Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D2181582	01/28/2022
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 initial survey was performed on 01/28/2022. The findings were reviewed with the testing person during an exit conference performed at the conclusion of the survey. The laboratory was found out of compliance with the following CLIA regulations: 493.1250; D5400: Analytic Systems 493.1403; D6000: Laboratory Director, Moderate Complexity Testing 493.1409; D6033: Technical Consultant 493.1441; D6076: Laboratory Director, High Complexity Testing
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 records, written policy, and interview with the testing person, the laboratory failed to follow a written technical consultant competency policy based on the position responsibilities as listed in Subpart M for one of one technical consultant. Findings include: (1) On 01/28/2022, surveyor #2 reviewed personnel records for competency assessments performed during 2020 and 2021. There was no evidence a competency had been performed for the technical consultant based on their job responsibilities; (2) Surveyor #2 asked the testing person if a written policy to evaluate the technical consultant based on job responsibilities was available. Testing person #1 provided the policy for surveyor #2 review; (3) Surveyor #2 reviewed the policy titled, "LABORATORY STAFF ORIENTATION, TRAINING, AND ASSESSMENT" which stated, (a) "PURPOSE" (i) "To provide a comprehensive plan for laboratory employees' orientation upon hire, for six month and annual evaluations, and for determination of competency within their respective departments. All employees should be knowledgeable of their job description and duties in each position throughout the laboratory."; (4) Surveyor #2 asked the testing person if

	competencies based on job responsibilities had been performed during the review period. Testing person #1 stated on 01/28/2022 at 11:50 am, competencies had not been performed.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on a review of records and interview with the testing person, the laboratory failed to review and evaluate proficiency testing results for three of nine events. Findings include: FAILURE (1) On 01/28/2022, surveyor #2 reviewed 2021 proficiency testing records and identified the following failure: (a) Third 2020 Hematology Event (i) Basophils- The laboratory failed the results for five of five samples (XE-11, XE-12, XE-13, XE-14, XE-15); (ii) Eosinophils - The laboratory failed the results for five of five samples (XE-11, XE-12, XE-13, XE-14, XE-15); (iii) Lymphocytes - The laboratory failed the results for one of five samples (XE-12); (2) The surveyor could not locate evidence in the records proving the failure had been addressed; (3) Surveyor #2 reviewed the records with the testing person, and asked if corrective action had been taken and documented for the failure. Testing person stated on 01/28/2022 at 10:45 am corrective action had not been taken. BIASES (1) On 01/28 /2022, surveyor #2 reviewed 2021 proficiency testing records. The following biases were identified (biases were identified using the SDI (Standard Deviation Index) values assigned by the proficiency program): (a) 2021 Third Chemistry Core Event (i) GGT (Gamma-Glutamyl Transferase) - three of five results exhibited a negative bias (aa) Sample CH-11 - SDI of -2.6 (bb) Sample CH-12 - SDI of -2.4 (cc) Sample CH-14 - SDI of -2.1 (a) 2021 Third Hematology Event (i) Hematocrit - three of five results exhibited a negative bias (aa) Sample XE-11- SDI of -2.3 (bb) Sample XE-13 - SDI of -2.6 (cc) Sample XE-14 - SDI of -3.0 (ii) MCHC (Mean Corpuscular Hemoglobin Concentration) - five of five results exhibited a positive bias (aa) Sample XE-11- SDI of 2.1 (bb) Sample XE-12 - SDI of 2.6 (cc) Sample XE-13 - SDI of 3.0 (dd) Sample XE-14 - SDI of 3.1 (ee) Sample XE-15 - SDI of 2.5 (iii) MCV (Mean Corpuscular Volume) - five of five results exhibited a negative bias (aa) Sample XE-11- SDI of -2.9 (bb) Sample XE-12 - SDI of -2.7 (cc) Sample XE-13 - SDI of -3.1 (dd) Sample XE-14 - SDI of -3.3 (ee) Sample XE-15 - SDI of -2.8 (iv) White Blood Cells - three of five results exhibited a positive bias (aa) Sample XE-12- SDI of 2.8 (bb) Sample XE-13 - SDI of 3.4 (cc) Sample XE-15 - SDI of 2.0 (2) Surveyor #2 could not locate evidence in the records proving the biases had been identified and addressed; (3) The records were reviewed with the testing person. The testing person stated on 01/28 /2022 at 10:50 am the biases had not been addressed.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).

