Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1038599	02/01/2019
Name of Provider or Supplier	**Street Address, City, State**	
Crosspoint Medical Clinic	2505 W Trenton, Edinburg, TX	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	A recertification survey was conducted 02/01/2019. This facility was found NOT in compliance with the CLIA conditions for specialties/subspecialties surveyed for 42 CFR 493.1250 Analytic systems 493.1403 Moderate complexity laboratory director
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, review of patient final reports, and confirmed in interview of facility personnel, the laboratory failed to follow the manufacturer's instructions for resulting Precision DX Drugs of Abuse Integrated Strip /Card Device/Cup (Urine). The findings were: 1. Review of the manufacturer's instructions for the Precision DX Drugs of Abuse Integrated Strip/Card/Device/Cup (Urine) (ML 20000.89 REV A) under, "Limitations of the Test" it stated, "2. This assay provides a preliminary analytical test result only. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/Mass spectrometry (GC/MS) has been established as the preferred confirmatory method by the National Institute on Drug Abuse (NIDA). Clinical consideration and professional judgement should be applied to any test result, particularly when preliminary positive results are indicated." 2. Random review of patient charts revealed the following patient reports were resulted as "Positive." The results had not been documented as preliminary or sent out for confirmation. Patient 1 (see patient alias list) Date: 03-09-2018 COC (Cocaine): Positive Patient 2 (see patient alias list) Date: 08-30-2018 THC (Marijuana): Positive COC (Cocaine): Positive Patient 3 (see patient alias list) Date: 03-07-2018 THC (Marijuana): Positive COC (Cocaine): Positive Patient 4 (see patient alias list) Date: 04-26-2018 THC

	(Marijuana): Positive BZO (Benzodiazepines): Positive COC (Cocaine): Positive 3. The above findings were confirmed in interview of the technical consultant on February 1, 2019 at 14:00 hours in the office.
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: Based on manufacturer's instructions, surveyor observations, review of laboratory policy, and confirmed in interview of facility personnel, the laboratory failed to follow its own policy for laboratory safety. The findings were: 1. Review of the manufacturer's instructions for the MEDICA EasyQC Chemistry reagent, Levels A and B (lot 15265) stated, "2. Carefully reconstitute each vial of lyophilized serum with exactly 5.0 mL of ambient temperature reagent-grade water using a volumetric pipet." 2. Surveyor observation on February 1, 2019 at 13:30 hours in the laboratory revealed the primary testing person demonstrate how quality control reagent is made up for the Medica EasyRA chemistry analyzer. She obtained a sealed 5.0 mL volumetric pipette, but no bulb was present. Once she opened the volumetric pipette and was asked how she would draw up the reagent-grade water used to reconstitute the reagent, she stated, "With my mouth." She went on to say that the service representative had demonstrated the pipetting technique to her when she was trained. 3. Review of the laboratory's policy titled, "Laboratory Safety" (no approval date), stated under the 6th bullet, "Never pipette reagents or specimens by mouth. Use a bulb or mechanical pipette." 4. An interview with the technical consultant on February 1, 2019 at 13:45 hours in the office confirmed the findings. She stated she was unaware of the primary testing person's practice of pipetting by mouth. Key: mL - milliliter
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 review of laboratory policy, review of the laboratory's American Proficiency Institute (API) proficiency testing records, and confirmed in interview of facility personnel, the laboratory failed to verify the accuracy of proficiency testing (PT) scores when the laboratory received an artificial 100%. The findings were: 1. Review of the laboratory's policy titled, "Proficiency Testing" signed and approved by the laboratory director on December 2, 2014, stated, "...PT samples shall be tested and results reported on a timely basis..." 2. Review of the laboratory's proficiency testing records from 2017 (events 1, 2, and 3) and 2018 (events 1, 2, and 3) revealed the laboratory failed to return the following events within the established timeframe: Chemistry 2017 (Event 3) Chemistry 2018 (Event 3) Hematology 2018 (Event 3) 3.

