Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2128678	12/14/2018
Name of Provider or Supplier	**Street Address, City, State**	
Altru Diagnostics Inc	8566 Katy Freeway Suite 121, Houston, 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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on a review of policies and procedures, the laboratory testing records, CMS 155 report, CMS 116 application and interview of facility personnel it was revealed that the laboratory failed to enroll in a proficiency testing program for each of the specialties and subspecialties for which it seeks certification. The laboratory performed patient testing in the specialties of Hematology (6 regulated analytes) and Chemistry; including the subspecialties of General Chemistry (22 regulated analytes) , Toxicology(2 regulated analytes) and Endocrinology (6 regulated analytes). The findings included: 1. Review of the laboratory's policy titled Laboratory Proficiency Testing Policy dated 02/17/2018 found on page 1 under the heading POLICY - " In compliance with CLIA regulations, this lab will perform proficiency testing at least semi-annually on all required laboratory tests. Testing will be performed on a rotating basis by all staff." 2. A review of facility records found no documentation of the laboratory being enrolled in or participating in a CMS approved proficiency testing program for Hematology or Chemistry in 2018. The laboratory started testing patient specimens for Hematology, General Chemistry, Toxicology and Endocrinology procedures in July 2018. Regulated analytes tested by the laboratory were: Hematology WBC Differential Erythrocyte Count Mean Corpuscular Volume (MCV)

	Hemoglobin Leukocyte Count Platelet Count General Chemistry Alanine Aminotransferase (ALT) Albumin Alkaline Phosphatase Amylase Aspartate Aminotransferase (AST) Bilirubin, total Calcium, total Chloride Cholesterol, total Cholesterol, HDL Creatine Kinase, total Creatinine Glucose Iron, total Lactate Dehydrogenase (LDH), total Magnesium Potassium Sodium Total Protein Triglycerides Urea Nitrogen Uric Acid Endocrinology Cortisol Free Thyroxine Human Chorionic Gonadotropin Triiodothyronine Thyroid Stimulating Hormone Thyroxine, total Toxicology Lithium Valproic Acid 3. Review of the CMS 155 report found no proficiency testing scores had been reported to the Centers for Medicare and Medicaid Services (CMS). 4. Documentation of enrollment in a proficiency testing program for each specialty and subspecialty was requested. Testing person 15 provided the enrollment form for proficiency testing in the 2018 College of American Pathologists (CAP) proficiency testing program for the Infectious disease respiratory panel. 5. Review of the CMS 116 application found that the laboratory recorded estimated volumes for each of the specialties: Hematology - 2000 Chemistry - 4000 6. Interview of testing person 15 listed on the CMS report 209 Laboratory Personnel Report conducted on November 28, 2018 at 2:07 PM confirmed that the laboratory did not enroll in, or participate in a proficiency testing program for the specialties of Hematology, Chemistry. He stated that he knew they were enrolled in proficiency testing for some tests, but not all.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Review of policies and procedures, proficiency testing records, patient test records, and interview of facility personnel found that the laboratory failed to follow their own Quality Assurance program for identifying monitoring and correcting problems in the general laboratory systems. The findings included: 1. Review of the laboratory's own policy titled Laboratory Quality Assessment Program dated 02/17/2018 found on page 2 under the heading INDICATORS OF QUALITY - "Quality indicators for this facility have been defined as, but not limited to: a. Personnel qualifications, training and performance evaluation b. Periodic evaluation of physical environment for safety and compliance. c. Communication and complaint investigation d. Evaluation of proficiency testing and split sample testing." Review of the laboratory's policy titled Laboratory Proficiency Testing Policy dated 02/17/2018 found on page 1 under the heading POLICY - " In compliance with CLIA regulations, this lab will perform proficiency testing at least semi-annually on all required laboratory tests. Testing will be performed on a rotating basis by all staff." 2. A review of facility records found no documentation of the laboratory being enrolled in or participating in a CMS approved proficiency testing program for Hematology or Chemistry in 2018. The laboratory started testing patient specimens for Hematology, General Chemistry, Toxicology and Endocrinology procedures in July 2018. 3. Review of the CMS 155 report found no proficiency testing scores had been reported to the Centers for Medicare and Medicaid Services (CMS). 4. Documentation of enrollment in a proficiency testing program for each specialty and subspecialty was requested. Testing person 15 provided the enrollment form for proficiency testing in the 2018 College of American Pathologists