	This STANDARD is not met as evidenced by: Based on a review of records and interview with the testing person, the laboratory failed to evaluate the accuracy of testing when proficiency results had not been graded by the proficiency program for one of nine proficiency testing events reviewed. Findings include: (1) On 01/28/2022, surveyor #2 reviewed 2021 proficiency testing records. The following was identified for two of nine testing events: (a) Third 2021 Hematology Event for Urobilinogen - one of one result had not been graded by the proficiency testing program: (i) For one of one result (UA-06), the following was identified: (aa) UA-06 - Under "Expected Results" it stated, "See Data Summary". There was no evidence the laboratory reviewed the commentary contained in the "Participant Summary Report" to evaluate their result. (2) Surveyor #2 reviewed the records with the testing person who stated on 01/28/2022 at 10:55 am, the laboratory had not evaluated the results that were not graded by the proficiency testing program.
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 records and interview with the testing person, the laboratory failed to verify the accuracy of C-Reactive Protein testing at least twice annually. Findings include: (1) On 01/28/2022 at 10:00 am, the testing person stated the following to surveyor #1: (a) The laboratory performed CRP (C-Reactive Protein) testing using the Abaxis Piccolo. (2) Surveyor #2 reviewed 2021 records and identified the testing had not been verified for accuracy twice annually during the review period; (3) The records were reviewed with testing person #1. The testing person stated on 01/28/2022 at 11:30 am, the laboratory had not verified the accuracy twice annually as indicated above.
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, procedure manual, FDA database, and interview with the testing person, 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. Findings include: (1) The laboratory failed to ensure the laboratory procedure manual had been approved, signed, and dated by the laboratory director. Refer to D5407; (2) The laboratory failed to demonstrate the performance specifications for six of 12 new test methods used for patient testing and six of 12 new test methods available for use on the Piccolo Xpress analyzer. Refer to D5421; (3)

	The laboratory failed to establish the performance specifications for two of two new analytes not cleared or approved by the FDA. Refer to D5423; (4) The laboratory failed to perform two levels of quality control materials each day of patient testing performed on the Piccolo Xpress analyzer for 50 of 55 days reviewed. Refer to D5447; (5) The laboratory failed to have a system that twice a year evaluated and defined the relationship between test results using different methods for six of six Piccolo Xpress reagent discs types. Refer to D5775; (6) The laboratory failed to have an ongoing mechanism for performing quality assessment. Refer to D5791.
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 the procedure manual and interview with the testing person, the laboratory failed to ensure the laboratory procedure manual had been approved, signed, and dated by the laboratory director. Findings include: (1) On 01/28/2022 at 10:00 am, the testing person stated to surveyor #1 the laboratory began performing the following testing on 06/25/2021: (a) CBC (Complete Blood Count) testing using the Sysmex XN-330 analyzer; (b) TSH (Thyroid Stimulating Hormone), FT4 (Free Thyroxine), Testosterone, Prolactin, T3 (Triiodthyronine), T4 (Thyroxine) and PSA (Prostate Specific Antigen) testing using the Tosoh AIA 360 analyzer; (c) Urine Drug Screen testing using the Siemens Viva Pro E analyzer; (d) Albumin, Alkaline Phosphatase, ALT (Alanine Aminotransferase), AST (Aspartate Aminotransferase), BUN, Calcium, Chloride, CO2, Creatinine, Glucose, Potassium, Sodium, Total Bilirubin, and Total Protein testing using the Comprehensive Metabolic Panel reagent disc and patient plasma specimens on the Piccolo Xpress analyzer; (e) Total Cholesterol, HDL (High Density Lipoprotein) Cholesterol, and Triglyceride testing using the Lipid Panel reagent disc and patient plasma specimens on the Piccolo Xpress analyzer; (f) BUN, Calcium, Chloride, CO2, Creatinine, Glucose, LDH (Lactate Deydrogenase), Magnesium, Potassium, and Sodium testing using the Basic Metabolic Panel Plus reagent disc and patient plasma specimens on the Piccolo Xpress analyzer; (f) ALT, AST, Total Cholesterol, HDL Cholesterol, Glucose, and Triglyceride testing using the Lipid Panel Plus Reagent disc and patient plasma specimens on the Piccolo Xpress analyzer; (g) BUN, Chloride, CK (Creatine Kinase), CO2, CRP (C-Reactive Protein), Creatinine, Glucose, Potassium, and Sodium testing using using the Metlyte Plus CRP reagent disc and patient plasma specimens on the Piccolo Xpress analyzer; (h) Albumin, Alkaline Phosphatase, ALT, Amylase, AST, GGT (Gamma-Glutamyl Transpeptidase), Total Bilirubin, and Total Protein testing using the Liver Panel Plus reagent disc and patient plasma specimens on the Piccolo Xpress analyzer. (2) Surveyor #1 reviewed the laboratory manual titled, "TruHealth Procedure Manual". It had not been approved, signed, and dated by the laboratory director; (3) Surveyor #1 showed the manual to the testing person, who stated on 01/28 /2022 at 11:30 am, the procedure manual had not been approved, signed, and dated by the laboratory director.