	Further review of the records for event 2018 Chemistry (Event 1) on the Performance Evaluation page the technical consultant documented, "Perform all samples - unable to perform by due date. Analyzer was down." The laboratory did not perform or score the event as instructed. 4. An interview with the technical consultant on February 1, 2019 at 15:00 hours in the office confirmed the findings.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of laboratory policy, review of patient test records from 2017 and 2018, and confirmed in interview of facility personnel, the laboratory failed to have documentation of performing twice annual accuracy assessments for Vitamin D and PSA (Prostate Specific Antigen) in 2017 and 2018. The findings were: 1. A review of the laboratory's policy titled, "Quality Assurance Plan" under, "Comparison of Results" it stated, [SIC] "Our laboratory will verify the accuracy of any test that is not enrolled in a proficiency testing program. We will do so by running at least 2 split specimens (a specimen that is divided into 2 parts after collection; the laboratory analyzes one portion and the other portion is sent to a reference laboratory for analysis) and comparing our results to those of the reference laboratory. Twice a year we will perform this verification on the methods or tests for which we are not enrolled in PT." 2. A random review of 5 patient chart records from 2017 and 2018 found the laboratory performed PSA (prostate specific antigen) testing on 1 of 5 patients in 2017. Patient ID: see patient alias report Date: 11-22-2017 Result: PSA = 0.32 ng/mL 3. A random review of 5 patient chart records from 2017 and 2018 found the laboratory performed Vitamin D testing on 1 of 5 patients in 2018. Patient ID: see patient alias report Date: 01-16-2018 Result: Vitamin D = 29.8 ng/mL 4. At 15:00 hours in the office on February 1, 2019, the laboratory was asked to provide documentation of being enrolled in proficiency testing or of performing twice annual accuracy assessments for PSA in 2017 and Vitamin D in 2018. No documentation was provided. 5. An interview with the technical consultant on February 1, 2019 at 13:45 hours in the office confirmed the findings. She stated she didn't know the facility had tested patients using the FREND analyzer. She went on to say the validation was not done because the facility notified her that they would not be using the FREND analyzer. She agreed twice annual accuracy assessments had not been performed.
D5293	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c) (b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities. This STANDARD is not met as evidenced by: Based on review of laboratory policy, review of proficiency testing (PT) records, review of twice annual accuracy assessments, and confirmed in interview of facility

	personnel, the laboratory's quality assessment policy failed to identify and correct errors in its general laboratory systems as evidenced by: 1. The laboratory failed to verify the accuracy of PT scores when the laboratory received a false 100% for Chemistry 2018 (event 1). (refer to D5215) 2. The laboratory failed to perform twice annual accuracy for PSA in 2017 and Vitamin D in 2018. (refer to D5217)
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 surveyor observations, review of manufacturer's instructions, review of performance verification records, review of quality control records, review of calibration verification records, review of maintenance records, and confirmed in interview of facility personnel revealed the laboratory failed to monitor and evaluate the overall quality of its analytic systems as evidenced by: 1. The laboratory failed to perform performance specifications (precision, accuracy, reportable range, and normal range) for the FREND analyzer. (refer to D5421) 2. The laboratory failed to provide documentation of performing annual maintenance on the Drew 3 hematology analyzer in 2018 - repeat deficiency. (D5429) 3. The laboratory failed to perform calibration verification every six months in 2018 for the MEDICA EasyRA - repeat deficiency. (repeat D5439) 4. The laboratory failed to perform at least two levels of quality control each day of patient testing for the FREND analyzer when testing TSH, Vitamin D, and PSA. (refer to D5447) 5. The laboratory failed to follow the manufacturer's instructions for verification of new lots of quality control on the MEDICA EasyRA. (refer to D5469)
