Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D2181582	02/22/2024
Name of Provider or Supplier	**Street Address, City, State**	
Truhealth Integrated Care	4103 S Yale Ave, Ste C, Tulsa, OK	

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	The recertification survey was performed on 02/20,21,22/2024. The laboratory was found out of compliance with the following CLIA Conditions: 493.1250; D5400: Analytic Systems 493.1405; D6000: Laboratory Director 493.1409; D6033: Technical Consultant The findings were reviewed with the technical consultant, testing person #1, and testing person #2 during an exit conference performed at the conclusion of the survey.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on a review of records, written policies and procedures, manufacturer's instructions, and interview with the technical consultant, the laboratory failed to monitor and evaluate the overall quality of analytic systems and correct identified problems for each specialty and subspecialty of testing performed during the review period of June 2022 through the current date. Findings include: (1) The laboratory failed to follow their written policy for performing quality control for CBC testing for one of one day of patient testing reviewed from 07/28/2023 through 08/15/2023. Refer to D5401; (2) The laboratory failed to have complete written procedures for one of one procedure reviewed. Refer to D5403; (3) The laboratory failed to ensure one of one policy had been approved, signed, and dated by the laboratory director. Refer to D5407; (4) The laboratory failed to ensure the laboratory humidity was maintained as required by the manufacturer of the TOSOH ALA-360 analyzer for three of three

	months reviewed. Refer to D5413; (5) The laboratory failed to ensure the manufacturer's instructions were followed for performing weekly maintenance procedures on the Sysmex XN-330 analyzer and the Siemens Viva Pro E analyzer during the review period of January 2023 through December 2023. Refer to D5429; (6) The laboratory failed to perform calibration verification procedures at least once every six months for the Piccolo test system during the review period of January 2023 through the current date. Refer to D5439; (7) The laboratory failed to perform quality control procedures each day of patient testing for eight of 40 days reviewed. Refer to D5447; (8) The laboratory failed to have a system that twice a year evaluated and defined the relationship between test results using different Piccolo reagent discs for three of 12 analytes reviewed from June 2022 through the current date. Refer to D5775; (9) The laboratory failed to have an ongoing mechanism for performing quality assessment. Refer to D5791. NOTE: D5400 was cited on the initial survey performed on 01/28/2022.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on a review of records, written policies and procedures, and interview with the technical consultant, the laboratory failed to follow their written policy for performing QC (quality control) for CBC testing for one of one day of patient testing reviewed between 07/28/2023 through 08/16/2023. Findings include: (1) On 02/20/2024 at 03: 00 pm, the technical consultant stated the following: (a) The laboratory performed CBC (Complete Blood Count) testing using the Sysmex XN-330 analyzer; (b) Three levels of XN-L CHECK QC (Quality Control) materials were tested each day of patient testing. (2) A review of the policy titled, "Complete Blood Count (CBC)" under section titled "Quality Control Procedure - QC Frequency" stated, "Test three levels of QC samples once per day using Commercial Control"; (3) A review of QC and patient test reports from 07/28/2023 through 08/16/2023 identified the laboratory had tested two levels of QC materials instead of three levels (no evidence the laboratory performed level 1 QC) for the following patients: (a) Patient #512714332831745, tested on 08/11/2023 at 11:52 am; (b) Patient #268257629503489, tested on 08/11/2023 at 01:41 pm. (4) The findings were reviewed with the technical consultant who stated on 02/21/2024 at 02:15 pm, the laboratory had not followed their policy for performing QC procedures as stated above.
