Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2128678	09/18/2024
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
D0000	An announced survey of the laboratory was conducted 09/16/2024 through 09/18 /2024. The laboratory was found in compliance with applicable CLIA regulations (42 CFR Part 493, Requirements for Laboratories) for the specialties/subspecialties for which it was surveyed. STANDARD LEVEL DEFICIENCIES were cited.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of laboratory's proficiency testing (PT) records, PT agency's instructions, laboratory's policies/procedures and staff interview, the laboratory failed to ensure attestations were signed by laboratory director and/or technologist as required for five of eighteen reviewed PT events from 2023 and 2024. Findings included: 1. Review of laboratories proficiency testing records revealed the laboratory used the American Proficiency Institute (API) and the College of American Pathologists (CAP) as PT providers. 2. Review of PT agencies' instructions revealed: a. For API PT results - "For all PT results, attestation statement must be signed by testing personnel and the laboratory director and retained for a minimum of 2 years." b. For CAP PT results - "The laboratory director or designee and the testing personnel must sign on the result form. You may use the attestation page provided in the kit instructions or, alternatively, print, sign, and retain a copy of this page for your records and inspection purposes." 3. Review of the PT records for 2023 and 2024 revealed the following 5 of 18 reviewed PT events did not have the required signatures of either laboratory director and/or testing personnel: a. For the API events the following signatures were missing: 2024 Microbiology 1st Event was missing laboratory director's signature. 2024 Chemistry - Core 2nd event was missing

	laboratory director's signature. 2024 hematology coagulation 1st event was missing laboratory director's signature. b. For the CAP events the following signatures were missing: Event IDR-B 2023 (Infectious Disease, Respiratory Panel Survey) was missing laboratory director and testing personnel #3 signatures. Event COV2-A 2023 (SARS-CoV-2 Molecular Survey) was missing laboratory director's signature. 4 Review of laboratory's policy "SOP Proficiency Testing" (document SOP PT 011, version 3.1, last reviewed 12/27/2023) revealed: "5.1 CAP Proficiency Testing ... 6.) ... Attestation signatures from all testing personnel on the sample should be obtained." There were no protocols in place requiring laboratory director's signatures or protocols for signing attestation forms for the API PT samples. 5. In an interview on 09/16/2024 at 12:40 p.m. in the office, the laboratory's technical supervisor number 1 (as indicated on submitted form CMS 116) confirmed the findings.
D5213	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1) The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program. This STANDARD is not met as evidenced by: Based on review of laboratory's proficiency testing (PT) records, PT agency's instructions, laboratory's policies/procedures and staff interview, the laboratory failed to ensure self-evaluation was documented for results that were "Not graded" or had "Note 26" for five of eighteen PT events reviewed from 2023 and 2024. Findings included: 1. Review of laboratories proficiency testing records revealed the laboratory used the American Proficiency Institute (API) and the College of American Pathologists (CAP) as PT providers. 2. Review of PT agencies' instructions revealed: a. For API: "Laboratories are responsible for documenting and performing corrective action for failures and must perform a self-evaluation using statistics presented in the Participant Data Summary for samples that have not been graded." b. For CAP: "Your laboratory must identify all analytes with an exception reason code, review, and document the acceptability of performance as outlined below and retain documentation of review for at least two years ... Code 26 Educational Challenge - review participant summary for comparative results and document performance accordingly." 3. Further review of laboratory's PT records from 2023 and 2024 revealed the laboratory did not have documentation of self-evaluation for results that were "Not graded" or had exception code "See Note [26]" for 5 of 18 reviewed PT events as follows: a. For API events: 2024 Microbiology - 1st Event - The following results had performance designated as "Not Graded": URINE CULTURE MIC/ZONE DIAMETER VALUE MIC Microscan/FDA / Amoxicillin/Clavulanic acid MIC Microscan/FDA / Ampicillin MIC Microscan/FDA / Ampicillin/Sulbactam MIC Microscan/FDA / Cefazolin MIC Microscan/FDA / Ceftaroline MIC Microscan/FDA / Ceftriaxone MIC Microscan/FDA / Ciprofloxacin MIC Microscan/FDA / Daptomycin MIC Microscan/FDA / Gentamicin MIC Microscan/FDA / Levofloxacin MIC Microscan/FDA / Linezolid MIC Microscan/FDA / Oxacillin MIC Microscan /FDA / Penicillin MIC Microscan/FDA / Rifampin MIC Microscan/FDA / Tetracycline MIC Microscan/FDA / Trimethoprim/Sulfamethoxazole MIC Microscan /FDA / Vancomycin URINE CULTURE SUSCEPTIBILITY INTERPRETATION MIC Testing / FDA / Rifampin MIC Testing / FDA / Trimethoprim/Sulfamethoxazole 2024 Hematology/Coagulation - 2nd Event - The following results (analyte; sample number) had performance designated as "Not Graded": URINALYSIS Urobilinogen,