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 review of the CLIA-FDA database, review of performance verification documentation, review of patient reports, and confirmed in interview of facility personnel, the laboratory failed to perform verification of performance specifications on the FREND Analyzer for Vitamin D, Prostate Specific Antigen (PSA), and Thyroid Stimulating Hormone (TSH) testing when put into service in 2017. The findings were: NOTE: The facility no longer had possession of the FREND analyzer

	and was not performing patient testing on the analyzer as of the onsite survey, February 1, 2019. 1. A review of the CLIA-FDA database found at https://www.accessdata.fda.gov revealed the following analytes were listed as moderate complexity: PSA Analyte Specialty: General Chemistry Document Number CR160457 25-hydroxyvitamin D (25-OH-D) Analyte Specialty: Endocrinology Document Number CR160536 TSH Analyte Specialty: Endocrinology Document Number K131928 2. A review of performance verification implementation manual for the FREND Analyzer (Serial Number F100161102-001) revealed no documentation that accuracy, precision, reportable range, or normal range studies had been performed. 3. Random review of patient chart reports revealed the following patients were tested when performance specification (accuracy, precision, reportable range, and patient normal ranges) on the FREND analyzer had not been verified: Patient ID: (see patient alias report) Test: PSA (Prostate Specific Antigen) Date: 11-22-2017 Result: 0.32 ng/mL Patient ID: (see patient alias report) Test: TSH (Thyroid Stimulating Hormone) Date: 12-08-2017 Result: 2.01 mIU/L Patient ID: (see patient alias report) Test: Vitamin D Date: 01-16-2018 Result: 29.8 ng/mL 4. In an interview of the technical consultant on February 1, 2019 at 13:30 hours in the office, she stated the facility notified her they would not be using the FREND. She agreed the verification study was not performed. She was unaware that facility had performed patient testing using the FREND analyzer. Key: CLIA - Clinical Laboratory Improvement Amendments FDA - Food and Drug Administration mIU/L - milliinternational units per liter ng/mL - nanograms per milliliter
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 review of laboratory policy, review of manufacturer's instructions, review of service reports, and confirmed in interview of facility personnel, the laboratory failed to perform maintenance procedures according to the manufacturer's instructions on the Drew 3 Hematology analyzer. The findings were: 1. This is a repeat deficiency from the survey dated January 4, 2017. 2. Review of the laboratory's policy titled, "Instrument Operation and Maintenance" approved by the laboratory director on December 2, 2014, it stated, " ...Maintenance of each piece of laboratory instrumentation shall be in accordance with the manufacturer's recommendations. Document all maintenance performed on the test systems in use ..." 3. A review of the manufacturer's instructions for the Drew 3 hematology analyzer (D3-US-OP, Rev. 1.06, August 2010) under the section, " 10.1 Maintenance," it stated, "Annually the service technician should perform needle O-ring replacement, Syringes O-ring replacement, and sensor screw lubrication." 4. Review of Drew 3 maintenance logs from January 2017 to February 1, 2019, the day of the survey, revealed no documentation of annual preventative maintenance for the Drew 3 hematology analyzer performed in 2018. 5. Review of preventative maintenance records performed by the service engineer for 2017 and 2018 revealed no report was available for review for 2018. 6. An interview with the technical consultant on February 1, 2019 at 15:45 hours in the office confirmed the findings.
D5439	CALIBRATION AND CALIBRATION VERIFICATION

	CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review of the laboratory's test menu as presented on the CMS Form CLIA 116, review of the laboratory's calibration verification records from 2017 and 2018, and confirmed in interview of facility personnel, the laboratory failed to have documentation of performing calibration verifications every six months. The findings were: 1. This is a repeat deficiency from the survey dated January 4, 2017. 2. A review of the laboratory's test menu as presented on the CMS CLIA 116 revealed the following analytes which were tested on the Medica EasyRA chemistry analyzer: Albumin Alkaline phosphatase Alanine aminotransferase Aspartate aminotransferase Blood urea nitrogen Calcium Cholesterol Chloride Carbon dioxide Creatinine Glucose High Density Lipoprotein Potassium Sodium Total Bilirubin Total Protein Triglyceride 3. The facility performs two levels of quality control once per day. The analytes required calibration verification every six months. 4. Review of calibration records from January 2017 to February 1, 2019 (the date of the survey) revealed the last time the laboratory had performed calibration verification for the listed analytes was March 13, 2018. As of the date of the survey, this calculated to be 10 months and 19 days since the previous calibration verification. 5. An interview with the technical consultant on February 1, 3019 at 14:30 hours in the office confirmed the findings. Key: CMS - Centers for Medicare and Medicaid Services CLIA - Clinical Laboratory Improvement Amendments
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 review of the CLIA-FDA database, review of laboratory policy, review of manufacturer's instructions, review of quality control records, random review of patient reports, and confirmed in interview of facility personnel, the laboratory failed to perform 2 levels of quality control each day of patient testing on the FREND Analyzer for Vitamin D, Prostate Specific Antigen (PSA), and Thyroid Stimulating Hormone (TSH) testing. The findings were: 1. A review of the CLIA-FDA database found at https://www.accessdata.fda.gov revealed the following analytes were listed as moderate complexity on the FREND analyzer: PSA Analyte Specialty: General Chemistry Document Number CR160457 25-hydroxyvitamin D (25-OH-D) Analyte Specialty: Endocrinology Document Number CR160536 TSH Analyte Specialty: Endocrinology Document Number K131928 2. A review of the laboratory's policy titled, "Control Policy" approved by the laboratory director on December 2, 2014, it stated, " ...For quantitative testing, two levels of control shall be run for every procedure on each day of use ..." 3. Review of the manufacturer's instructions for the MEDICA EasyRA quality control procedures, retrieved by the technical consultant from the instrument's desktop under, "Quality Control Procedures," it stated, "Daily Use of QC Material: Two levels of quality control material should be run for each chemistry which is being reported by the laboratory, each day..." 4. The laboratory had not developed an IQCP (Individualized Quality Control Plan) to reduce the frequency of quality control testing. The laboratory was required to perform at least two levels of quality control each day of patient testing. 5. Random review of patient results from 2017 and 2018 revealed the following patient results were tested when quality control testing was not performed: Patient ID: (see patient alias report) Test: PSA (Prostate Specific Antigen) Date: 11-22-2017 Result: 0.32 ng/mL Patient ID: (see patient alias report) Test: TSH (Thyroid Stimulating Hormone) Date: 12-08-2017 Result: 2.01 mIU/L Patient ID: (see patient alias report) Test: Vitamin D Date: 01-16-2018 Result: 29.8 ng/mL 6. The above findings were confirmed in interview with the technical consultant on February 1, 2019 at 15:30 hours in the office. Key: QC - quality control CLIA - Clinical Laboratory Improvement Amendments FDA - Food and Drug Administration ng/mL - nanograms per milliliter mIU/L - milliinternational units per liter
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(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--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, review of manufacturer quality

	control range assay sheets, direct observation of quality control records available electronically for the MEDICA EasyRA, and confirmed in interview of facility personnel, the laboratory failed to follow the manufacturer's instructions for verifying quality control ranges for 4 of 4 lot numbers. The findings were: 1. Review of the manufacturer's instructions (operator's manual) retrieved by the technical consultant from the instrument's desktop under, "Assay Values on the Quality Control Assay Disk," it stated, "The mean value obtained by the analyzer for the quality control material should be within the assay values shown on the Quality Control Assay CD for each chemistry. If not, the QC value for that chemistry will be shown with a flag, (symbol QC). After 20 days of QC results, QC limits should be entered which are equal to the actual 2 standard deviation limits so that flags reflect QC results against true statistics as calculated by EasyRA." 