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 a review of the Medica EasyLyte policy and procedure manual, and interview with the technical consultant, the laboratory failed to have complete written procedures for one of one procedure reviewed. Findings include: (1) On 02/20/2024 at 03:00 pm, the technical consultant stated the Medica EasyLyte analyzer was available for use to perform serum Lithium testing beginning 12/01/2023 (the laboratory had not yet tested a patient to date); (2) A review of the procedure titled, "EasyLyte" identified the procedure did not include the reportable range for test results that had been demonstrated during the verification of performance specifications; (3) The findings were reviewed with the technical consultant who stated on 02/22/2024 at 09: 15 am, the Medica EasyLyte policy and procedure did not include all of the required information.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on a review of policies and interview with the technical consultant, the laboratory failed to ensure one of one policy had been approved, signed, and dated by the laboratory director. Findings include: (1) On 02/20/2023 03:20 pm, the technical consultant stated the following testing was performed using the Piccolo analyzer and an IQCP (Individualized Quality Control Plan) had been developed for the test systems: (a) BUN, Calcium, Chloride, Glucose, CO2, Creatinine, Potassium, Sodium, Total Bilirubin, Total Protein, ALT (Alanine Aminotransferase), AST (Aspartate Aminotransferase), Albumin, and Alkaline Phosphatase using the Comprehensive Metabolic Panel reagent disc and plasma specimens; (b) Total Bilirubin, Total Protein, ALT, AST, Albumin, Alkaline Phosphatase, Amylase, and GGT (Gamma-Glutamyl Transferase) testing using the Liver Panel Plus reagent disc and plasma specimens; (c) Glucose, ALT, AST, Total Cholesterol, HDL (High Density Lipoprotein) Cholesterol, and Triglycerides testing using the Lipid Panel Plus reagent disc and plasma specimens; (d) BUN, Chloride, Glucose, CO2, Creatinine, Potassium, Sodium, CRP (C-Reactive Protein), and CK (Creatine Kinase) testing using the Metlyte Plus reagent disc and plasma specimens; (e) BUN, Calcium, Chloride, Glucose, CO2, Creatinine, Potassium, Sodium, LDH (Lactate Dehydrogenase), and Magnesium testing using the Basic Metabolic Panel Plus reagent disc. (2) A review of the IQCP identified the QCP (Quality Control Plan) for the test system had not been

	approved, signed, and dated by the laboratory director; (3) The records were reviewed with the technical consultant who stated on 01/21/2024 at 10:25 am, the QCP for the above test systems had not been approved, signed, and dated by the laboratory director. NOTE: D5407 was cited on the initial survey performed on 01/28/2022.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the technical consultant, the laboratory failed to ensure the laboratory humidity was maintained as required by the manufacturer of the TOSOH ALA-360 analyzer for three of three months reviewed. Findings include: (1) On 02/21/2024 at 10:00 am, the technical consultant stated that thyroid stimulating hormone (TSH), testosterone, total thyroxine (T4), Triiodothyronine (TT3), free thyroxine (FT4), and prostate specific antigen (PSA) testing were performed using the TOSOH ALA-360 analyzer; (2) A review of the operator's manual for the test system identified the manufacturer required the analyzer be operated at a humidity of 40-80% with no condensation; (3) A review of humidity records from October through December 2023 identified the humidity readings were less than 40% for three of three months as follows: (a) October 2023 - 22 of 22 humidity readings were documented as less than 40%; (b) November 2023 - 18 of 18 humidity readings were documented as less than 40%; (c) December 2023 - 19 of 19 humidity readings were documented as less than 40%. (4) The records were reviewed with the technical consultant who stated on 02/21/2024 at 10:00 am, the laboratory humidity had not been maintained as required by the manufacturer.