

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2128678	(X3) Date Survey Completed 09/24/2026
Name of Provider or Supplier Altru Diagnostics Inc	Street Address, City, State 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 09/22/2026 through 09/24/2026. The laboratory was found in substantial 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.
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 a review of the laboratory's submitted CMS 209 form, the laboratory's policies, the laboratory's personnel records, and staff interview, the laboratory failed to have a policy for performing competency assessments for laboratory consultants and failed to perform competency assessments for two of two technical consultants in 2025. Findings include: 1. A review of the laboratory's submitted CMS 209 form revealed the laboratory identified 2 technical consultants. 2. A review of the laboratory's policies revealed the laboratory failed to have a policy that included competency assessment requirements for laboratory consultants. 3. A review of the laboratory's personnel records revealed the laboratory failed to have documentation of a competency assessment for both technical consultants in 2025. 4. In an interview on 9/22/26 at 11:40 a.m. in the office, after review of the records, technical consultant #1 confirmed the above findings.
D5219	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(2)

(c)(2) Any test or procedure listed in subpart I of this part for which compatible proficiency testing samples are not offered by a CMS-approved proficiency testing program.

This STANDARD is not met as evidenced by:

Based on review of laboratory's test menu, policies/procedures, instrument printouts and patient reports, proficiency testing (PT) records and staff interview, the laboratory failed to ensure accuracy verification of two of two microbial susceptibility tests without compatible PT samples offered (Gentamycin Synergy and Streptomycin Synergy) was documented in 2025 and 2026. Findings included: 1. Review of laboratory's test menu revealed the laboratory performed Urine Culture organism identification and sensitivity using the Beckman Coulter DXM 1096 MicroScan WalkAway Positive Combo 45 (PC45) panels. 2. Review of laboratory's policy "Proficiency Testing Policy, Altru DX Molecular Department and Microbiology Section, ADX-M SOP 011" (last reviewed 04/01/2026) revealed: "Internal proficiency testing must be performed for any analytes not covered by CAP or SPLIT PT." 3. Review of DXM 1096 MicroScan WalkAway PC45 panels instrument printouts and random patient results revealed the reported antimicrobial susceptibility for Enterococcus included Gentamycin Synergy and Streptomycin Synergy. 4. Review of laboratory's College of American Pathologists Urine Culture Survey instructions revealed the PT did not include Gentamycin Synergy and Streptomycin Synergy as part of the susceptibility evaluation for Gram positive organisms. 5. Review of laboratory's PT records revealed the laboratory did not have documentation of "internal proficiency testing" verification of accuracy of testing for Gentamycin Synergy and Streptomycin Synergy in 2025 and 2026. 6. In an interview on 09/22/2026 at 1336 hours in the office, the laboratory's Testing Person number 13 (as indicated on submitted From CMS 209) confirmed the findings.

D5415

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(c)

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

This STANDARD is not met as evidenced by:

Based on a review of the laboratory's policies, surveyor observation, and staff interview, the laboratory failed to document the lot number, date frozen, and expiration date on ten of ten vials of aliquoted Tosoh Bioscience Hemoglobin A1c Control material for testing on the Tosoh G8 analyzer in September 2026. Findings include: 1. A review of the laboratory's policy titled 'Tosoh G8 HbgA1c Analyzer' revealed the following: "- Reconstitution: Reconstitute the third-party control per the manufacturer's package insert (typically 250uL of DI water). Cap immediately after reconstitution. - Aliquoting: Aliquot 10uL of reconstituted control into labeled micro-tubes. Cap each tube immediately. - Labeling: Label each aliquot tube with: material name, level, lot number, date frozen, and expiration date." 2. Surveyor observation of the laboratory's freezer on 9/23/26 at 9:54 a.m. revealed the following 10 vials of aliquoted Tosoh Bioscience Hemoglobin A1c control material: - 5 vials labeled G8 L - 5 vials labeled G8 H *All 10 vials failed to include the lot number, date frozen, and