	UA-04 EDUCATIONAL BLOOD CELL IDENTIFICATION Basophil (DIF) (%); DIF-02 Eosinophil (DIF) (%); DIF-02 Lymphocyte (DIF) (%); DIF-02 Lymphocyte, reactive (DIF) (%); DIF-02 Monocyte (DIF) (%); DIF-02 Neutrophil, segmented (DIF) (%); DIF-02 Platelet estimate (DIF); DIF-02 RBC Morphology (DIF); DIF-02 Blood Cell ID (Educational); ECI-06 Blood Cell ID (Educational); ECI-07 Blood Cell ID (Educational); ECI-08 Blood Cell ID (Educational); ECI-09 Blood Cell ID (Educational); ECI-10 b. For CAP events: Event JIP-B 2023 Joint Infection Panel - The following results (analyte; sample number) had laboratory's grade designated as "See Note [26]": Resistance Mechanism, OTHER; JIP-06 Resistance Mechanism, OTHER; JIP-07 Resistance Mechanism, OTHER; JIP-08 Resistance Mechanism, OTHER; JIP-09 Resistance Mechanism, OTHER; JIP-10 Event IDR-B 2023 infectious Disease, Respiratory - The following results (analyte; sample number) had laboratory's grade designated as "See Note [26]": Coronavirus Strain LAB-DEVELOPED TEST; IDR-06 Coronavirus Strain LAB-DEVELOPED TEST; IDR-07 Coronavirus Strain LAB-DEVELOPED TEST; IDR-08 Coronavirus Strain LAB-DEVELOPED TEST; IDR-09 Coronavirus Strain LAB-DEVELOPED TEST; IDR-10 Event IDR-C 2023 infectious Disease, Respiratory - The following results (analyte; sample number) had laboratory's grade designated as "See Note [26]": Influenza A Serotype LAB-DEVELOPED TEST; IDR-11 Influenza A Serotype LAB-DEVELOPED TEST; IDR-12 Influenza A Serotype LAB-DEVELOPED TEST; IDR-13 Influenza A Serotype LAB-DEVELOPED TEST; IDR-14 Influenza A Serotype LAB-DEVELOPED TEST; IDR-15 Parainfluenza Serotype LAB-DEVELOPED TEST; IDR-11 Parainfluenza Serotype LAB-DEVELOPED TEST; IDR-12 Parainfluenza Serotype LAB-DEVELOPED TEST; IDR-13 Parainfluenza Serotype LAB-DEVELOPED TEST; IDR-14 Parainfluenza Serotype LAB-DEVELOPED TEST; IDR-15 Coronavirus Strain LAB-DEVELOPED TEST; IDR-11 Coronavirus Strain LAB-DEVELOPED TEST; IDR-12 Coronavirus Strain LAB-DEVELOPED TEST; IDR-13 Coronavirus Strain LAB-DEVELOPED TEST; IDR-14 Coronavirus Strain LAB-DEVELOPED TEST; IDR-15 4. Review of laboratory's policy "SOP Proficiency Testing" (document SOP PT 011, version 3.1, last reviewed 12/27/2023) revealed: "5.1 ... 11. There will be a Self-Evaluation for all the non-graded evaluations by CAP. 12. Self-Evaluation will be documented. 13. Original Evaluation will be reviewed. All the code 26 Educational Challenge results that do not match with the majority of the participants will be addressed by documenting the reasoning /explanation and appropriate action. 14. Code 26 educational challenge will be reviewed as follows: Each code 26 will be referred to the Participant Summary provided by CAP. If the majority of the participants result match with the Altru Dx result, write down the percentage and "Acceptable" next to the Result. If the AltruDx Results does not match with the majority, write explanation." There were no protocols in place requiring laboratory's self-evaluation for the API PT "Not Graded" samples. 5. In an interview on 09/16/2024 at 4:15 p.m. in the office, the laboratory's technical supervisor number 1 and technical consultant number 2 (as indicated on submitted form CMS 116) confirmed the findings.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies, the laboratory's records and staff

	interview, the laboratory failed to have documentation of performing two of two accuracy assessments in 2023 for three analytes: IGF binding protein-3 (IGFBP3), lipoprotein-associated phospholipase A2 (Lp-PLA2), and fecal immunochemical test (FIT). Findings include: 1. A review of the laboratory's policy titled 'Quality Assurance/Quality Improvement (QA/QI)' revealed the following: "The lab must participate in an external proficiency test such as CAP PT program for every test methodology that is performed in the laboratory. If no commercial proficiency test is available for a test methodology, the lab will set up parallel testing with another CLIA certified lab that is doing the test at least every 6 months (Split PT). If this is not possible, the lab must establish a system for verifying the accuracy and reliability of the test results (ex. running known, previously tested, or reference samples.)" 2. A review of the laboratory's records revealed the laboratory failed to have documentation of performing twice annual accuracy assessments for the following non-regulated analytes in 2023: - IGFBP-3 tested on the IDS- ISYS immunoassay analyzer - Lp-PLA2 tested on the Beckman Coulter DxC700 chemistry analyzer - FIT tested on the Hemosure Accu-Reader A100 analyzer 3. In an interview on 9/17/24 at 10:20 a.m. in the office, after review of the records, technical consultant #2 (as indicated on the CMS 209 form) confirmed the above findings.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on review of laboratory's proficiency testing (PT) records, PT agency's instructions, laboratory's policies/procedures and staff interview, the laboratory failed to ensure PT results' evaluation was documented for five of eight events reviewed from 2024. Findings included: 1. Review of laboratories proficiency testing records revealed the laboratory used the American Proficiency Institute (API) as one of its PT providers. 2. Review of API agencies' instructions revealed: "PERFORMANCE REVIEW AND CORRECTIVE ACTION After reviewing the evaluation reports, complete the information below and retain this form along with the enclosed reports for your records. Reviewed by(laboratory director or designee): Corrective action taken (if indicated):" 3. Further review of laboratory's PT records revealed the following 2024 PT events did not have documentation of PT results' evaluation: API 2024 Hematology/Coagulation - 1st Event API 2024 Chemistry - Miscellaneous - 1st Event API 2024 Chemistry - Core - 1st Event API 2024 Immunology /Immunohematology - 1st Event API 2024 Hematology/Coagulation - 2nd Event API 2024 Immunology/Immunohematology - 2nd Event API 2024 Chemistry - Core - 2nd Event 4. Review of laboratory's policy "SOP Proficiency Testing" (document SOP PT 011, version 3.1, last reviewed 12/27/2023) revealed the policy did not address requirements for evaluation of API PT results. 5. In an interview on 09/16/2024 at 4: 15 p.m. in the office, the laboratory's technical consultant number 2 (as indicated on submitted form CMS 116) confirmed the findings.