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document 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 a review of records, manufacturer's instructions, and interview with the technical consultant, the laboratory failed to follow the manufacturer's instructions for performing weekly maintenance procedures for 12 of 12 months reviewed from January through December 2023 for Urine Drug Screen testing performed on the Siemens Viva Pro E analyzer. Findings include: (1) On 02/20/2024 at 03:40 pm, the technical consultant stated Urine Drug Screen testing, which included the analytes Amphetamines, Barbiturates, Benzodiazepines, Buprenorphine, Cannabinoids, Cocaine, Opiates, Oxycodone, and Methadone was performed using the Siemens Viva

	Pro E analyzer; (2) A review of the manufacturer's maintenance log showed the following required weekly maintenance procedures: (a) "Perform Rinse" (b) "Probe Procedure" (3) A review of maintenance logs from January through December 2023 identified no documentation weekly maintenance had been performed as follows: (a) Prior to 08/24/2023 (the prior months had been documented as performed with a checkmark only and no dates, therefore it could not be definitively concluded maintenance had been performed weekly) (b) Between 08/24/2023 and 09/05/2023 (c) Between 09/05/2023 and 09/18/2023 (d) Between 09/25/2023 and 10/27/2023 (between these dates, the maintenance had been documented with checkmarks only and no dates) (c) After 10/27/2023 (the maintenance had been documented with checkmarks only and no dates) (4) The records were reviewed with the technical consultant who stated on 02/21/2024 at 03:50 pm, the weekly maintenance had not been documented as performed as shown above; (5) The following were examples of patient Urine Drug Testing performed: (a) Patient ID #523897900761089 - testing performed on 11/13/2023 (b) Patient ID #670762210426881 - testing performed on 11 /22/2023 (c) Patient ID #673916519841793 - testing performed on 11/30/2023 NOTE: D5429 was cited on the initial survey performed on 01/28/2022. 47979 Based on a review of records, manufacturer's instructions, and interview with the technical consultant, the laboratory failed to ensure the manufacturer's instructions were followed for performing weekly maintenance procedures on the Sysmex XN-330 analyzer during the review period of January 2023 through December 2023. Findings include: (1) On 02/20/2024 at 03:00 pm, the technical consultant stated CBC (Complete Blood Count) testing was performed using the Sysmex XN-330 analyzer; (2) A review of the "XN-330 Maintenance Log" provided by the manufacturer required weekly "routine cleaning" procedures; (3) A review of maintenance logs from January 2023 through December 2023 identified weekly maintenance had not been documented as performed for the following: (a) Between 01/27/2024 and 02/06 /2024; (b) Between 07/14/2024 and 07/24/2024; (c) Between 11/27/2024 and 12/15 /2024. (4) The records were reviewed with the laboratory manager who stated on 02 /21/2024 at 1:40 pm, maintenance procedures had not been documented as performed as stated above. NOTE: D5429 was cited on the initial survey performed on 01/28 /2022.
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 records and interview with the technical consultant, the laboratory failed to perform calibration verification procedures at least once every six months for the Piccolo test system during the review period of January 2023 through the current date. Findings include: (1) On 02/20/2023 03:20 pm, the technical consultant stated the following testing was performed using the Piccolo analyzer: (a) BUN, Calcium, Chloride, Glucose, CO2, Creatinine, Potassium, Sodium, Total Bilirubin, Total Protein, ALT (Alanine Aminotransferase), AST (Aspartate Aminotransferase), Albumin, and Alkaline Phosphatase using the Comprehensive Metabolic Panel (CMP) reagent disc and plasma specimens; (b) Total Bilirubin, Total Protein, ALT, AST, Albumin, Alkaline Phosphatase, Amylase, and GGT (Gamma-Glutamyl Transferase) testing using the Liver Panel Plus reagent disc and plasma specimens; (c) Glucose, ALT, AST, Total Cholesterol, HDL (High Density Lipoprotein) and Triglycerides testing using the Lipid Panel Plus reagent disc and plasma