	expiration date. 3. In an interview on 9/23/26 at 9:54 a.m. in the laboratory, after review of the records, technical consultant#1 confirmed the above findings.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (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 observation, the laboratory's patient test records, and staff interview, the laboratory failed to ensure two of two Iris System analyzer reagents, used for patient urinalysis testing in August and September 2026, were not used beyond their expiration dates. Findings include: 1. Surveyor observation of the laboratory on 9/24/26 at 11:00 a.m. revealed the following Iris System analyzer reagents were being used for testing and were beyond their expiration date: - Iris System Cleanser Lot number: 069-25 Expiration Date: 8/31/26 Open date: 8/14/26 - Iris System Diluent Lot number: 083-25 Expiration Date: 2/28/26 Open date: 8/28/26 2. A review of laboratory's patient test records revealed the laboratory estimated performing 180,000 urinalysis tests annually. 3. In an interview on 9/24/26 at 11:00 a.m. in the laboratory, after review of the records, technical consultant #1 confirmed the above findings.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) (b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(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: Based on surveyor's observations, review of laboratory's test menu, policies /procedures, new instrument verification studies and staff interview, the laboratory failed to document verification of accuracy and normal ranges verification, and follow its own protocols for documentation for instrument verification studies for three of three Beckman Coulter DXI9000 chemistry analyzers implemented in August 2025. Findings included: 1. Surveyor's observations on 09/22/2026 at 0910 hours during the laboratory tour revealed the laboratory used three new Beckman Coulter DXI9000 chemistry analyzers Serial Numbers (SN): 300620 300636 300652 2. Review of laboratory's provided Test Menu revealed the laboratory tested 29 analytes on the Beckman Coulter DXI9000 chemistry analyzers. 3. Review of laboratory's policy "Laboratory Policy: Test Verification & Validation" (policy ALTRU 72 DEPT LAB-VAL-POL, approved 6/23/2026) revealed: "The following items are required for every study, regardless of type: Written study plan (pre-execution) with Laboratory Director signature ... Acceptance determination record: each performance parameter listed with its stated acceptance threshold (source cited), the laboratory's obtained

	result in a pass/fail determination ... Completed study summary report with Laboratory Director review and signature." And, "Requirement: Accuracy Minimum Protocol Requirement: Replicates of linearity material or patient samples (3-5 reps per level)." The policy did not address the requirement of verifying normal ranges. 4. Review of new instrument verification studies for the above three Beckman Coulter DXI9000 instruments SN 300620, 300636 and 300652 revealed the studies were completed in August 2025, however, there was no documentation of accuracy or normal range verification for any analyte tested. Further review of these verification studies revealed there was no documentation of a written study plan or a completed study summary report for these instruments. 5. In an interview on 09/23/2026 at 1335 hours in the office, the laboratory's Technical Consultant number 1 (as indicated on submitted From CMS 209) confirmed the findings.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) (a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on review of manufacturer instructions, laboratory's policies/procedures, instrument maintenance logs and staff interview, the laboratory failed to follow its own protocols and document Quant Studio 12K Flex analyzers' weekly maintenance for two of five Quant Studio 12K Flex analyzers in use in 2025 and 2026. Findings included: 1. Review of manufacturer instructions "Applied Biosystems Instrument Logbook" (Part Number:4384647 Rev. A, 05/2007) revealed: " - routine cleaning of components such as sample compartment windows ... - routine maintenance such as vent cleaning" 2. Review of laboratory's policy "SOP INSTRU 013 SOP 013 Instrument Qualification" (last revised 06/09/2026) revealed: "10.3 Quant Studio 12K Flex system Weekly Maintenance Perform Quant Studio 12K Flex instrument Self-Test Power off computer that controls Quant Studio 12K Flex Clean the Plate Adaptor, Sample Block and Heal Cover with 95% Ethanol" The protocols did not address vent cleaning. 3. Review of laboratory's Quant Studio 12K Flex systems' maintenance records for 2025 and 2026 revealed the following weeks instrument maintenance was not documented for two of five analyzers in use: Quant Studio 12K Flex Serial Number (SN) 285881752 (QS4) did not have documentation of weekly maintenance for the week of: 01/05/2025 - 01/11/2025 01/12/2025 - 01/18/2025 08/24/2025 - 08/30/2025 02/02/2026 - 02/08/2026 Quant Studio 12K Flex SN 285881702 (QS5) did not have documentation of weekly maintenance for the week of: 01/05/2025 - 01/11/2025 01/12/2025 - 01/18/2025 01/19/2025 - 01/25/2025 03/30/2025 - 04/05/2025 04/06/2025 - 04/12/2025 4. In an interview on 09/23/2026 at 1240 hours in the office, the laboratory's General Supervisor number 1 (as indicated on submitted From CMS 209) confirmed the findings.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) (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 two of two calibration verification procedures every six months in 2026 for Insulin-like Growth Factor 1 and Insulin-like Growth Factor Binding Protein 3 tested on the two IDS- ISYS immunoassay analyzers. Findings include: 1. 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. 2. A review of the calibration verification records revealed the laboratory performed calibration verification procedures for IGF-1 and IGFBP-3 on the following dates in 2025 but the laboratory failed to have documentation of performing a calibration verification in 2026: IGF-1 and IGFBP-3 on the IDS- ISYS serial number: B300B0573 Calibration verification run 12/2025 Next calibration verification due: June 2026 IGF-1 and IGFBP-3 on the IDS- ISYS serial number: B300B1331 Calibration verification run 9 /2025 Next calibration verification due: March 2026 3. In an interview on 9/24/26 at 10:30 a.m. in the laboratory, after review of the records, technical consultant #1 confirmed the above findings. *NOTE: This is a repeat deficiency from the previous survey conducted in 09/2024.