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 review of laboratory's Microbiology policies/procedures, patient final reports and staff interview, the laboratory failed to define protocols for microbial quantitation in culture and corresponding reporting requirements for one of two Microbiology test platforms performed by the laboratory, Urine Reflex Culture. Findings included: 1. Review of laboratory's Microbiology policies/procedures revealed the laboratory did not have protocols in place for microbial quantitation in culture and corresponding reporting requirements based on clinical relevance for organisms isolated through its Urine Reflex Culture. 2. In an interview on 09/17/2024 at 4:30 p.m. in the office, the laboratory's technical supervisor number 1 (as indicated on submitted form CMS 116) confirmed the findings.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on surveyor's observations, review of manufacturer's instructions for use, laboratory's policies/procedures, hematology analyzer's quality control records, patient test records and staff interview, the laboratory failed to ensure hematology controls were not used beyond their stability for two of three controls in use. Findings included: 1. Surveyor's observations on 09/16/2024 at 1330 hours in the laboratory revealed three opened hematology Coulter 6C Cell Controls stored in the refrigerator: Coulter 6C Cell Control Level 1 Lot number: 123175540 Opened: 9/12/24 Coulter 6C Cell Control Level 2 Lot number: 133185540 Opened: 09/06/2024 Coulter 6C Cell Control Level 3 Lot number: 143195540 Opened: 09/06/2024 2. Review of manufacturer's instructions in the package insert for the Coulter 6C Cell Controls (document C82641-AC) revealed: "*Assumes that the Instructions for Use section of the package insert is performed a maximum of 18 times within 16 days." 3. Review of laboratory's policy "DX H600 Hematology Analyzer" (approved by laboratory director on 09/16/2024) revealed: "The Coulter 6C Control must be tightly capped and stored at 2-10C. Unopened vials are good till the manufacturer expiration date. Open vial stability is 8 consecutive days." The policy did not address the maximum number

	of piercings allowed for open hematology controls. 4. Review of laboratory's QC records revealed the Coulter 6C Cell Level 2 and Level 3 Controls opened on 09/06 /2024 were used 18 times by 0800 hours on 09/13/2024. 5. Review of laboratory patient test records revealed 220 patient tests were performed from 09/13/2024 to 09 /16/2024 where controls were tested beyond their allowed number of piercings per vial. Refer to the master list for a full list of accession numbers tested. 6. In an interview on 09/16/2024 at 2:20 p.m. in the laboratory, the laboratory's testing person number 11 (as indicated on submitted form CMS 116) confirmed the findings.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i) (B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: A. Based on a review of the laboratory's verification studies from May 2023 and staff interview, the laboratory failed to have documentation of verifying four of four reference intervals for two analytes tested on the IDS- ISYS immunoassay analyzer. Findings include: 1. A review of the laboratory's verification studies for the IDS-ISYS immunoassay analyzer (serial number: B300B0573) from May 2023 revealed the laboratory failed to have documentation of verifying the following 4 reference intervals, prior to patient testing: Insulin-like Growth Factor 1 (IGF-1) for Females: 57 - 202 ng/mL Insulin-like Growth Factor 1 (IGF-1) for Males: 109 - 353 ng/mL Insulin-like growth factor binding protein 3 (IGFBP-3) for Females: 2.16 - 5.69 ug /mL Insulin-like growth factor binding protein 3 (IGFBP-3) for Males: 2.75 - 6.36 ug /mL 2. In an interview on 9/17/24 at 10:20 a.m. in the office, after review of the records, technical consultant #2 (as indicated on the CMS 209 form) confirmed the above findings. B. Based on a review of the laboratory's verification studies from 2022 and 2023 and staff interview, the laboratory failed to have documentation of performing the following studies: a) one of one precision study for Lipoprotein-associated phospholipase A2 (Lp-PLA2) tested on the Beckman Coulter DxC 700 chemistry analyzer b) three of three studies (accuracy, precision, linearity) for Homocysteine tested on the Beckman Coulter DxC 700 chemistry analyzer c) three of three studies (accuracy, precision, linearity) for T3 Uptake tested on both Beckman Coulter DxI 800 chemistry analyzers Findings include: 1. A review of the laboratory's verification records revealed the laboratory installed the following analyzers in 2022 and 2023: - Beckman Coulter DxC 700 chemistry analyzer (serial number 2022123260) installed on 5/4/23 - Beckman Coulter DxI 800 chemistry analyzer (serial number 609452) installed on 11/28/22 - Beckman Coulter DxI 800 chemistry analyzer (serial number 609750) installed on 5/4/23 2. Further review of the laboratory's verification studies revealed the laboratory failed to have documentation of performing the following studies, prior to patient testing: a) one of one precision study for Lipoprotein-associated phospholipase A2 (Lp-PLA2) tested on the Beckman Coulter DxC 700 chemistry analyzer (serial number 2022123260) b) three of three studies (accuracy, precision, linearity) for Homocysteine tested on the Beckman Coulter DxC 700 chemistry analyzer (serial number 2022123260) c) three of three