specimens; (d) BUN, Chloride, Glucose, CO2, Creatinine, Potassium, Sodium, CRP (C-Reactive Protein), and CK (Creatine Kinase) testing using the Metlyte Plus reagent disc and plasma specimens; (e) BUN, Calcium, Chloride, Glucose, CO2, Creatinine, Potassium, Sodium, LDH (Lactate Dehydrogenase), and Magnesium testing using the Basic Metabolic Panel (BMP) Plus reagent disc. (2) A review of records from January 2023 through the current date identified no evidence calibration verification had been performed at least once every six months for each of the reagent cartridges listed above during the review period; (3) The records were reviewed with the technical consultant who stated on 02/21/2024 at 02:00 pm, calibration verification procedures had not been performed every six months as stated above; (4) The following were examples of patient testing performed: (a) Patient ID #0265683046367233 - Chloride, CO2, Potassium, Total Protein, and Albumin, testing using the CMP reagent reagent disc and Total Cholesterol, Triglycerides, and HDL testing using the Lipid Panel Plus reagent disc on 04/05/2023; (b) Patient ID #402406616155649 - Chloride, CO2, Potassium, Total Protein, and Albumin, testing using the CMP reagent reagent disc and Total Cholesterol, Triglycerides, and HDL testing using the Lipid Panel Plus reagent disc on 04/06/2023; (c) Patient ID #404773483839489 - Sodium, Potassium, Chloride, CO2, Total Protein, and Albumin, testing using the CMP reagent reagent disc and Total Cholesterol, Triglycerides, and HDL testing using the Lipid Panel Plus reagent disc on 05/03/2023; (d) Patient ID#311381983100929 - BUN, Calcium, Chloride, Glucose, CO2, Creatinine, Potassium, Sodium, Total Bilirubin, Total Protein, ALT, AST, Albumin, and Alkaline Phosphatase using the CMP reagent disc and Total Cholesterol, Triglycerides, and HDL testing using the Lipid Panel Plus reagent disc on 05/04/2023; (e) Patient ID #268196212637697 - BUN, Calcium, Chloride, Glucose, CO2, Creatinine, Potassium, Sodium, Total Bilirubin, Total Protein, ALT, AST, Albumin, and Alkaline Phosphatase using the CMP reagent disc and Total Cholesterol, Triglycerides, and HDL testing using the Lipid Panel Plus reagent disc on 05/17/2023; (f) Patient ID #498595537491969 - Sodium, Potassium, Chloride, CO2, Total Protein, and Albumin, testing using the CMP reagent reagent disc and Total Cholesterol, Triglycerides, and HDL testing using the Lipid Panel Plus reagent disc on 05/18/2023; (g) Patient ID #454761249636353 - Sodium, Potassium, Chloride, CO2, Total Protein, and Albumin, testing using the CMP reagent reagent disc and Total Cholesterol, Triglycerides, and HDL testing using the Lipid Panel Plus reagent disc on 05/24/2023; (h) Patient ID #605385792356353 - Sodium, Potassium, Chloride, CO2,

	Total Protein, and Albumin, testing using the CMP reagent reagent disc and Total Cholesterol, Triglycerides, and HDL testing using the Lipid Panel Plus reagent disc on 05/30/2023; (i) Patient ID #604769322598401 - BUN, Calcium, Chloride, CO2, Creatinine, Potassium, Sodium, Total Bilirubin, Total Protein, Albumin, and Alkaline Phosphatase using the CMP reagent disc and Glucose, ALT, AST, Total Cholesterol, HDL, and Triglycerides testing using the Lipid Panel Plus reagent disc on 08/29/2023; (j) Patient ID #508868823285761 - BUN, Calcium, Chloride, CO2, Creatinine, Potassium, Sodium, Total Bilirubin, Total Protein, Albumin, and Alkaline Phosphatase using the CMP reagent disc and Glucose, ALT, AST, Total Cholesterol, HDL, and Triglycerides testing using the Lipid Panel Plus reagent disc on 11/09/2023; (k) Patient ID #559581476814849 - BUN, Calcium, Chloride, CO2, Creatinine, Potassium, Sodium, Total Bilirubin, Total Protein, Albumin, and Alkaline Phosphatase using the CMP reagent disc on 11/09/2023; (l) Patient ID #512197879136257 - BUN, Calcium, Chloride, CO2, Creatinine, Potassium, Sodium, Total Bilirubin, Total Protein, Albumin, and Alkaline Phosphatase using the CMP reagent disc on 11/14/2023; (m) Patient ID #688456748957697 - BUN, Calcium, Chloride, CO2, Creatinine, Potassium, Sodium, Total Bilirubin, Total Protein, Albumin, and Alkaline Phosphatase using the CMP reagent disc and