D5445

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

(d) 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. (d)(3) At least once each day patient specimens are assayed or examined perform the following for:

This STANDARD is not met as evidenced by:

Based on surveyor's observations, review of laboratory's 2025/2026 quality control (QC) records for microorganism identification and susceptibility testing by Beckman Coulter Microscan Panels, Individualized Quality Control Plan (IQCP) and staff interview, the laboratory failed to identify IQCP targets, error frequency and

effectiveness of corrective action, and define IQCP reevaluation frequency for two of two Microscan Panels, the Positive Combo 45 (PC45) and the Negative Urine Combo 101 (NUC101). Findings included: 1. Surveyor's observations on 09/22/2026 at 0920 hours in the laboratory revealed the laboratory used the following Beckman Coulter Microscan Panels for microorganism identification and susceptibility testing: PC45 for Gram positive organisms NUC101 for Gram negative organisms 2. Review of laboratory's 2025/2026 QC records for microorganism identification and susceptibility testing by Beckman Coulter Microscan Panels revealed the laboratory performed Microscan panel QC on a weekly basis, requiring an IQCP. 3. Review of laboratory's IQCP records revealed IQCP documents "170845.217 IQCO - MIC Testing" (last approved 06/19/2024) and "170845.431 Risk Assessment - weeklytodailyQC(sic)" (last approved 10/21/2024) did not have a summary addressing which specific panels' QC was reviewed to generate the Risk Assessment, what was the extent of data collected, what was the frequency/source of errors, nor the extent of effectiveness of corrective action. These IQCP documents did not specify the required frequency of reevaluation of the IQCP. 4. In an interview on 09/22/2026 at 1400 hours in the office, the laboratory's Testing Person number 13 (as indicated on submitted From CMS 209) confirmed the findings.

D5447

CONTROL PROCEDURES
CFR(s): 493.1256(d)(3)(i)(g)

(d)(3)(i) Each quantitative procedure, include two control materials of different concentrations;

This STANDARD is not met as evidenced by:
Based on review of laboratory's policies/procedures, 2025/2026 chemistry analyzers' quality control (QC) records, patient test records and staff interview the laboratory failed to follow its own policies and document passing QC for eleven of eleven instances passing QC records were required prior to reporting patient samples on Beckman Coulter DXI9000 chemistry analyzers serial number (SN) 300620 and 300652. Findings included: 1. Review of laboratory's policy "Standard Operating Procedure: DXI9000 Access Immunoassay Analyzer" (document: LAB- DXI9000-SOP, Ver. 2.3, effective 06/2026) revealed: "Frequency: Run three levels of control for every active assay once per 24 hours on any day patient testing is performed for that assay." And, "QC Failure Action: If QC fails, do not report patient results. Follow the "Do Not Just Repeat" corrective action workflow ..." 2. Review of 2025/2026 Beckman Coulter DXI9000 chemistry analyzers' QC records revealed the following failures in QC: On Beckman Coulter DXI9000 SN 300620: Analyte: TPO Ab, Total Date: QC Level: Status: 09/25/2025 1 Rejected 09/25/2025 2 Rejected 09/25/2025 3 Rejected Analyte: Vitamin B12 Date: QC Level: Status: 03/26/2026 1 Rejected 03/26/2026 2 Rejected 03/26/2026 3 Rejected And, 03/27/2026 1 Rejected 03/27/2026 2 Rejected 03/27/2026 3 Rejected On Beckman Coulter DXI9000 SN 300652: Analyte: Vitamin B12 Date: QC Level: Status: 03/26/2026 1 Rejected 03/26/2026 2 Rejected 03/26/2026 3 Rejected And, 03/27/2026 1 Rejected 03/27/2026 2 Rejected 03/27/2026 3 Rejected Analyte: T3, Free Date: QC Level: Status: 04/02/2026 1 Rejected 04/02/2026 2 Rejected 04/02/2026 3 Rejected And, 04/04/2026 1 Rejected 04/04/2026 2 Not documented 04/04/2026 3 Not documented And, 04/06/2026 1 Rejected 04/06/2026 2 Rejected 04/06/2026 3 Rejected And, 04/07/2026 1 Rejected 04/07/2026 2 Rejected 04/07/2026 3 Rejected Analyte: Folate Date: QC Level: Status: 09/27/2025 1 Rejected 09/27/2025 2 Rejected 09/27/2025 3 Rejected And, Date: QC Level: Status: 09/29/2025 1 Rejected 09/29/2025 2 Rejected 09/29/2025 3 Rejected "QC Failure