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:
Based on a review of records and interview with the testing person, the laboratory failed to demonstrate the performance specifications for six of 12 new test methods used for patient testing and six of 12 new test methods available for use on the Piccolo Xpress analyzer. Findings include: TEST METHODS USED FOR PATIENT TESTING (1) On 01/28/2022 at 10:10 am, the testing person stated to surveyor #1 the following had been used to perform patient testing beginning 06/25/2021: (a) Albumin, Alkaline Phosphatase, ALT (Alanine Aminotransferase), AST (Aspartate Aminotransferase), BUN, Calcium, Chloride, CO2, Creatinine, Glucose, Potassium, Sodium, Total Bilirubin, and Total Protein testing using the Comprehensive Metabolic Panel reagent disc and patient plasma specimens on the Piccolo Xpress analyzer; (b) Total Cholesterol, HDL (High Density Lipoprotein) Cholesterol, and Triglyceride testing using the Lipid Panel reagent disc and patient plasma specimens on the Piccolo Xpress analyzer; (d) BUN, Calcium, Chloride, CO2, Creatinine, Glucose, LDH (Lactate Deydrogenase), Magnesium, Potassium, and Sodium testing using the Basic Metabolic Panel Plus reagent disc and patient plasma specimens on the Piccolo Xpress analyzer; (e) ALT, AST, Total Cholesterol, HDL Cholesterol, Glucose, and Triglyceride testing using the Lipid Panel Plus reagent disc and patient plasma specimens on the Piccolo Xpress analyzer; (f) BUN, Chloride, CK (Creatine Kinase), CO2, CRP (C-Reactive Protein), Creatinine, Glucose, Potassium, and Sodium testing using the Metlyte Plus CRP reagent disc and patient plasma specimens on the Piccolo Xpress analyzer; (g) Albumin, Alkaline Phosphatase, ALT, Amylase, AST, GGT (Gamma-Glutamyl Transpeptidase), Total Bilirubin, and Total Protein testing using the Liver Panel Plus reagent disc and patient plasma specimens on the Piccolo Xpress analyzer. (2) Surveyor #1 reviewed records for the above test methods and identified the following: (a) There was no evidence precision, reportable ranges, and normal reference ranges had been demonstrated for each analyte using the Comprehensive Metabolic Panel reagent disc, Lipid Panel reagent disc, and Lipid Panel Plus reagent disc; (b) There was no evidence accuracy, precision, reportable ranges, and normal reference ranges had been demonstrated for each analyte using the Basic Metabolic Panel Plus reagent disc, Liver Panel Plus reagent disc, and Metlyte Plus CRP reagent disc. (3) Surveyor #1 reviewed the findings with the testing person who stated on 01/28/2022 at 03:00 pm the laboratory had not demonstrated the performance specifications for the test systems as stated above; (4) Refer to D5447 for patient testing that had been performed using each reagent disc type. TEST METHODS AVAILABLE FOR USE (1) On 01/28/2022 at 10:10 am, the testing person stated to surveyor #1 the following had not been used to perform patient testing as of the survey date, but were in the refrigerator and available for use if ordered by the physician: (a) Albumin, BUN, Calcium, Chloride, CO2, Glucose, Lactate, Magnesium, Phosphorus, Potassium, and Sodium testing using the Metlac 12 reagent disc and patient plasma specimens on the Piccolo Xpress analyzer; (b) Albumin, BUN, Calcium, Chloride, Creatinine, Glucose, Phosphorus, Potassium, and Sodium testing using the Renal Function Panel reagent disc and patient plasma specimens on the Piccolo Xpress analyzer. (c) Albumin, Alkaline Phosphatase, ALT, AST, Direct Bilirubin, Total Bilirubin, and Total Protein testing using the Hepatic Function Panel

	reagent disc and patient plasma specimens on the Piccolo Xpress analyzer; (d) BUN, CO2, Chloride, CK (Creatine Kinase), Creatinine, Glucose, Potassium, and Sodium testing using the Metlyte 8 reagent disc and patient plasma specimens on the Piccolo Xpress analyzer; (e) Albumin, Alkaline Phosphatase, ALT, Amylase, AST, BUN, Calcium, Creatinine, CRP (C-Reactive Protein), Glucose, GGT, Total Protein, and Uric Acid testing using the Biochemistry Panel Plus reagent disc and patient plasma specimens on the Piccolo Xpress analyzer; (f) Chloride, CO2, Potassium, and Sodium testing using the Electrolyte Panel reagent disc and patient plasma specimens on the Piccolo Xpress analyzer. (2) Surveyor #1 reviewed records for the above test methods. There was no evidence precision, reportable ranges and normal reference ranges had been demonstrated for each analyte using the Metlac 12 reagent disc, Renal Function Panel reagent disc, Hepatic Function Panel reagent disc, Metlyte 8 reagent disc, and Biochemistry Panel Plus reagent disc; (3) Surveyor #1 reviewed the findings with the testing person who stated on 01/28/2022 at 03:00 pm the laboratory had not demonstrated the performance specifications for the test systems as stated above. 