Glucose, ALT, AST, Total Cholesterol, HDL, and Triglycerides testing using the Lipid Panel Plus reagent disc on 11/14/2023; (n) Patient ID #402190749990913 - BUN, Calcium, Chloride, CO2, Creatinine, Potassium, Sodium, Total Bilirubin, Total Protein, Albumin, and Alkaline Phosphatase using the CMP reagent disc and Glucose, ALT, AST, Total Cholesterol, HDL, and Triglycerides testing using the Lipid Panel Plus reagent disc on 11/28/2023; (o) Patient ID #291880316764161 - BUN, Calcium, Chloride, CO2, Creatinine, Potassium, Sodium, Total Bilirubin, Total Protein, Albumin, and Alkaline Phosphatase using the CMP reagent disc and Glucose, ALT, AST, Total Cholesterol, HDL, and Triglycerides testing using the Lipid Panel Plus reagent disc on 11/29/2023.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of records and interview with the technical consultant, the laboratory failed to perform quality control procedures each day of patient testing for eight of 40 days reviewed. Findings include: (1) On 02/21/2024 at 10:00 am, the technical consultant stated that thyroid stimulating hormone (TSH), testosterone, total thyroxine (T4), Triiodothyronine (TT3), free thyroxine (FT4), and prostate specific antigen (PSA) testing were performed using the TOSOH analyzer; (2) A review of QC (Quality Control) and patient testing records from September 2023 through October 2023 identified QC testing had not been performed each day of patient testing reviewed for eight of 40 days of patient testing: (a) On 09/19/2023 patient #501011628949505 had a T4 test; (b) On 09/22/2023 patient #531353086132225 had a TT3 test; (c) On 09/27/2023 patient #311381983100929 had a T4 test, patient # 655805991223297 had a testosterone test, patient #400786652921857 had a PSA test; (d) On 10/13/2023 patient #667053956071425 had a T4 and TT3 test; (e) On 10/18

	/2023 patient #268257619017729 had a TSH test; (f) On 10/19/2023 patient #345342052007937 had a testosterone test; (g) On 10/26/2023 patient #365603615211521 had a TSH test; (h) On 10/30/2023 patient #07051984MB had a T4 test. (3) The records were reviewed with with the technical consultant who stated on 02/21/2024 at 10:00 am, the laboratory had not performed QC testing each day of patient testing as stated above. NOTE: D5447 was cited on the initial survey performed on 01/28/2022.
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 records and interview with the technical consultant, the laboratory failed to have a system that twice a year evaluated and defined the relationship between test results using different Piccolo reagent discs for three of 12 analytes reviewed from June 2022 through the current date. Findings include: (1) On 02/20/2024 at 03:20 pm, the technical consultant stated the following testing were performed using the Piccolo analyzer and plasma specimens: (a) Glucose testing using the Basic Metabolic Panel Plus reagent disc, the Comprehensive Metabolic Panel reagent disc, the Metlyte Plus CRP reagent disc, and the Lipid Panel Plus reagent disc; (b) ALT (Alanine Aminotransferase), and AST (Aspartate Aminotransferase) testing using the Comprehensive Metabolic Panel reagent disc, Lipid Panel Plus reagent disc, and the Liver Panel Plus reagent disc. (2) On 02/21/2024, a review of records from June 2022 through the current date identified no evidence the relationship between the analytes tested on the reagent discs had been evaluated twice annually as follows: (a) Glucose testing performed on the Lipid Panel Plus reagent disc had not been compared to the Glucose testing performed on the Basic Metabolic Panel Plus, the Comprehensive Metabolic Panel, and the Metlyte Panel Plus reagent discs; (b) ALT and AST testing performed on the Lipid Panel Plus reagent disc had not been compared to the ALT and AST testing performed on the Comprehensive Panel Plus and the Liver Panel Plus reagent discs. (3) The records were reviewed with the technical consultant who stated on 02/21/2024 at 01:30 pm, the relationship between the reagent discs had not been evaluated as stated above; (4) Refer to D5439 for examples of patient testing performed. NOTE: D5775 was cited on the initial survey performed on 01/28/2022.