	Action" was not documented as per SOP for any of the above QC failures. 3. The laboratory was asked for patient test records for the failed QC analytes' testing on the two DXI9000 SN 300620 and 300652, but the laboratory was unable to differentiate which sample was tested on which analyzer on dates of QC failures. 4. In an interview on 09/23/2026 at 1335 hours in the office, the laboratory's Technical Consultant number 1 (as indicated on submitted From CMS 209) 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. 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 the laboratory director reviewing and approving one of one analyzer comparison study in 2026 between the two Beckman Coulter DxH 900 hematology analyzers. Findings include: 1. A review of the laboratory's policy titled 'Instrument Comparison' revealed the following: "Laboratory Director: Defines acceptable limits (Total Allowable Error) for all analytes listed in Appendix A; reviews and approves all biannual comparison reports before results are accepted; authorizes any permanent instrument or method changes following a failed comparison." 2. A review of the laboratory's records revealed the laboratory used the following analyzers for Complete Blood Count (CBC) testing in 2026: - Beckman Coulter DxH 900 hematology analyzer (serial number: 84353940) - Beckman Coulter DxH 900 hematology analyzer (serial number: 84384070) * Comparison studies were performed between the two DxH analyzers in July and August 2026. 3. Further review of the laboratory's records revealed the laboratory director failed to review and approve the comparison studies between the two DxH analyzers, per the laboratory's policy. 4. A review of the laboratory's test records revealed the laboratory estimated performing 1,227,696 hematology tests annually. 5. In an interview on 9/22/26 at 2:00 p.m. in the office, after review of the records, technical consultant #1 confirmed the above findings.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (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 analytic systems specified in 493.1251 through 493.1283. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies, Coulter LIN-X Linearity Control Report, the laboratory's records, and staff interview, the laboratory's quality assessment program failed to ensure investigations were performed as required for two of two failed linearity studies on the two Beckman Coulter DxH 900 hematology analyzers in February 2026. Findings include: 1. A review of the laboratory's policy titled 'DxH 900 and SMS II Hematology Analyzer' revealed the following: "Linearity studies verify the upper and lower limits of the reportable range using a graded series

	of materials. - Linearity: Performed at a minimum every 6 months and after aperture bath replacement, flow cell replacement, or any service event affecting the reportable range. - Failure action: If calibration verification or linearity fails, suspend patient testing for the affected analytes, investigate root cause, perform full calibration if indicated, and re-verify before resuming patient testing." 2. A review of the laboratory's Coulter LIN-X Linearity Control Report revealed the laboratory performed linearity studies in February 2026 on the following analyzers: - Beckman Coulter DxH 900 hematology analyzer (serial number: 84353940/BJ04036) - Beckman Coulter DxH 900 hematology analyzer (serial number: 84384070/BJ06068) 3. Further review of the laboratory's Coulter LIN-X Linearity Control Report revealed the laboratory's Bias for Level 3 was outside of the acceptable range for Red Blood Cell (RBC)/ Erythrocyte (Eryth) on both analyzers: DxH analyzer BJ040036 - Expected Bias +/- 0.11 - Laboratory's Bias 0.11 DxH analyzer BJ06068 - Expected Bias +/- 0.11 - Laboratory's Bias 0.14 *Both of the laboratory's Linearity evaluation summaries for RBC/Eryth were colored red and resulted as 'Review' 4. The laboratory's quality assessment program failed to ensure investigations were performed as required for two of two failed linearity studies. 5. A review of the laboratory's records revealed the laboratory estimated performing 1,227,696 hematology tests annually. 6. In an interview on 9/22/26 at 11:50 a.m. in the office, after review of the records, technical consultant #1 confirmed the above findings.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) (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 a review of the laboratory's personnel records and staff interview, the laboratory director failed to ensure that testing personnel had documentation of training and competency was evaluated prior to patient testing in 2025.(Refer to D6055 and D6066)
D6055	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) (b)(9) unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation. This STANDARD is not met as evidenced by: Based on a review of the laboratory's records, the laboratory's personnel files, and staff interview, the technical consultant failed to evaluate and document the competency for six of six testing personnel performing testing using new methodologies, prior to patient testing in 2025. Findings include: 1. A review of the laboratory's records revealed the laboratory began testing using the following new methodologies: a) Beckman Coulter DxI immunology analyzer in August 2025 b) Beckman Coulter DxH hematology analyzer in March 2025 c) Beckman Coulter DxU urinalysis analyzer in May 2025 d) Tosoh G8 automated glycohemoglobin analyzer in

