| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 45D2128678 | 06/03/2026 |
| **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 |
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| **D0000** | As a result of complaint TX00562383, an unannounced survey of the facility was conducted on 06/03/2026. The laboratory was found out of compliance with the CLIA regulations (42 CFR Part 493, Requirements for Laboratories). The CONDITIONS NOT MET were: D5300 - 42 C.F.R. 493.1240 Condition: Preanalytic systems; D6076 - 42 C.F.R. 493.1441 Condition: Laboratories performing high complexity testing; laboratory director; |
| **D5300** | PREANALYTIC SYSTEMS<br>CFR(s): 493.1240<br><br>Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in 493.1241 and 493.1242, 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 preanalytic systems and correct identified problems as specified in 493. 1249 for each specialty and subspecialty of testing performed.<br><br>This CONDITION is not met as evidenced by:<br>Based on review of laboratory's test add-on records, computerized specimen problem logs, Client Relations department's communications and specimen problem resolution records, patient test records, quality assurance and staff interview, the laboratory failed to ensure overall quality of preanalytic systems was maintained. Findings included: 1. The laboratory failed to ensure oral test requests for "Add On" tests were followed up with written or electonic autherizations. Refer to D5303. 2. The laboratory failed to ensure patient information was transcribed accurately into the Laboratory Information System. Refer to D5309. 3. The laboratory failed to ensure sample storage temperature monitoring was documented. Refer to D5311 A & B. 4. The laboratory's quality assurance failed to identify and correct issues in Client |

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| | Relations specimen problem resolution documentation, written request documentation for Add-on tests, test order transcription and specimen storage temperature monitoring. Refer to D5391A, B, C and D. |
| **D5303** | TEST REQUEST<br>CFR(s): 493.1241(b)<br><br>(b) The laboratory may accept oral requests for laboratory tests if it solicits a written or electronic authorization within 30 days of the oral request and maintains the authorization or documentation of its efforts to obtain the authorization.<br><br>This STANDARD is not met as evidenced by:<br>Based on the review of the laboratory's records, CR to the laboratory's emails, and confirmed in an interview, the laboratory failed to follow up 9 of 9 oral test requests from 5/12/2026 to 6/1/2026 with written or electronically authorized requests regarding additional testing that may be requested at a later date by a physician. The findings were: 1. Review of the laboratory's records revealed there was not a current policy in place regarding oral test requests, and what steps are necessary to properly accept oral test requests for additional testing. 2. In an interview on 06/03/2026 at 120: 20 pm in the clinical supervisor's office, the clinical supervisor stated the add-on test procedures were as followed: A) The client called CR to request additional testing to a patient with 2 patient identifiers. B) CR called or emailed the laboratory to check if the additional testing could be added to the original tubes. C) The laboratory called or emailed CR to confirm or reject the additional testing request. D) CR called the client back to confirm additional testing or rejection. 3. Review of the additional testing request emails from 5/12/2026 to 6/1/2026 from CR revealed the laboratory failed to follow up 9 of 9 oral test requests with written or electronically authorized requests regarding additional testing that may be requested at a later date by a physician. Collection Date: 05/12/2026 Accession#: 260513BM0370 Requested Date: 05/15 /2026 Additional testing requested: Lipid Panel Collection Date: 05/15/2026 Accession#: 260516BM0177 Requested Date: 05/18/2026 Additional testing requested: Urine culture and sensitivity Collection Date: 05/19/2026 Accession#: 260521BM0248 Requested Date: 05/20/2026 Additional testing requested: Alpha-Gal IgE Panel Collection Date: 05/26/2026 Accession#: 260527BM0038 Requested Date: 05/29/2026 Additional testing requested: Vitamin D Collection Date: 05/26/2026 Accession#: 260527BM0293 Requested Date: 05/28/2026 Additional testing requested: Vitamin D, CRP (C-Reactive Protein) Collection Date: 05/27/2026 