39088 Based on a review of records and interview with the testing person, the laboratory failed to demonstrate the normal reference range for two of two new test methods. Findings include: (1) On 01/28/2022 at 10:10 am, the testing person stated the following to surveyor #1: (a) The laboratory began performing routine CBC (Complete Blood Count) testing using the Sysmex XN-330 analyzer on 06/25/2021; (b) The laboratory began performing Testosterone testing using the Tosoh AIA 360analyzer on 06/25/2021. (2) Surveyor #2 reviewed the performance specification records for the new test systems and could not locate documentation to prove the laboratory had demonstrated the normal reference ranges for the above testing; (3) On 01/28/2022, surveyor #2 reviewed the findings with the testing person. The testing person stated on 01/28/2022 at 03:00 pm, the laboratory did not demonstrate the normal reference ranges.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on a review of records, FDA database, and interview with the testing person, the laboratory failed to establish the performance specifications for two of two new analytes not cleared or approved by the FDA. Findings include: (1) On 01/28/2022 at 10:10 am, the testing person stated to surveyor #1 pH and Specific Gravity were performed using the Viva-E Pro analyzer beginning 06/25/2021; (2) Surveyor #2 attempted to verify the classification of the analytes using the Viva-E Pro analyzer on the FDA (Food and Drug Administration) test classification database, since classification of test systems are performed by the FDA. The database did not include a classification for the analytes/analyzer combination (if a test is not included on the

	FDA site, then it did not go through the FDA approval process, which defaults the classification of the test as high complexity). Therefore, surveyor #2 determined the performance specifications of accuracy, precision, reportable range, analytical sensitivity, analytical specificity, and reference intervals (normal values) were required to be established; (3) Surveyor #2 reviewed the implementation records for the analyzer. There was no evidence the performance specifications of accuracy, precision, reportable range, analytical sensitivity, analytical specificity, and reference intervals (normal values) had been established; (4) Surveyor #2 reviewed the validation records with the testing person who stated on 01/28/2022 at 03:40 pm the performance specifications had not been established because it was believed the entire test system had been FDA approved; (5) Examples of patient testing (a) Patient #1 tested on 08/25/2021 at 02:24 pm (b) Patient #2 tested on 12/15/2021 at 10:24 am
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 testing person, the laboratory failed to follow the manufacturer's instructions for performing maintenance procedures for seven of seven months. Findings include: (1) On 01/28/2022 at 10:10 am, the testing person stated to surveyor #1 that CBC (Complete Blood Count) testing was performed on the Sysmex XN-330 analyzer; (2) Surveyor #2 reviewed the manufacturer's maintenance requirements. The requirements for maintenance were as follows: (a) Daily (i) Shutdown (b) Weekly (i) Clean the SRV tray (c) Monthly (i) Clean the Waste Chamber (ii) Clean Transducer (3) Surveyor #2 then reviewed maintenance records for seven months (July 2021 through the day of the survey). There was no evidence the maintenance had been performed during the review period; (4) Surveyor #2 reviewed the records with the testing person. The testing person stated on 01/28/2022 at 03:30 pm, the maintenance had not been performed.