	November 2025 2. A review of the laboratory's personnel files revealed the technical consultant failed to evaluate and document the competency of the following testing personnel using the new methodologies, prior to patient testing: a) Testing person #1 - Missing competency for DxI, DxH, DxU, and G8 analyzers b) Testing person #2 - Missing competency for DxI, DxH, DxU, and G8 analyzers c) Testing person #3 - Missing competency for DxI, DxH, DxU, and G8 analyzers d) Testing person #8 - Missing competency for DxH analyzer e) Testing person #10 - Missing competency for DxI, DxU, and G8 analyzers f) Testing person #11 - Missing competency for DxI, DxH, DxU, and G8 analyzers 3. In an interview on 9/22/26 at 2:00 p.m. in the laboratory, after review of the records, technical consultant #1 confirmed the above findings.
D6066	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(4)(ii) (b)(6)(ii) Have documentation of laboratory training appropriate for the testing performed prior to analyzing patient specimens. Such training must ensure that the individual has- (b)(6)(ii)(A) 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)(6)(ii)(B) The skills required for implementing all standard laboratory procedures; (b)(6)(ii)(C) The skills required for performing each test method and for proper instrument use; (b)(6)(ii)(D) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(6)(ii)(E) A working knowledge of reagent stability and storage; (b)(6)(ii)(F) The skills required to implement the quality control policies and procedures of the laboratory; (b)(6)(ii)(G) An awareness of the factors that influence test results; and (b)(6)(ii)(H) The skills required to assess and verify the validity of patient test results through the evaluation of quality control sample values prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on a review of the laboratory's submitted CMS 209 form, personnel records, and staff interview, the laboratory failed to have documentation of training for three of eight testing personnel prior to performing moderate complexity testing in 2025. Findings include: 1. A review of the laboratory's submitted CMS 209 form revealed the laboratory identified 8 testing personnel performing moderate complexity testing in 2025. 2. A review of the laboratory's personnel records revealed the laboratory failed to have documentation of training for the following 3 testing personnel prior to performing testing: a) Testing person #8 hired 5/6/25 - Missing training documents for the DxH hematology analyzer b) Testing person #11 hired 5/5/25 - Missing training documents for the DxH hematology analyzer, DxC chemistry analyzer, DxI immunology analyzer, Tosoh G8 glycohemoglobin analyzer, DxU urinalysis analyzer c) Testing person #16 hired 6/3/25 - Missing training documents for the DxH hematology analyzer, DxC chemistry analyzer, DxI immunology analyzer, Tosoh G8 glycohemoglobin analyzer, DxU urinalysis analyzer, IDS immunoassay analyzer 3. In an interview on 9/22/26 at 11:00 a.m. in the office, after review of the records, technical consultant #1 confirmed the above findings.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) (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;

This STANDARD is not met as evidenced by:

Based on review of laboratory's policies/procedures, Individualized Quality Control Plan (IQCP) and quality control (QC) records and staff interview, the laboratory director failed to ensure QC was maintained to identify errors for two of two test platforms used by the laboratory, the Beckman Coulter Microscan Walkaway and the Beckman Coulter DXI9000 chemistry analyzers. Refer to D5445 and D5447.

D6128

TECHNICAL SUPERVISOR RESPONSIBILITIES

CFR(s): 493.1451(b)(9)

(b)(9) Thereafter, evaluations must be performed at least annually unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individuals performance must be reevaluated to include the use of the new test methodology or instrumentation.

This STANDARD is not met as evidenced by:

Based on a review of the laboratory's submitted CMS 209 form, the laboratory's personnel files, and staff interview, the technical supervisor failed to evaluate and document the competency for one of nine testing personnel performing high complexity testing in 2025. Findings include: 1. A review of the laboratory's submitted CMS 209 form revealed the laboratory identified nine testing personnel performing high complexity testing. 2. A review of the laboratory's personnel records revealed the technical supervisor failed to evaluate and document the competency for Testing person #17 for the following testing: - Respiratory TaqMan Array - NWP OA Assay + Analysis - RPP OA Assay - UTI OA Assay + Analysis - ABR OA Assay 3. In an interview on 9/22/26 at 11:20 p.m. in the office, after review of the records, technical supervisor #1 confirmed the above findings.