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D5405	PROCEDURE MANUAL CFR(s): 493.1251(c) Manufacturer's test system instructions or operator manuals may be used, when applicable, to meet the requirements of paragraphs (b)(1) through (b)(12) of this section. Any of the items under paragraphs (b)(1) through (b)(12) of this section not provided by the manufacturer must be provided by the laboratory. This STANDARD is not met as evidenced by: Review of the operator ' s manual, laboratory policies and procedures, and interview of facility personnel found that the laboratory failed to have a policy for handling flagged results obtained on patient CBC (complete blood count) results when using the Coulter AcT 5 diff hematology analyzer. The laboratory also failed to establish and define a frequency of calibration procedures. Findings included: A. Handling of Flagged results obtained on CBC results 1. Review of the operator ' s manual found: a. on page 9-34 under the heading REVIEWING RESULTS - "Carefully review all parameter results, especially results with flags and/or messages . Verify flagged results for accuracy and review any result that exceeds your laboratory's limits." 2. Review of the laboratory's policies and procedures found no written instruction for handling flagged results obtained on patient CBC results. 3. Interview of testing person 4 on the CMS report 209 Laboratory personnel report confirmed that there was no additional written policy available to testing personnel defining actions to be taken when flagged results occur. B. Calibration and Calibration verification procedures Based on review of the operator's manual, calibration records, and staff interview, the laboratory failed to establish and define the frequency of calibration and or calibration verification procedures for the Coulter ACT 5 diff hematology analyzer. The findings include: 1. Review of the Coulter AcT5 diff hematology analyzer operators manual found on page 10-1 When to Calibrate - "Calibrate your instrument: During installation After a Beckman Coulter service representative has replaced an analytical component. as instructed by a Beckman Coulter representative." Further review found under the heading When to Verify Calibration - "Verify calibration of your instrument: As required by your laboratory procedures, and as required by local or national regulations. When cell controls, such as AcT 5diff Control Plus, exceeds the manufacturer's defined acceptable limits" 2. Review of policies and procedures found that the laboratory did not have a policy defining the frequency of calibration and or calibration verification of the Coulter AcT 5 diff hematology analyzer. 3. Review of calibration log from 2018 found that the laboratory calibrated the Coulter AcT 5 diff hematology analyzer: January 22, 2018 (installation) January 23, 2018 March 8, 2018 April 13, 2018 May 11, 2018 June 16, 2018 July 11, 2018 September 6, 2018 September 27, 2018 October 19, 2018 October 23, 2018 November 9, 2018 4. Interview of the testing person 4 on the CMS report 209 conducted on November 28,

	2018 at 3:29 PM confirmed that the laboratory did not have a written policy defining the frequency of calibration for the Coulter AcT 5diff. he stated that he " calibrates the analyzer with each new lot of Quality control material
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) 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) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on review of laboratory records and interview of facility personnel the laboratory director failed to ensure the laboratory was enrolled in a proficiency testing program for the specialties of Hematology and Chemistry (including the subspecialties of general chemistry, endocrinology and toxicology. (see D 2000)
D6082	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1) The laboratory director must ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing. This STANDARD is not met as evidenced by: An unannounced revisit was performed on 11/27/18 - 11/30/18. Based on review of the laboratory records, patient records, and confirmed in interview, the laboratory director failed to ensure the laboratory provided quality laboratory services for all aspectes of test performance. Refer to D5311, D5469
D6168	TESTING PERSONNEL CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: An unannounced revisit was performed on 11/27/18 - 11/30/18. Based on a review of the Laboratory Personnel Report, personnel records and staff interview, it was revealed that 8 of 13 testing personnel performing high complexity testing did not have the appropriate education credentials required to perform high complexity testing (refer to D6171).
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b)

(b) Meet one of the following requirements: (b)(1) 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 or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations.

	This STANDARD is not met as evidenced by: An unannounced revisit was performed on 11/27/18 - 11/30/18. Based on a review of personnel files and interview of facility personnel it was revealed that the facility failed to provide documentation of education credentials to quality all testing personnel to perform high complexity testing at the end of the survey on 11/30/18. Findings were: 1. A review of facility personnel files revealed that 8 of 13 testing personnel failed to have appropriate educational documentation available for review at the time of the survey to qualify them to perform high complexity testing. Testing Person #1, hire date 3/12/18 Testing Person #12, hire date 2/15/18 Testing Person #13, hire date 7/19/18 Testing Person #8, hire date 11/14/18 Testing Person #9, hire date 11/19/18 Testing Person #5, hire date 3/1/18 Testing Person #4, hire date 7/30/18 Testing Person #7, hire date 10/8/18 2. An interview of the testing person #12 on 11/30 /2018 at 1125 hours in the break room confirmed the above findings.