Accession#: 260529BM0124 Requested Date: 06/01/2026 Additional testing requested: HgbA1C Collection Date: 05/28/2026 Accession#: 260528BM0627 Requested Date: 06/03/2026 Additional testing requested: FSH (Follicle-Stimulating HC-Rormone), LH (Luteinizing Hormone), Progesterone, Prolactin, Testosterone free /Total Collection Date: 06/01/2026 Accession#: 260602BM0370043 Requested Date: 06/02/2026 Additional testing requested: ANA by IFA Reflex to titer and pattern Collection Date: 06/01/2026 Accession#: 260602BM0310 Requested Date: 06/01 /2026 Additional testing requested: CK (Creatine Kinase), LDH (Lactate Dehydrogenase) 4. An interview on 06/03/2065 at 13:59 pm in the middle desk area, the clinical supervisor confirmed the above findings. Key: CR=Client Relation |
| **D5309** | TEST REQUEST<br>CFR(s): 493.1241(e)<br><br>(e) If the laboratory transcribes or enters test requisition or authorization information |

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| | into a record system or a laboratory information system, the laboratory must ensure the information is transcribed or entered accurately.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory's computerized specimen problem logs, Client Relations department's specimen problem resolution records, patient test records and staff interview, the laboratory failed to ensure patient information was transcribed accurately into the LIS for one of four mislabeled patient samples reviewed from January and May 2026. Findings included: 1. Review of laboratory's computerized specimen problem logs from January and May 2026, revealed the following sample was marked as mislabeled due to mismatch in date of birth (DOB): Requisition number: 45148MB20 Sample: 260107-WM0015 Issue: Incorrect birthday on specimen Requisition form DOB: 03/03/1961 Specimen Container DOB: 3-3-1963 2. Review of Client Relations (CR) department's specimen resolution records revealed the CR obtained a copy of the chart from the provider to verify DOB for requisition number: 45148MB20, sample 260107-WM0015. The chart's DOB was documented as 03/03/1963. 3. Review of laboratory's final report for requisition number: 45148MB20, sample 260107-WM0015 revealed the report contained the wrong DOB, 03/03/1961. The laboratory's CR department failed to ensure correct DOB was input into the system after verification. 4. In an interview on 06/03/2026 at 1230 hours in the office, the laboratory's clinical supervisor confirmed the findings. |
| **D5311** | SPECIMEN SUBMISSION, HANDLING, AND REFERRAL<br>CFR(s): 493.1242(a)<br><br>(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (a)(1) Patient preparation. (a)(2) Specimen collection. (a)(3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (a)(4) Specimen storage and preservation. (a)(5) Conditions for specimen transportation. (a)(6) Specimen processing. (a)(7) Specimen acceptability and rejection. (a)(8) Specimen referral.<br><br>This STANDARD is not met as evidenced by:<br>A. Based on surveyor's observations, review of laboratory's policies/procedures, temperature records and staff interview, the laboratory failed to ensure sample storage temperature monitoring was documented for Refrigerator 5 and Freezer 6 for six of six months reviewed from January through June 2025. Findings included: 1. Surveyor's observations on 06/03/2026 at 1400 in the specimen processing area revealed samples were stored in Refrigerator 5 and Freezer 6, as indicated by labels on the devises. 2. Review of laboratory's policy "Clinical and Molecular Sample Acceptance Criteria" (document: ALTRU 08 DEPT, version 1.1, effective date: 04/29 /2026) revealed: "C. Appendix A: Clinical Samples Acceptable Devices, Shipment, Stability. ... Storage REF 2C-8C (degrees Celsius) 7 DAYS" 3. Review of laboratory's temperature records for refrigerators and freezers from January through June 2025 revealed there was no documentation of temperature monitoring for Refrigerator 5 and Freezer 6 for the six months reviewed. 4. In an interview on 06/03/2026 at 1500 hours in the clean desk area the laboratory's clinical supervisor stated that the frozen samples in Freezer 6 are for send-out to reference laboratory but confirmed that documentation of temperature recording for either Refrigerator 5 or Freezer 6 was not traceable, thus not available for review. B. Based on the direct observation of the surveyor, review of the temperature requirement from the vacutainer pack labels, the |