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 testing person, the laboratory failed to perform two levels of quality control materials each day of patient testing for each reagent disc type on the Piccolo Xpress analyzer for 50 of 55 days of patient testing reviewed. Findings include: (1) On 01/28/2022 at 10:00 am, the testing person stated the following to surveyor #1: (a) The laboratory began performing the following testing on 06/25/2021: (i) Albumin, Alkaline Phosphatase, ALT (Alanine

Aminotransferase), AST (Aspartate Aminotransferase), BUN, Calcium, Chloride, CO2, Creatinine, Glucose, Potassium, Sodium, Total Bilirubin, and Total Protein testing using the Comprehensive Metabolic Panel reagent disc and patient plasma specimens on the Piccolo Xpress analyzer; (ii) Total Cholesterol, HDL (High Density Lipoprotein) Cholesterol, and Triglyceride testing using the Lipid Panel reagent disc and patient plasma specimens on the Piccolo Xpress analyzer; (iii) BUN, Calcium, Chloride, CO2, Creatinine, Glucose, LDH (Lactate Deydrogenase), Magnesium, Potassium, and Sodium testing using the Basic Metabolic Panel Plus reagent disc and patient plasma specimens on the Piccolo Xpress analyzer; (iv) ALT, AST, Total Cholesterol, HDL Cholesterol, Glucose, and Triglyceride testing using the Lipid Panel Plus reagent disc and patient plasma specimens on the Piccolo Xpress analyzer; (v) BUN, Chloride, CK (Creatine Kinase), CO2, CRP (C-Reactive Protein), Creatinine, Glucose, Potassium, and Sodium testing using using the Metlyte Plus CRP reagent disc and patient plasma specimens on the Piccolo Xpress analyzer; (vi) Albumin, Alkaline Phosphatase, ALT, Amylase, AST, GGT (Gamma-Glutamyl Transpeptidase), Total Bilirubin, and Total Protein testing using the Liver Panel Plus reagent disc and patient plasma specimens on the Piccolo Xpress analyzer. (b) Two levels of Piccolo QC (quality control) materials were performed with new boxes and new lots of reagent discs. (2) Surveyor #1 asked the testing person if an IQCP (Individualized Quality Control Plan) had been developed for the test system. The testing person stated on 01/28/2022 at 10:30 am, the laboratory had not developed an IQCP. Therefore, surveyor #1 determined two levels of QC materials must be performed each day of patient testing for each analyte and each reagent disc; (3) Surveyor #1 reviewed QC and patient testing records from 06/25/2021 through 01/28 /2022 and identified that two levels of QC testing had not been performed for each analyte and each reagent disc on each day of patient testing as follows: (a) Comprehensive Metabolic Panel reagent disc - 21 of 23 days reviewed (b) Lipid Panel reagent disc - 17 of 19 days reviewed (c) Basic Metabolic Panel Plus reagent disc - six of seven days reviewed (d) Lipid Panel Plus reagent disc - three of three days reviewed (e) Metlyte Plus CRP reagent disc - one of one day reviewed (f) Liver Panel Plus reagent disc - two of two days reviewed (4) The following were patients and reagent disc types that had been tested when at least two levels of QC materials for that reagent disc type had not been performed: (a) Comprehensive Metabolic Panel reagent disc (i) Patient #3 - Testing performed on 06/25/2021 (ii) Patient #4 - Testing performed on 06/28/2021 (iii) Patient #5 - Testing performed on 08/03/2021 (iv) Patient #6 - Testing performed on 08/06/2021 (v) Patient #7 - Testing performed on 08 /10/2021 (vi) Patient #8 - Testing performed on 08/18/2021 (vii) Patient #10 - Testing performed on 09/07/2021 (viii) Patient #11 - Testing performed on 09/13/2021 (ix) Patient #12 - Testing performed on 12/05/2021 (x) Patient #13 - Testing performed on 10/12/2021 (xi) Patient #14 - Testing performed on 11/02/2021 (xii) Patient #15 - Testing performed on 11/12/2021 (xiii) Patient #16 - Testing performed on 11/29 /2021 (xiv) Patient #17 - Testing performed on 12/07/2021 (xv) Patient #18 - Testing performed on 12/13/2021 (xvi) Patient #19 - Testing