	studies (accuracy, precision, linearity) for T3 Uptake tested on both Beckman Coulter DxI 800 chemistry analyzers (serial numbers 609452 and 609750) 3. In an interview on 9/17/24 at 11:00 a.m. in the office, after review of the records, technical consultant #2 (as indicated on the CMS 209 form) confirmed the above findings. 44698 C. Based on review of laboratory's policies/procedures, verification studies for the Beckman Coulter MicroScan antimicrobial susceptibility and microorganism identification system and staff interview, the laboratory failed to document verification studies for one of one inoculation system used by the laboratory to make suspensions of specific bacterial concentrations for inoculation of the MicroScan panels, the Prompt Inoculation System. Findings included: 1. Review of the laboratory's policy "MICRO. 005 Weekly QC" (effective date 03/26/2024) for use with Beckman Coulter MicroScan antimicrobial susceptibility and microorganism identification system revealed the laboratory used the Prompt Inoculation System for preparation of bacterial suspensions for use with the MicroScan susceptibility and microorganism identification panels. 2. Review of laboratory's verification studies for the Beckman Coulter MicroScan antimicrobial susceptibility and microorganism identification system revealed the study did not include documentation of verification of the Prompt Inoculation System to verify appropriate concentrations of bacterial suspensions were achieved to ensure accurate results. 3. In an interview on 09/17/2024 at 3:30 p.m. in the office, the laboratory's technical supervisor number 1 (as indicated on submitted form CMS 116) confirmed the findings.
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on review of laboratory's DXH 600 hematology analyzer's user manual, instrument's function check documents and onboard logs, laboratory's policies /procedures, patient test logs and staff interview, the laboratory failed to ensure DXH 600 analyzer's required background checks were documented for nine of one hundred and six days reviewed from May through August 2024. Findings included: 1. Review of laboratory's DXH 600 hematology analyzer's user manual (document B26647AG) revealed: "Running Daily Checks on Individual Modules ...3 Select OK to run Daily Checks 4 Review Daily Checks Be aware that the system automatically repeats the failed Background Check cycle one time." 2. Review of laboratory's policy "DX H600 Hematology Analyzer" (approved by laboratory director on 09/16/2024) revealed: "Perform Daily Instrument Checks. Daily Checks must pass." 3. Review of DXH 600 hematology analyzer's daily function check documents and onboard logs from May through August 2024 revealed the following 9 of 106 reviewed days instrument's Background Checks were not documented: Date: 05/31/2024 06/22/2024 06/29/2024 07/08/2024 07/19/2024 07/20/2024 07/23/2024 08/03/2024 08/06/2024 4. Review of laboratory's patient test logs for the above dates revealed the following 624 patient samples were tested on the DX H600 hematology analyzer without the documentation of background checks: Date: Tests performed: 05/31/2024 60 06/22/2024 74 06/29 /2024 32 07/08/2024 3 07/19/2024 75 07/20/2024 99 07/23/2024 103 08/03/2024 44

	08/06/2024 134 Refer to the master list for a full list of accession numbers tested. 5. In an interview on 09/17/2024 at 9:30 a.m. in the laboratory, the laboratory's testing person number 11 (as indicated on submitted form CMS 116) confirmed the findings.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) 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 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 a review of the laboratory's records, the calibration verification records, and staff interview, the laboratory failed to have documentation of performing calibration verification procedures every six months in 2023 and 2024 for one of one analyte tested on the Beckman Coulter DxI 800 chemistry analyzer and two of two analytes tested on the IDS- ISYS immunoassay analyzer. Findings include: 1. A review of the laboratory's records for the Beckman Coulter DxI chemistry analyzer revealed T3 Uptake was calibrated using 1 calibrator and the laboratory tested 2 levels of quality control once a day, thus calibration verification was required at least every 6 months. 2. A review of the laboratory's records for the IDS- ISYS immunoassay analyzer revealed Insulin-like Growth Factor 1 (IGF-1) and Insulin-like growth factor binding protein 3 (IGFBP-3) were calibrated using 2 calibrators and the laboratory tested 3 levels of quality control once a day, thus calibration verification was required at least every 6 months. 3. A review of the calibration verification records revealed the laboratory performed calibration verification procedures for T3 Uptake, IGF-1, and IGFBP-3 on the following dates but the laboratory failed to have documentation of performing a calibration verification in 2023 and 2024: T3 Uptake on DxI serial number: 609452 Calibration verification run 11/28/22 Next calibration verifications due: May 2023, November 2023, May 2024 T3 Uptake on DxI serial number 609750 Calibration verification run 5/4/23 Next calibration verifications due: November 2023, May 2024 IGF-1 and IGFBP-3 on the IDS- ISYS serial number: B300B0573 Calibration verification run 5/17/23 Next calibration verifications due: November 2023, May 2024 4. In an interview on 9/18/24 at 1:50 p.m. in the laboratory, after review of the records, technical consultant #2 (as indicated on the CMS 209 form) confirmed the above findings.

