AM, WBC low QC lot # 069000 exp. date 3/1/2021 flagged as low. b. On 2/12/2021 at 8:21 AM, WBC low QC lot # 069000 exp. date 3/1/2021 flagged as low. c. On 2/13/2021 at 7:55 AM, WBC low QC lot # 069000 exp. date 3/1/2021 flagged as low. d. On 2/16/2021 at 8:22 AM, WBC low QC lot # 069000 exp. date 3/1/2021 flagged as low. e. Corrective action was not documented for the above QC failures. 2. Record review on 6/8/2022 of the laboratory's patient logs for the dates listed in 1a-1d above revealed

patient results were reported on the following dates: a. On 2/9/2021 two patient results were reported. b. On 2/12/2021 two patient results were reported. 3. Record review on 6/8/2022 of the laboratory's 'Quality Control Program' procedure Calibration/Controls section revealed, "At least two levels of controls must be tested daily and results must be in expected ranges before patient test results are reported." 4. Staff interview with technical consultant (TC) 1 on 6/8/2022 at 12:17 PM confirmed the above findings. TC 1 stated, "I only realized it a month later." 5. The laboratory performs 18,000 Hematology tests annually.

D5805

TEST REPORT
CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:
Based on record review and staff interview the laboratory failed to indicate the name and address of the laboratory location where the test was performed on the final patient test report in the specialties of Chemistry and Hematology. Findings include: 1. Record review of a patient final Chemistry report on 6/8/2022 revealed the name and address of the laboratory performing patient testing was not on the report. 2. Record review of a patient final Hematology report on 6/8/2022 revealed the address of the laboratory performing patient testing was not on the report. 3. Staff interview with technical consultant 1 on 6/8/2022 at 12:00 PM confirmed the above findings. 4. The laboratory performs 180 Chemistry and 18,000 Hematology tests annually

D5807

TEST REPORT
CFR(s): 493.1291(d)

Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.

This STANDARD is not met as evidenced by:
Based on record review and staff interview the reference ranges reported on the final patient test report did not correlate with the reference ranges in the procedure manual in the specialty of Hematology. Findings include: 1. Record review on 6/8/2022 of the 'Act diff Series Analyzer' Hematology procedure manual compared to final patient test reports revealed the reference range on patient reports did not correlate with the reference range in the procedure manual for complete blood count. Analyte Procedure Manual Test Report WBC 3.38-8.68 4.5-10.5 RBC 3.75-5.25 4.00-6.00 HGB 11.69-15.82 11.0-18.0 HCT 34.69-45.88 35.0-60.0 MCV 78.68-96.04 80.0-99.9 MCH 26.16-33.05 27.0-31.0 MCHC 32.58-36.19 33.0-37.0 PLT 116.10-329.27 150-450 RDW

	<p>11.55-15.86 11.6-13.7 MPV 7.10-10.54 7.8-11.0 2. Staff interview with technical consultant 1 on 6/8/2022 at 12:30 confirmed the above findings. 3. The laboratory performs 18,000 Hematology tests annually.</p>
D6000	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on lack of documentation, surveyor observation, record review and staff interview, the laboratory director failed to provide overall management and direction in accordance with 493.1407. The cumulative effect of this lack of oversight resulted in the laboratory director's inability to ensure the accuracy and reliability of patient test results in the specialties Hematology and Chemistry. Refer to D6016, D6020, D6022, D6025, D6026 and D6029.</p>
D6016	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i)</p> <p>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)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;</p> <p>This STANDARD is not met as evidenced by: Refer to D2007 and D2015.</p>
D6020	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</p> <p>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 program is established and maintained to assure the quality of laboratory services provided.</p> <p>This STANDARD is not met as evidenced by: Refer to D5545 and D5783.</p>
D6022	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform</p>

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:
Refer to D5783.

D6025

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(7)

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)(7) Ensure that patient test results are reported only when the system is functioning properly.

This STANDARD is not met as evidenced by:
Refer to D5783.

D6026

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(8)

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)(8) Ensure that reports of test results include pertinent information required for interpretation.

This STANDARD is not met as evidenced by:
Refer to D5807.

D6029

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(11)

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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:
Based on record review and staff interview, the lab director (LD) failed to ensure testing personnel (TP) received appropriate training to perform moderate complexity

testing prior to reporting patient test results in the specialty of Chemistry. Findings Include: 1. Record review of the laboratory's 2020 and 2021's TP files on 6/8/2022 revealed a lack of Chemistry training documentation for 14 of 14 TP. 2. Staff Interview on 6/8/2022 at 10:30 AM with technical consultant (TC) 1 and TC 2 confirmed the above findings. 3. The laboratory performs 180 Chemistry tests annually.

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 record review and staff interview the technical consultant (TC) failed to assess testing personnel (TP) using all 6 competency assessment elements in the specialties of Chemistry and Hematology. Findings Include: 1. Record review on 6/8/2022 of the laboratory's 2020 and 2021 Chemistry competency records revealed: a. 14 of 14 TP were evaluated using only a written quiz. b. 13 of 14 TP were not evaluated using blind samples or Proficiency Testing (PT). c. 14 of 14 TP were not evaluated on direct observation of routine patient test performance. d. 14 of 14 TP were not evaluated on the recording and reporting of test results. e. 13 of 14 TP were not evaluated by review of intermediate test results, quality control records, and PT records. 2. Record review on 6/8/2022 of the laboratory's 2020 and 2021 Hematology competency records revealed: a. 13 of 14 TP were not evaluated using blind samples or Proficiency Testing (PT). 3. Interview with TC 1 on 6/8/2022 at 10:58 AM confirmed the above findings. TC 1 further stated "They run the routine patient samples and I watch them. These are the blind samples." 4. The laboratory performs 180 Chemistry and 18,000 Hematology tests annually.

D6066

TESTING PERSONNEL QUALIFICATIONS
CFR(s): 493.1423(b)(4)(ii)

Have documentation of training appropriate for the testing performed prior to analyzing patient specimens.

This STANDARD is not met as evidenced by:

Based on lack of documentation, record review and staff interview, the lab director failed to document training for testing personnel (TP) in moderate complexity testing prior to testing and reporting patient test results in the specialty of Chemistry. 1. Record review of the laboratory's new TP files on 6/8/2022 revealed: a. 8 of 8 new TP did not have training in the specialty of Chemistry. 2. Staff Interview on 6/8/2022 at 10:30 AM with technical consultant (TC) 1 and TC2 confirmed 8 of 8 new TP did not have documented Chemistry training prior to testing and reporting patient results. 3. The laboratory performs 180 Chemistry tests annually.