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. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by:

	Based on a review of records, written policies and procedures, manufacturer's instructions, and interview with the technical consultant, the laboratory failed to monitor and evaluate the overall quality of analytic systems and correct identified problems for each specialty and subspecialty of testing performed during the review period of June 2022 through the current date. Findings include: (1) It was determined the laboratory did not have an effective mechanism for performing analytic quality assessment because of the following issues identified during the survey: (a) The laboratory failed to follow their written policy for performing quality control for CBC testing for one of one day of patient testing reviewed from 07/28/2023 through 08/15 /2023. Refer to D5401; (b) The laboratory failed to have complete written procedures for one of one procedure reviewed. Refer to D5403; (c) The laboratory failed to ensure one of one policy had been approved, signed, and dated by the laboratory director. Refer to D5407; (d) The laboratory failed to ensure the laboratory humidity was maintained as required by the manufacturer of the TOSOH ALA-360 analyzer for three of three months reviewed. Refer to D5413; (e) The laboratory failed to ensure the manufacturer's instructions were followed for performing weekly maintenance procedures on the Sysmex XN-330 analyzer and the Siemens Viva Pro E analyzer during the review period of January 2023 through December 2023. Refer to D5429; (f) The laboratory failed to perform calibration verification procedures at least once every six months for the Piccolo test system during the review period of January 2023 through the current date. Refer to D5439; (g) The laboratory failed to perform quality control procedures each day of patient testing for eight of 40 days reviewed. Refer to D5447; (h) The laboratory failed to have a system that twice a year evaluated and defined the relationship between test results using different Piccolo reagent discs for three of 12 analytes reviewed from June 2022 through the current date. Refer to D5775. NOTE: D5791 was cited on the initial survey performed on 01/28/2022.
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 a review of records, urine drug assay package inserts, and interview with the technical consultant, the laboratory failed to ensure test reports for Urine Drug Screen testing included information required for interpretation for two of two patient reports. Findings include: (1) On 02/20/2024 at 03:40 pm, the technical consultant stated Urine Drug Screen testing, which included the analytes Amphetamines, Barbiturates, Benzodiazepines, Buprenorphine, Cannabinoids, Cocaine, Opiates, Oxycodone, and Methadone was performed using the Siemens Viva Pro E analyzer; (2) A review of the manufacturer's instructions contained in the assay package inserts for each analyte stated, "The assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgement should be applied to any

	drug of abuse test result, particularly when preliminary positive results are used"; (3) A review of two patient reports with Urine Drug Screen test results reported identified the reports did not include a disclaimer with the manufacturer's statement that the results were preliminary and guidance on obtaining a confirmed analytical result: (a) Patient #523897900761089 - results reported on 11/13/2023 (b) Patient #670762210426881 - results reported on 11/22/2023 (4) The findings were discussed with the technical consultant who stated on 02/21/2024 at 03:50 pm, the patient reports did not include the disclaimer.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on a review of records, policies and procedures, manufacturer's instructions, and interview with the technical consultant, the laboraory director failed to provide overall management and direction during the review period of June 2022 through the current date. Findings include: (1) The laboratory director failed to ensure test methods were performed as required by the manufacturer to ensure accurate and reliable results during the review period of January through December 2023. Refer to D6014; (2) The laboratory director failed to attest that, at the time of testing, proficiency testing samples were tested in the same manner as patient specimens as required under Subpart H for two of six Hematology and Chemistry Core proficiency testing events reviewed in 2023. Refer to D6016; (3) The laboratory director failed to ensure a quality control program was maintained to ensure the quality of laboratory services. Refer to D6020; (4) The laboratory director failed to ensure a quality assessment program had been established and maintained during the review period of June 2022 through the current date. Refer to D6021; (5) The laboratory director failed to ensure test reports included pertinent information required for interpretation for two of two patient reports. Refer to D6026; (6) The laboratory director failed to ensure an approved procedure manual was available and followed by all personnel responsible for the testing process. Refer to D6031. NOTE: D6000 was cited on the initial survey performed on 01/28/2022.