D5471	CONTROL PROCEDURES CFR(s): 493.1256(e)(1)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(i) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: A. Based on review of laboratory's media receipt logs for its microbiology department, policies/procedures, microbiology quality control (QC) records, patient test statistics and staff interview, the laboratory failed to document QC for media for eleven of eleven instances from May to August 2024 QC was required to verify product performance prior to use with patient samples. Findings included: 1. Review of laboratory's media receipt logs for its microbiology department revealed the following media were delivered to the laboratory: Blood Agar, 5% Sheep Blood, 100 pack Lot: Received: 103070 04/19/2024 116970 05/20/2024 128753 06/20/2024 144207 07/18/2024 149660 07/31/2024 164775 09/06/2024 Columbia CAN with 5% Sheep Blood/ MacConkey Biplate, 100 pack Lot: Received: 100390 04/11/2024 120542 05/20/2024 140250 07/10/2024 152300 08/06/2024 168282 09/13/2024 2. Review of laboratory's policies/procedures revealed the laboratory did not have protocols in place to address QC for microbiology media to verify media's integrity, sterility, ability to support/inhibit growth and reactivity. 3. Review of microbiology quality control (QC) records revealed there was no documentation of QC for the above media prior to use with patient samples. 4. Review of laboratory's patient test statistics from May to August 2024 revealed the laboratory performed 259 culture tests where the above media was used. 5. In an interview on 09/17/2024 at 3:30 p.m. in the office, the laboratory's technical supervisor number 1 (as indicated on submitted form CMS 116) confirmed the findings. B. Based on review of laboratory's reagent onboarding logs for its microbiology MicroScan instrument, manufacturer instructions, policies/procedures, microbiology quality control (QC) records, random patient test records and staff interview, the laboratory failed to document QC for MicroScan reagents for one of thirteen instances from May to August 2024 QC was required to verify product performance prior to/concurrent with use with patient samples. Findings included: 1. Review of laboratory's reagent onboarding logs for its microbiology MicroScan instrument revealed the following new MicroScan reagents were placed into use on the instrument as follows: On 05/22/2024: Reagent: Lot: TDA 2024-09-06 NIT1 2024-08-23 NIT2 2024-08-21 PEP 2024-10-05 IND 2024-08-22 VP1 2024-08-31 VP2 2024-11-27 On 06/22/2024: Reagent: Lot: VP1 2025-05-17 On 07/06/2024: Reagent: Lot: VP2 2024-12-18 NIT2 2024-12-29 On 07/09/2024: Reagent: Lot: IND 2024-09-22 NIT1 2024-09-19 VP1 2024-12-18 Key: TDA = MicroScan Ferric Chloride Reagent NIT1 = MicroScan 0.8% Sulfanilic Acid Reagent NIT2 = MicroScan 0.5% N,N-Dimethylalphanaphthylamine Reagent PEP = MicroScan Peptidase Reagent IND = MicroScan Kovac's Reagent VP1 = MicroScan 40% Potassium Hydroxide Reagent VP2 = MicroScan Alpha Naphthol Reagent 2. Review of the manufacturer's instructions "Quality Control Testing for MicroScan Reagents" (Technical Support bulletin TSB 150, Rev. D, 2024-06) revealed: "Instruction There are Clinical and Laboratory Improvement Amendments (CLIA) requirements for quality control (QC) testing of each new lot number or shipment of

	reagents with live organisms to determine a positive and negative reaction ... this requirement has also been demonstrated in College of American Pathologists (CAP) surveys and also applies to the reagents used on MicroScan panels ..." 3. Review of laboratory policy "Quality Assurance/Quality Improvement (QA/QI)" (GENSOP 10, effective 12/27/2023) revealed: "New reagent lots must be qualified by running assay with a previously run or known sample concurrently or prior to being placed into service." 4. Review of microbiology QC records revealed there was no QC documented for the new reagent lots prior to or concurrent with patient testing for reagents onboarded on 06/22/2024. QC was documented with the next weekly QC cycle on 06/29/2024. 5. Review of random patient test records revealed 240622YM00008 patient sample was tested on 06/24/2024 using the new lots of MicroScan reagents prior to their QC performance verification. 6. In an interview on 09/17/2024 at 4:00 p.m. in the office, the laboratory's technical supervisor number 1 (as indicated on submitted form CMS 116) confirmed the findings.