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| | laboratory's temperature logs, CMS 116, and confirmed in an interview, the laboratory failed to record temperature of the phlebotomy room Suite 120 that stores 3 of 3 types of vacutainers. The findings were: 1. Surveyor's direct observation on 06/03/26 at 10: 00am revealed a phlebotomy room, Suite 120, for walk-in patients and the room stored 3 types of vacutainers. BD Vacutainer Urinalysis Urine Tubes No Additive Lot#: 5260128 Exp. 2027-09-30 BD Vacutainer SST Blood Collection Tubes Lot#: 5272810 Exp. 2026-08-31 BD Vacutainer K2E 7.2 mg Blood Collection Tubes Lot#: 5225497 Exp. 2026-12-31 2. Review of the temperature requirement from the vacutainer pack labels revealed the temperature requirements for the above tubes were 4C to 25C. 3. Review of the laboratory's temperature logs revealed no temperature records or logs kept for phlebotomy room suite 120. 4. Review of the laboratory's CMS 116, signed by the laboratory director on 06/03/2026 electronically, revealed the annual volume for chemistry and hematology were 2,800,000. 5. An interview on 06 /03/2065 at 10:05 am in the clinical supervisor's office, the pre-analytical supervisor and the clinical supervisor confirmed the above findings. Key: C=Celsius CMS=Center for Medicare and Medicaid |
| **D5391** | PREANALYTIC SYSTEMS QUALITY ASSESSMENT<br>CFR(s): 493.1249(a)<br><br>(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 preanalytic systems specified at 493.1241 through 493.1242.<br><br>This STANDARD is not met as evidenced by:<br>A. Based on review of laboratory's and Client Relations (CR) department's policies /procedures/instructions, specimen problem logs, CR department's specimen resolution records, quality assurance (QA) records and staff interview, the laboratory's quality assurance (QA) failed have processes in place to ensure specimen problem resolution was documented by CR department as required for one of four sample problem categories reviewed, mislabeled samples. Findings included: 1. Review of laboratories policy "Accessioning SOP" [document: GENSOP 7 (version 5.0), effective 12/23/2025] revealed: "Mislabeled Form If a sample is received with only one identifier, a mislabeled form must be filled out ... client relations will contact the client to confirm the patient information." And, "Doctors Order Mismatch A Dr. Order Mismatch hold will be placed on samples that come with a doctor's order that does not match the panel selected on the requisition form. Client relations will then contact the client to confirm which panel needs to be performed." 2. Review of CR department's policies/procedures revealed: a. Policy "Rejection Notification SOP" (date updated: March 4, 2022) stated: " Invalid Label ... determine if the labeling issue is correctable. o If yes is marked, ask the client if they are familiar with how to correct through the portal- if yes, just remind them to have the collector make sure to provide the information that was not provided or wrong on the rejected sample. - Note: You can also e-mail the correction form ... - Once the form is returned to client relations follow these steps: Invalid Label Correction SOP" b. Policy "Invalid Label Correction SOP" (date updated: June 3, 2026) stated: "The purpose of this document is to describe the process of how to handle and update a sample once a completed invalid label correction form is received." And, "1. Review correction form to ensure it's accurately completed and is for a specimen eligible for correction. 2. Locate sample in LIS. 3. Upload completed form to LIS ... ... 6. Ensure all data entry is accurate based on req (requisition) form and name/DOB (date of birth) is accurate per correction form." 3. Review of the laboratory's "Mislabeled Specimen Correction Form" |

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| | revealed: "Labeling information on the specimen container and the request form must be identical and contain at least two unique identifiers (including FULL name and birthday). If a specimen is mislabeled, recollection of the specimen is highly recommended to eliminate any possible testing errors ... If the specimen cannot be recollected and or the client insists on analyzing the sample, they will be required to fill out this form below and return to Altru Diagnostics Lab." 4. Review of laboratory's computerized specimen problem logs from January and May 2026, revealed the following three samples were marked as mislabeled and were issued Mislabeled Specimen Correction Forms: Requisition number: 45148MB20 Sample 260107-WM0015 Requisition number: 44560MB833 Sample 260117-BM0416 and Requisition number: 26077KDC Sample 260520-YM0076 The forms had the section "TO BE COMPLETE BY THE CLIENT" and "Authorization in writing to run the sample using the corrected information ..." sections empty. 