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the technical consultant, the laboratory director failed to ensure test methods were performed as required by the manufacturer to ensure accurate and reliable results

	during the review period of January through December 2023. Findings include: (1) The laboratory director failed to ensure the laboratory humidity was maintained as required by the manufacturer of the TOSOH ALA-360 analyzer for three of three months reviewed. Refer to D5413; (2) The laboratory director failed to ensure the manufacturer's instructions were followed for performing weekly maintenance procedures for the Siemens Viva Pro E analyzer and Sysmex XN-330 analyzer during the review period of January through December 2023. Refer to D5429.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on a review of records and interview with the technical consultant, the laboratory director failed to attest that, at the time of testing, proficiency testing samples were tested in the same manner as patient specimens as required under Subpart H for two of six Hematology and Chemistry Core proficiency testing events reviewed in 2023. Findings include: (1) A review of 2023 Hematology and Chemistry Core proficiency testing events identified attestation statements had been signed up to two months after the samples had been tested for two of six events reviewed: (a) First Hematology Event 2023 - The sample testing had been completed on 03/13/2023 and the attestation statement had not been signed by the laboratory director until 05/05 /2023; (b) Second Chemistry Core Event 2023 - The sample testing had been completed on 06/06/2023 and the attestation statement had not been signed by the laboratory director until 07/23/2023. (2) The records were reviewed with the technical consultant who stated on 02/20/2024 at 04:20 pm, the attestation statements had not been signed until up to two months after the proficiency samples had been tested.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on a review of records and interview with the technical consultant, the laboratory director failed to ensure a quality control program was maintained to ensure the quality of laboratory services during the review period of June 2022 through the current date. Findings include: (1) The laboratory director failed to ensure calibration verification procedures were performed at least once every six months for the Piccolo test system during the review period of January 2023 through the current

	date. Refer to D5439; (2) The laboratory director failed to ensure quality control procedures had been performed each day of patient testing for eight of 40 days reviewed. Refer to D5447; (3) The laboratory director failed to ensure a system was in place that twice a year evaluated and defined the relationship between test results using different Piccolo reagent discs for three of 12 analytes reviewed from June 2022 through the current date. Refer to D5775. NOTE: D6020 was cited on the initial survey performed on 01/28/2022.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on a review of records, written policies and procedures, manufacturer's instructions, and interview with the technical consultant, the laboratory director failed to ensure a quality assessment program had been established and maintained. Findings include: (1) The laboratory director failed to ensure the laboratory had an ongoing mechanism for performing effective analytic quality assessment. Refer to D5791.