D5507	BACTERIOLOGY CFR(s): 493.1261(b)(c) (b) For antimicrobial susceptibility tests, the laboratory must check each batch of media and each lot number and shipment of antimicrobial agent(s) before, or concurrent with, initial use, using approved control organisms. (b)(1) Each day tests are performed, the laboratory must use the appropriate control organism(s) to check the procedure. (b)(2) The laboratory's zone sizes or minimum inhibitory concentration for control organisms must be within established limits before reporting patient results. (c) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review of laboratory's quality control records (QC), manufacturer instructions, CLSI document M50-A, laboratory's verification studies, patient test records and staff interview, the laboratory failed to ensure quality control for antimicrobial susceptibility testing (AST) was performed each day of use for one of one AST methods used by the laboratory from May 6 to June 4 2024 (testing period prior to approval of streamlined QC), the AST by Beckman Coulter MicroScan panels. Findings included: 1. Review of laboratories QC records revealed the laboratory used 2 panels to perform AST testing, the MicroScan PC45 (Gram Positive Panel) and the NUC101 (Gram Negative Panel). QC on AST MicroScan panels was performed once each week of use. 2. Review of manufacturer's instructions for the PC45 (document C29868-AG) and the NUC101 (document C62720-AF) AST panels revealed: "Key indicators for Quality Control are provided for streamlined QC per CLSI document M50-A. Before implementing the streamlined QC program, refer to the M50-A document for details and check with applicable regulatory agencies and inspecting groups to confirm acceptance." 3. Review of the CLSI (Clinical and Laboratory Standards Institute) document M50-A revealed: "The user should integrate the manufacturer's risk mitigation information (risk assessment) with the unique characteristics of its environment to develop effective QC protocols for in vitro diagnostic devices. Environmental characteristics can include unique factors (eg, personnel competency, testing location, test volume, temperature) that may impact test results." And, "The user must meet the following responsibilities for each MIS to initiate performance of streamlined QC: 1. Maintain current documentation of the manufacturer's conformance with ISO 1348520 and QSR5 requirements as described in Section 6.1. This includes certification in the form of a COC, COA, or a

	certification statement in the manufacturer's instructions for use. 2. Meet one of the following: a. If the user has performed a verification study for the MIS to demonstrate it can obtain performance specifications comparable to the manufacturer, as described in the CLIA regulations at 42 CFR 493.1253(b)(1),7 streamlined QC may be implemented immediately. Documentation of the verification study must be available." 4. Review of laboratory's verification studies for the MicroScan panels PC-45 and NUC 101 (document MICRO 001 MicroScan Studies Protocol, effective date 06/04/2024) revealed: "4 CONCLUSION ... The performing laboratory is now able to move from daily QC to weekly QC ..." 5. Further review of the verification studies for the MicroScan panels PC-45 and NUC 101 revealed there was no documentation of Risk Assessment with unique characteristics of the laboratory's environment to mitigate validity of streamlined QC. 6. Review of laboratory's patient test records from May 6 to June 4, 2024 (testing period prior to approval of streamlined QC) revealed the following patient samples were tested without daily AST QC: Sample: 240508YM0093 Panel type: PC45 Date tested: 05/08/2024 Sample: 240508YM0093 Panel type: NUC101 Date tested: 05/10/2024 Sample: 240507YM0010 Panel type: PC45 Date tested: 05/10/2024 Sample: 240531YM0077 Panel type: PC45 and NUC101 Date tested: 05/31/2024 7. In an interview on 09/17/2024 at 2:15 p.m. in the office, the laboratory's technical supervisor number 1 (as indicated on submitted form CMS 116) confirmed the findings.
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. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on a review of the laboratory's records and staff interview, the laboratory failed to have documentation of performing one of two analyzer comparison studies in 2023 between the two Beckman Coulter DxC 700 chemistry analyzers and the two Beckman Coulter DxI 800 chemistry analyzers. Findings include: 1. A review of the laboratory's records revealed the laboratory used the following analyzers for testing in 2023: - 1 Beckman Coulter DxC 700 chemistry analyzer (serial number 2022092979) installed in November 2022 - 1 Beckman Coulter DxC 700 chemistry analyzer (serial number 2022123260) installed in May 2023 - 1 Beckman Coulter DxI 800 chemistry analyzer (serial number 609452) installed in November 2022 - 1 Beckman Coulter DxI 800 chemistry analyzer (serial number 609750) installed in May 2023 * Comparison studies were performed between the two Beckman Coulter DxC 700 chemistry analyzers and the two Beckman Coulter DxI 800 chemistry analyzers in May 2023. 2. Further review of the laboratory's records revealed the laboratory failed to have documentation of performing a second comparison study in 2023 between the two DxC analyzers and the two DxI analyzers. 3. In an interview on 9/17/24 at 3:30 p. m. in the office, after review of the records, technical supervisor #2 (as indicated on the CMS 209 form) confirmed the above findings.