performed on 12/29/2021 (xvii) Patient #20 - Testing performed on 01/05/2022 (xviii) Patient #21 - Testing performed on 01/12/2022 (xix) Patient #22 - Testing performed on 01/17/2022 (xx) Patient #23 - Testing performed on 01/26/2022 (xxi) Patient #24 - Testing performed on 01/27 /2022 (b) Lipid Panel reagent disc (i) Patient #5 - Testing performed on 08/03/2021 (ii) Patient #32 - Testing performed on 08/04/2021 (iii) Patient #6 - Testing performed on 08/06/2021 (iv) Patient #7 - Testing performed on 08/10/2021 (v) Patient #8 - Testing performed on 08/18/2021 (vi) Patient #10 - Testing performed on 09/07/2021 (vii) Patient #11 - Testing performed on 09/13/2021 (viii) Patient #14 - Testing performed on 11/02/2021 (ix) Patient #15 - Testing performed on 11/12/2021 (x) Patient #16 - Testing performed on 11/29/2021 (xi) Patient #17 - Testing performed

	on 12/07/2021 (xii) Patient #25 - Testing performed on 12/08/2021 (xiii) Patient #18 - Testing performed on 12/13/2021 (xiv) Patient #19 - Testing performed on 12/29 /2021 (xv) Patient #20 - Testing performed on 01/05/2022 (xvi) Patient #21 - Testing performed on 01/12/2022 (xvii) Patient #24 - Testing performed on 01/27/2022 (c) Basic Metabolic Panel Plus reagent disc (i) Patient #27 - Testing performed on 09/08 /2021 (ii) Patient #28 - Testing performed on 09/22/2021 (iii) Patient #29 - Testing performed on 10/27/2021 (iv) Patient #30 - Testing performed on 11/05/2021 (v) Patient #31 - Testing performed on 11/17/2021 (vi) Patient #25 - Testing performed on 12/08/2021 (d) Lipid Panel Plus reagent disc (i) Patient #9 - Testing performed on 09/01/2021 (ii) Patient #12 - Testing performed on 10/05/2021 (iii) Patient #13 - Testing performed on 10/12/2021 (e) Metlyte Plus CRP reagent disc (i) Patient #15 - Testing performed on 11/12/2021 (f) Liver Panel Plus reagent disc (i) Patient #33 - Testing performed on 11/12/2021 (ii) Patient #26 - Testing performed on 01/26/2022
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 testing person, the laboratory failed to have a system that twice a year evaluated and defined the relationship between test results using different methods for six of six Piccolo Xpress reagent discs types. Findings include: (1) On 01/28/2022 at 10:00 am, the testing person stated to surveyor #1 the laboratory began performing the following testing using multiple reagent discs and patient plasma specimens on the Piccolo Xpress analyzer on 06/25 /2021: (a) Albumin, Alkaline Phosphatase testing using the Comprehensive Metabolic Panel reagent disc and the Liver Panel Plus reagent disc; (b) ALT (Alanine Aminotransferase), AST (Aspartate Aminotransferase) using the Comprehensive Metabolic Panel reagent disc, Lipid Panel Plus reagent disc and the Liver Panel Plus reagent disc; (c) BUN, CO2, Creatinine, Potassium, Sodium, testing using the Comprehensive Metabolic Panel reagent disc, Basic Metabolic Panel Plus reagent disc, and Metlyte Plus CRP reagent disc; (d) Calcium, Chloride, testing using the Comprehensive Metabolic Panel reagent disc and Basic Metabolic Panel Plus reagent disc; (e) Glucose testing using the Comprehensive Metabolic Panel reagent disc, Basic Metabolic Panel Plus reagent disc and Lipid Panel Plus reagent disc; (f) Total Bilirubin testing using the Comprehensive Metabolic Panel reagent disc and Liver Panel Plus reagent disc; (g) Total Cholesterol, HDL (High Density Lipoprotein) Cholesterol, and Triglyceride testing using the Lipid Panel reagent disc and Lipid Panel Plus reagent disc. (2) Surveyor #1 asked the testing person if the relationship between the testing performed on multiple disc types had been evaluated twice annually during the review period of 06/25/2021 through 01/28/2022. The testing person stated to surveyor #1 on 01/28/2022 at 04:00 pm the relationship between the test results from the different reagent disc types had not been evaluated; (3) Refer to D5447 for patient testing that had been performed using each reagent disc type.