D6026	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(8) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(8) Ensure that reports of test results include pertinent information required for interpretation. This STANDARD is not met as evidenced by: Based on a review of records, urine drug assay package inserts, and interview with the technical consultant, the laboratory director failed to ensure test reports included pertinent information required for interpretation for two of two patient reports. Findings include: (1) The laboratory director failed to ensure test reports for Urine Drug Screen testing included information required for interpretation for two of two patient reports. Refer to D5805.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(13) Ensure that an approved procedure manual is available to all

	personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based on a review of records, written policies and procedures, and interview with the technical consultant, the laboratory director failed to ensure an approved procedure manual was available and followed by all personnel responsible for the testing process. Findings include: (1) The laboratory director failed to ensure the laboratory followed their written policy for performing QC (quality control) for CBC testing for one of one day of patient testing reviewed between 07/28/2023 through 08/16/2023. Refer to D5401; (2) The laboratory director failed to ensure the laboratory had complete written procedures for one of one procedure reviewed. Refer to D5403; (3) The laboratory director failed to ensure one of one policy had been approved, signed, and dated by the laboratory director. Refer to D5407. NOTE: D6031 was cited on the initial survey performed on 01/28/2022.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on a review of records and interview with the technical consultant, the technical consultant failed to provide technical oversight in accordance with 493.1413 of this subpart. Findings include: (1) The technical consultant failed to ensure the correct Chemistry Core methodology was reported for five of five proficiency testing events reviewed in 2022 and 2023. Refer to D6041; (2) The technical consultant failed to establish a quality control program which ensured the establishment and maintenance of acceptable levels of analytic performance. Refer to D6042. NOTE: D6033 was cited on the initial survey performed on 01/28/2022.
D6041	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(3) (b) The technical consultant is responsible for-- (b)(3) Enrollment and participation in an HHS approved proficiency testing program commensurate with the services offered; This STANDARD is not met as evidenced by: Based on a review of records and interview with the technical consultant, the technical consultant failed to ensure the correct Chemistry Core methodology was reported for five of five proficiency testing events reviewed in 2022 and 2023. Findings include: (1) On 02/20/2023 at 3:20 pm, the technical consultant stated the laboratory performed the following testing using the Piccolo analyzer and plasma specimens: (a) Albumin, Alkaline Phosphatase, ALT (Alanine Aminotransferase), AST (Aspartate Aminotransferase), Total Bilirubin, Calcium, Chloride, CO2, Creatinine, Glucose, Potassium, Sodium, Total Protein, and BUN using the Comprehensive Metabolic Panel reagent disc; (b) Amylase and GGT (Gamma-Glutamyl Transferase) testing using the Liver Panel Plus reagent disc; (c) HDL (High Density Lipoprotein)

	Cholesterol, Triglycerides, and Total Cholesterol testing using the Lipid Panel Plus reagent disc; (d) CK (Creatine Kinase) testing using the Metlyte Plus reagent disc; (e) LDH (Lactate Dehydrogenase) and Magnesium testing using the Basic Metabolic Panel Plus reagent disc. (2) A review of 2022 and 2023 Chemistry Core proficiency testing records identified the laboratory had selected the incorrect methodology of "Waived" for the second and third 2022 events; and the first, second, and third 2023 events; (3) The records were reviewed with the technical consultant who stated on 02 /20/2024 at 04:10 pm, the laboratory performed the above testing on the Piccolo analyzer as non-waived test systems and had reported the incorrect methodology of waived for the five events in 2022 and 2023; (4) Refer to D5439 for examples of non-waived patient testing performed when proficiency testing had been performed as a waived test method.
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the technical consultant, the technical consultant failed to establish a quality control program which ensured the establishment and maintenance of acceptable levels of analytic performance. Findings include: (1) The technical consultant failed to ensure the laboratory humidity was maintained as required by the manufacturer of the TOSOH ALA-360 analyzer for three of three months reviewed. Refer to D5413; (2) The technical consultant failed to ensure the manufacturer's instructions were followed for performing weekly maintenance procedures for the Siemens Viva Pro E analyzer and Sysmex XN-330 analyzer during the review period of January through December 2023. Refer to D5429; (3) The technical consultant failed to ensure calibration verification procedures were performed at least once every six months for the Piccolo test system during the review period of January 2023 through the current date. Refer to D5439; (4) The technical consultant failed to ensure quality control procedures had been performed each day of patient testing for eight of 40 days reviewed. Refer to D5447; (5) The technical consultant failed to ensure a system was in place that twice a year evaluated and defined the relationship between test results using different Piccolo reagent discs for three of 12 analytes reviewed from June 2022 through the current date. Refer to D5775. NOTE: D6042 was cited on the initial survey performed on 01/28/2022.