D5801	TEST REPORT CFR(s): 493.1291(a)

	The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: Based on a review of patient test reports, the laboratory's policies, the laboratory's records, and staff interview, the laboratory failed to ensure that eleven of eleven tests, that formulate results from calculated data, were verified in the LIS (laboratory information system) in 2024. Findings include: 1. A random review of patient test records from 2024 revealed the following patient reports included 11 tests, that formulate results from calculated data: Patient ID: 44674CB130 Resulted: 8/14/24 Patient ID: CB789658 Resulted: 8/14/24 Patient ID: CB789295 Resulted: 8/16/24 Patient ID: 44461CC338 Resulted: 8/21/24 Patient ID: 44461CC333 Resulted: 8/27 /24 Patient ID: CB795347 Resulted: 8/28/24 Patient ID: CB789794 Resulted: 8/29/24 Calculated tests: - Albumin/Globulin Ratio (AG Ratio) - Anion Gap - Estimated Glomerular Filtration Rate (eGFR) - Globulin - Low-density Lipoprotein (LDL) - Cholesterol/High Density Lipoprotein (HDL) Ratio - Non- HDL Cholesterol - Total Iron Binding Capacity (TIBC) - Testosterone, Free - Apolipoprotein B/A1 Ratio - Estimated Average Glucose (eAG) 2. A review of the laboratory's policies revealed the laboratory failed to have documentation of a policy that included the formulas for how the 11 tests listed above were calculated. 3. A review of the laboratory's records revealed the laboratory failed to have documentation of verifying the calculations in the LIS to ensure the calculations were accurate. 4. In an interview on 9/17/24 at 11: 20 a.m. in the laboratory, after review of the records, technical supervisor #2 (as indicated on the CMS 209 form) confirmed the findings.
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 review of laboratory's microbiology culture reports and staff interview, the laboratory failed to document microbial quantitation in culture and its clinical relevance for six of six random culture reports reviewed from June, July and August 2024. Findings included: 1. Review of laboratory's random final reports for Urine Reflex Culture tests from June, July and August 2024 revealed no quantitation of organisms obtained from the culture (colony forming units/milliliter - CFU/mL), or interpretative criteria. Reviewed culture reports were: Sample: 240605YM0047

	Tested: 06/04/2024 Organism isolated with AST (antimicrobial susceptibility testing): Enterococcus faecalis Sample: 240622YM0008 Tested: 06/22/2024 Organism isolated with AST: Enterobacter cloacae Sample: 240710YM0021 Tested: 07/10/2024 Organism isolated with AST: Escherichia coli Sample: 240710YM0022 Tested: 07/10 /2024 Organism isolated with AST: Providencia stuartii and Staphylococcus cohnii subspecies cohnii Sample: 240806YM0049 Tested: 08/06/2024 Organism isolated with AST: Streptococcus agalactiae (Group B) Sample: 240822YM0006 Tested: 08/22 /2024 Organism isolated with AST: Pseudomonas aeruginosa 2. Further review of the final culture reports revealed culture reports were bundled up with molecular amplification findings. Molecular and culture reports did not correlate (240710YM0022 sample's UTI-ABR Molecular Assay Results contained Proteus mirabilis and Providencia stuartii), and reports did not have any explanation for the discrepancy. The reports did not specify that the organisms for which susceptibility was performed were isolated from reflex culture. There were no interpretative criteria included as to the clinical relevance of the culture's findings. 3. In an interview on 09 /17/2024 at 4:30 p.m. in the office, the laboratory's technical supervisor number 1 (as indicated on submitted form CMS 116) confirmed the findings.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on a review of the laboratory's submitted CMS 209 form, the laboratory's records, the laboratory's personnel records, and staff interview, the laboratory failed to have documentation of the technical consultant performing a competency assessment, at least twice during the first year of testing, for one of seven testing personnel performing moderate complexity testing in 2023 and 2024. Findings include: 1. A review of the laboratory's submitted CMS 209 form revealed the laboratory identified 7 testing personnel performing moderate complexity testing. 2. A review of the laboratory's records revealed the laboratory performed moderate complexity testing on the following: - Beckman Coulter DxH 600 hematology analzyer - 2 Beckman Coulter DxC 700 chemistry analyzers - 2 Beckman Coulter DxI 800 analyzers - Hemosure Accu-Reader A100 analyzers - IDS- ISYS immunoassay analyzer - Urinalysis microscopic examinations 3. A review of the laboratory's personnel records revealed the following testing personnel, their hire date, and date(s) a competency assessment was performed: a) Testing person #3 Hire date: April 2023 Competency assessment performed: April 2023 Based on the hire date, testing person #3 should have had at least 2 competency assessments performed prior to April 2024. 4. In an interview on 9 /16/24 at 3:00 p.m. in the laboratory, after review of the records, technical consultant #2 (as indicated on the CMS 209 form) confirmed the above findings.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

	This STANDARD is not met as evidenced by: Based on a review of the laboratory's submitted CMS 209 form, personnel files, and staff interview, the laboratory failed to have documentation of the technical consultant performing a competency assessment on two of seven testing personnel in 2023 for moderate complexity testing. Findings include: 1. A review of the laboratory's submitted CMS 209 form revealed the laboratory identified 7 testing personnel performing moderate complexity testing in 2023. 2. A review of the laboratory's personnel records revealed the laboratory failed to have documentation of the technical consultant performing a competency assessment for testing person #1 and testing person #5 for moderate complexity testing on the following: - Beckman Coulter DxH 600 hematology analzyer - 2 Beckman Coulter DxC 700 chemistry analyzers - 2 Beckman Coulter DxI 800 analyzers - Hemosure Accu-Reader A100 analyzers - IDS- ISYS immunoassay analyzer - Urinalysis microscopic examinations 3. In an interview on 9/16/24 at 3:00 p.m. in the laboratory, after review of the records, technical supervisor #2 (as indicated on the CMS 209 form) confirmed the above findings.