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, procedure manual, FDA database, manufacturer's instructions, and interview with the testing person, the laboratory failed to have an ongoing mechanism for performing effective analytic quality assessment. 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 ensure the laboratory procedure manual had been approved, signed, and dated by the laboratory director. Refer to D5407; (b) The laboratory failed to demonstrate the performance specifications for new test methods. Refer to D5421; (c) The laboratory failed to establish the performance specifications for two of two new analytes not cleared or approved by the FDA. Refer to D5423; (d) The laboratory failed to follow the manufacturer's instructions for performing maintenance procedures. Refer to D5429; (e) The laboratory failed to perform two levels of quality control materials each day of patient testing. Refer to D5447; (f) The laboratory failed to have a system that twice a year evaluated and defined the relationship between test results using different methods. Refer to D5775.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on a review of a patient report and interview with the testing person, the laboratory failed to provide normal reference intervals for one of one Urine Drug Screen test report. Findings include: (1) On 01/28/2022 at 10:10 am, the testing person stated the following to surveyor #1: (a) The laboratory performed qualitative Amphetamine, Barbiturate, Benzodiazepine, Buprenorphine, Cocaine, Methadone, Opiate, and Oxycodone testing for urine specimens on the Viva Pro E analyzer; (b) The laboratory performed quantitative Specific Gravity and pH testing for urine specimens on the Viva Pro E analyzer. (2) Surveyor #2 reviewed one test report for Patient #1 tested on 08/25/2021 at 02:24 pm. The report did not include a normal reference range for all of the analytes listed above; (3) The report was reviewed with the testing person, who stated on 01/28/2022 at 03:40 pm the patient report did not include a normal reference range.
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, procedure manual, FDA database, and interview with the testing person, the laboratory director failed to provide overall management and direction. Findings include: (1) The laboratory director failed to ensure verification procedures for new test systems were adequate to determine the performance characteristics. Refer to D6013; (2) The laboratory director failed to ensure a quality control program was maintained to ensure the quality of laboratory services. Refer to D6020; (3) The laboratory director failed to ensure a quality assessment program had been established and maintained. Refer to D6021; (4) The laboratory director failed to ensure that an approved procedure manual was available to all personnel responsible for the testing process. Refer to D6031.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) 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)(ii) 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 a review of records, FDA database, and interview with the testing person, the laboratory director failed to ensure verification procedures for new test systems were adequate to determine the performance characteristics. Findings include: (1) The laboratory director failed to ensure the performance specifications had been demonstrated for six of 12 new test methods used for patient testing and six of 12 new test methods available for use on the Piccolo Xpress analyzer. Refer to D5421; (2) The laboratory director failed to ensure the performance specifications had been established for two of two new analytes not cleared or approved by the FDA (refer to D6078 for laboratory director regulatory qualifications). Refer to D5423.
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 testing person, the laboratory director failed to ensure a quality control program was maintained to ensure the quality of laboratory services. Findings include: (1) The laboratory director failed to ensure two levels of quality control materials had been performed each day of patient testing for each reagent disc type on the Piccolo Xpress analyzer for 50 of 55 days of

	patient testing reviewed. Refer to D5447; (2) The laboratory director failed to ensure there was a system that twice a year evaluated and defined the relationship between test results using different methods for six of six Piccolo Xpress reagent discs types. Refer to D5775.
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, procedure manual, FDA database, and interview with the testing person, 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.
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 the procedure manual and interview with the testing person, the laboratory director failed to ensure policies and procedures had been approved. Findings include: (1) The laboratory director failed to ensure the laboratory procedure manual had been approved, signed, and dated by the laboratory director. Refer to D5407.
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 testing person, 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 that

	verification procedures were adequate to determine the performance characteristics. Refer to D6040; (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; (3) The technical consultant failed to ensure semi-annual evaluations of all moderate complexity testing had been performed for one of one person. Refer to D6053.
D6040	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(2) The technical consultant is responsible for-- (b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system. This STANDARD is not met as evidenced by: Based on a review of records, FDA database, and interview with the testing person, the technical consultant failed to ensure that verification procedures were adequate to determine the performance characteristics. Findings include: (1) The technical consultant failed to ensure the performance specifications had been demonstrated for six of 12 new test methods used for patient testing and six of 12 new test methods available for use on the Piccolo Xpress analyzer. Refer to D5421; (2) The technical consultant failed to ensure the performance specifications had been established for two of two new analytes not cleared or approved by the FDA. Refer to D5423.
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 and interview with the testing person, 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 two levels of quality control materials had been performed each day of patient testing for each reagent disc type on the Piccolo Xpress analyzer for 50 of 55 days of patient testing reviewed. Refer to D5447; (2) The technical consultant failed to ensure there was a system that twice a year evaluated and defined the relationship between test results using different methods for six of six Piccolo Xpress reagent discs types. Refer to D5775.