5. Review of the CR department's specimen resolution records and corresponding LIS records for the above mislabeled samples revealed there was no documentation of corrections completed by the client nor any "Authorization in writing to run the sample using the corrected information ..." as per requirements of the Mislabeled Specimen Correction Form. Further review of the information in the laboratory's LIS system provided by CR revealed the "Hold" was released, but there was no documentation or record (date/time /person contacted) of any communication with the client to obtain the correct information. 6. Review of laboratory's QA revealed the laboratory's QA did not identify or address process issues within the CR department and ensure proper documentation of CR department's activities regarding sample issues. 7. In an interview on 06/03/2026 at 1500 hours in the office the laboratory's clinical supervisor confirmed the findings. B. Based on the review of the laboratory's records, Client Relations (CR) records, CR communications with the laboratory, and confirmed in an interview, the laboratory's quality assurance failed to have processes in place to identify and correct issues with oral test requests for "Add On" tests having a follow up with written or electronic authorization requests. Refer to D5303. C. Based on review of laboratory's computerized specimen problem logs, Client Relations department's specimen problem resolution records, patient test records, quality assurance and staff interview, the laboratory's quality assurance failed to have processes in place to identify and correct issues with accurate patient information transcription into the Laboratory Information System. Refer to D5309. D. Based on surveyor's observations, review of laboratory's policies/procedures, temperature records, quality assurance and staff interview, the laboratory's quality assurance failed to have processes in place to identify and correct issues with sample storage temperature monitoring documentation. Refer to D5311. |
| **D6076** | LABORATORY DIRECTOR<br>CFR(s): 493.1441<br><br>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.<br><br>This CONDITION is not met as evidenced by:<br>Based on review of laboratory and Client Relations (CR) department's policies /procedures/instructions, specimen problem logs, CR department's communication and specimen resolution records, sample storage conditions and test records, quality assurance (QA) records and staff interviews, the laboratory director failed to provide overall oversight and management of the laboratory for one of three phases of testing, |

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| | preanalytic systems. Findings included: 1. Laboratory director failed to ensure Laboratory director failed to ensure overall quality of preanalytic systems was maintained. Refer to D6082. 2. Laboratory director failed to ensure laboratory's quality assurance for preanalytic systems was established and maintained. Refer to D6093. |
| **D6082** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(1)<br><br>(e) The laboratory director must-- (e)(1) 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;<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory and Client Relations (CR) department's policies /procedures/instructions, specimen problem logs, CR department's communication and specimen resolution records, sample storage conditions and test records and staff interviews, the laboratory director failed to ensure Laboratory director failed to ensure overall quality of preanalytic systems was maintained. Refer to D5303, D5309 and D5311. |
| **D6093** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(5)<br><br>(e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory and Client Relations (CR) department's policies /procedures/instructions, specimen problem logs, CR department's communication and specimen resolution records, sample storage conditions and test records, quality assurance (QA) records and staff interviews, the laboratory director failed to ensure laboratory's quality assurance for preanalytic systems was established and maintained. Refer to D5391A, B, C and D. |