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 a review of the laboratory's policies, the laboratory's submitted CMS 209 form, the laboratory's records, personnel records, and staff interview, the laboratory failed to have documentation of training for three of seven testing personnel prior to performing moderate complexity testing in 2022 and 2023. Findings include: 1. A review of the laboratory's policy titled 'Quality Assurance/ Quality Improvement (QI /QA)' revealed the following: "New Methodologies - Whenever a new methodology or instrument is introduced into clinical workflow of the lab, there must be documentation of training of all staff that will be performing the procedure." 2. A review of the laboratory's submitted CMS 209 form revealed the laboratory identified 7 testing personnel performing moderate complexity testing on the Hemosure Accu-Reader A100 analyzer and the Beckman Coulter DxI 800 analyzer. 3. A review of the laboratory's records revealed the following new instrumentation and the install dates: a) Hemosure Accu-Reader A100 analyzer - installed September 2023 b) Beckman Coulter DxI 800 (serial number 609452) - installed November 2022 c) Beckman Coulter DxI 800 (serial number 609750) - installed May 2023 4. A review of the laboratory's personnel records revealed the laboratory failed to have documentation of training for the following testing personnel prior to performing patient testing: - Testing person #1 missing training for the Hemosure Accu-Reader A100 analyzer and the Beckman Coulter DxI 800 analyzer - Testing person #2 missing training for the Hemosure Accu-Reader A100 analyzer - Testing person #5 missing training for the Hemosure Accu-Reader A100 analyzer and the Beckman Coulter DxI 800 analyzer 5. In an interview on 9/16/24 at 3:00 p.m. in the laboratory, after review of the records, technical consultant #2 (as indicated on the CMS 209 form) confirmed the above findings.
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii)

	The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method. This STANDARD is not met as evidenced by: Based on review of laboratory's policies/procedures, verification studies and staff interview the laboratory director failed to ensure verification studies were completed for two of two test systems used by the laboratory in 2023 and 2024. Refer to D 5421 A and B.
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. This STANDARD is not met as evidenced by: Based on review of laboratory's proficiency testing (PT) records, PT agency's instructions, laboratory's policies/procedures and staff interview, the laboratory director failed to ensure PT was evaluated for two of two PT programs used by the laboratory in 2023 and 2024. Refer to D5213 and D5221.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of laboratory's quality control (QC) records, policies, procedures and staff interview, the laboratory director failed to ensure QC was maintained for three of tree test system used by the laboratory, hematology cell count, microbiology culture and automated microbiology test system. Refer to D5417, D5507 and D5471.
D6098	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(8) The laboratory director must ensure that reports of test results include pertinent information required for interpretation. This STANDARD is not met as evidenced by: Based on review of laboratory's patient reports and staff interview, the laboratory director failed to ensure reports had information relevant for interpretation of results for two of two test systems, Microbiology Culture and Calculated Chemistry results. Refer to D5801 and D5805.

D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must 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 a review of the laboratory's submitted CMS 209 form, the laboratory's personnel records, and staff interview, the laboratory director failed to ensure documentation of training for two of eight testing personnel performing high complexity testing on the QuantStudio 12K Flex systems in 2023. Findings include: 1. A review of the laboratory's submitted CMS 209 form revealed the laboratory identified 8 testing personnel performing Real-Time Polymerase Chain Reaction (RT-PCR) testing on the QuantStudio 12K Flex systems. 2. A review of the laboratory's personnel records revealed testing person # 5 and testing person #6 failed to have documentation of training for RT-PCR testing on the QuantStudio 12K Flex systems. 3. In an interview on 6/16/24 at 2:55 p.m. in the office, after review of the records, the technical supervisor confirmed the above findings.