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 records and interview with the testing person, the technical consultant failed to ensure semi-annual evaluations of all moderate complexity testing had been performed for one of one person. Findings include: (1) On 01/28/2022 at 10: 10 am, the tsting person stated to surveyor #1 the following testing were performed in the laboratory: (a) CBC (Complete Blood Count) using the Sysmex XN330 analyzer; (b) Chemistry testing using the Abaxis Piccolo analyzer; (c) Endocrinology testing using the Tosoh analyzer; (d) Urine Drug Testing using the Viva-E analyzer. (2) Surveyor #2 then reviewed personnel records for the testing person who had been hired on 03/15/2021 to perform the above testing with the following identified: (a) Semi-annual competency had not been performed (3) Surveyor #2 reviewed the findings with the testing person who stated on 01/28/2022 at 01:00 pm that the semi-annual competency had not been performed.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on a review of records, FDA database, and interview with the testing person, the laboratory director failed to meet the qualification requirements for high complexity testing and failed to provide overall management and direction. Findings include: (1) The laboratory performed high complexity pH and Specific Gravity testing and the laboratory director did not meet the requlatory qualifications for high complexity testing. Refer to D6078; (2) The laboratory director failed to ensure verification procedures were adequate to determine the performance characteristics. Refer D6086.
D6078	LABORATORY DIRECTOR QUALIFICATIONS CFR(s): 493.1443 The laboratory director must be qualified to manage and direct the laboratory personnel and performance of high complexity tests and must be eligible to be an operator of a laboratory within the requirements of subpart R. (a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if such licensing is required; and (b) The laboratory director must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2) Be a doctor of medicine, a doctor of osteopathy or doctor of podiatric medicine licensed to practice medicine, osteopathy or podiatry in the State in which the laboratory is located; and (b)(2)(i) Have at least one year of laboratory training during medical residency (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or (b)(2)(ii) Have at least 2 years of experience directing or supervising high complexity testing; or (b)(3) Hold an earned doctoral degree in a chemical, physical, biological or clinical

	laboratory science from an accredited institution and-- (b)(3)(i) Be certified and continue to be certified by a board approved by HHS; or (b)(3)(ii) Before February 24, 2003, must have served or be serving as director of a laboratory performing high complexity testing and must have at least-- (b)(3)(ii)(A) Two years of laboratory training or experience, or both; and (b)(3)(ii)(B) Two years of laboratory experience directing or supervising high complexity testing. (b)(4) Be serving as a laboratory director and must have previously qualified or could have qualified as a laboratory director under regulations at 42 CFR 493.1415, published March 14, 1990 at 55 FR 9538, on or before February 28, 1992; or (b)(5) On or before February 28, 1992, be qualified under State law to direct a laboratory in the State in which the laboratory is located; or (b)(6) For the subspecialty of oral pathology, be certified by the American Board of Oral Pathology, American Board of Pathology, the American Osteopathic Board of Pathology, or possess qualifications that are equivalent to those required for certification. This STANDARD is not met as evidenced by: Based on a review of records, FDA database, and interview with the testing person, the laboratory director failed to ensure the laboratory director met the regulatory qualifications for two of two new analytes not cleared or approved by the FDA. Findings include: (1) On 01/28/2022 at 10:10 am, the testing person stated to surveyor #1 pH and Specific Gravity were performed using the Viva-E Pro analyzer beginning 06/25/2021; (2) Surveyor #2 attempted to verify the classification of the analytes using the Viva-E Pro analyzer on the FDA (Food and Drug Administration) test classification database, since classification of test systems are performed by the FDA. The database did not include a classification for the analytes/analyzer combination (if a test is not included on the FDA site, then it did not go through the FDA approval process, which defaults the classification of the test as high complexity); (3) Surveyor #2 reviewed the laboratory director credentials and identified that, although the laboratory director met the educational qualifications for a moderate complexity laboratory director as stated in 493.1405(b)(5)(i)(ii)(iii), the laboratory director did not meet the regulatory qualifications for a high complexity laboratory director.
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 a review of records, FDA database, and interview with testing person #1, the laboratory director failed to ensure verification procedures were adequate to determine the performance characteristics. Findings include: (1) The laboratory failed to ensure the performance specifications of precision, reportable range, analytical sensitivity, analytical specificity, and reference intervals had been established for the pH and Specific Gravity testing not cleared or approved by the FDA. Refer to D5423.