2. Review of quality control records for the laboratory's current lot number (1727, expiration date: July 31, 2020) and the laboratory's previous lot number (1526, expiration date: August 2018) revealed the laboratory did not follow the manufacturer's instructions to enter QC limits after 20 days of performing quality control. 3. Review of the MEDICA EasyRA Chemistry QC ranges obtained from the assay sheets revealed that for each of the above lot numbers, the laboratory's ranges reflected the manufacturer's ranges for the duration of the lot numbers: Lot 15265 (Level A): Expiration Date: 2018-08-31 Analyte Range (1SD) ALB 2.2 - 2.8 ALP 66 - 90 ALT 30.2 - 44.2 AST 27.5 - 39.5 TBIL .73 - 1.13 CA 8.75 - 10.15 CO2 10 - 16 CHOL 73 - 97 CREA .72 - 1.12 GLUH 85- 97 HDL 23 - 33 LDL 31 - 41 TP 3.7 - 4.7 TRIG 105 - 121 BUN 9.1 - 15.1 Na 112.9 - 122.9 K 4.54 - 5.14 Cl 83.1 - 93.1 Lot 15266 (Level B): Expiration Date: 2018-31-08 Analyte Range (1SD) ALB 3.9 - 4.9 ALP 255 - 335 ALT 87.2 - 117.2 AST 105 - 135 TBIL 5.36 - 6.96 CA 10.87 - 12.87 CO2 16 - 26 CHOL 190 - 230 CREA 5.33 - 6.33 GLUH 238 - 268 HDL 60 - 80 LDL 96 - 116 TP 5.8 - 7.8 TRIG 216 - 246 BUN 42.7 - 54.7 Na 141.8 - 151.8 K 6.65 - 7.25 Cl 94.8 - 104.8 Lot 17270 (Level A): Expiration Date: 07-31-2020 Analyte Range (1SD) ALB 2.6 - 3.2 ALP 55 - 79 ALT 19 - 33 AST 25.7 - 37.7 TBIL 0.79 - 1.19 CA 8.14 - 9.54 CO2 9 - 15 CHOL 71 - 95 CREA .92 - 1.32 GLUH 90 - 106 HDL 26 - 36 LDL 35 - 45 TP 4.2 - 5.2 TRIG 85 - 109 BUN 9 - 15 Na 111.2 - 121.2 K 3.69 - 4.29 Cl 79.4 - 89.4 Lot 17271 (Level B): Expiration Date: 07-31-2020 Analyte Range (1SD) ALB 3.7-4.7 ALP 207 - 287 ALT 88.5 - 118.5 AST 177 - 207 TBIL 5.93 - 7.53 CA 10.07 - 12.07 CO2 16 - 26 CHOL 182 - 222 CREA 5.55 - 6.55 GLUH 216 - 256 HDL 52 - 72 LDL 97 - 117 TP 5.3 - 7.3 TRIG 190 - 230 BUN 38.9 - 50.9 Na 134.3 - 144.3 K 5.83 - 6.43 Cl 87.9 - 97.9 4. Interview of the technical consultant on February 1, 2019 at 14:00 hours in the office confirmed the findings. She agreed it appeared that the laboratory was working off a running mean and that the laboratory had not established its own QC ranges. Key: QC - quality control ALB - Albumin ALP - Alkaline phosphatase ALT - Alanine aminotransferase AST - Aspartate aminotransferase BUN - Blood urea nitrogen CA - Calcium CHOL - Cholesterol Cl - Chloride CO2 - Carbon dioxide CREA - Creatinine GLUCH - Glucose HDL - High density lipoprotein K - Potassium Na - Sodium TBIL - Total Bilirubin TP - Total Protein TRIG - Triglyceride
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities.

	This STANDARD is not met as evidenced by: Based on surveyor observations, review of laboratory policy, review of manufacturer's instructions, review of performance verification records, review of quality control records, review of calibration verification records, review of maintenance records, and confirmed in interview of facility personnel revealed the laboratory failed to monitor and evaluate the overall quality of its analytic systems as evidenced by: 1. The laboratory failed to perform performance specifications (precision, accuracy, reportable range, and normal range) for the FREND analyzer. (refer to D5421) 2. The laboratory failed to provide documentation of performing annual maintenance on the Drew 3 hematology analyzer in 2018 - repeat deficiency. (refer to D5429) 3. The laboratory failed to perform calibration verification every six months in 2018 for the MEDICA EasyRA - repeat deficiency. (refer to D5439) 4. The laboratory failed to perform at least two levels of quality control each day of patient testing for the FREND analyzer when testing TSH, Vitamin D, and PSA. (refer to D5447) 5. The laboratory failed to follow the manufacturer's instructions for verification of new lots of quality control on the MEDICA EasyRA. (refer to D5469)
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: Based on review of laboratory calculations and confirmed in interview of facility personnel, the laboratory failed to have documentation of verifying calculations for 2017 and 2018. The findings were: 1. This is a repeat deficiency from the survey conducted January 4, 2017. 2. A review of laboratory records revealed the laboratory performs the following calculations: a) Glomerular Filtration Rate b) BUN/Creatinine ratio d) Low Density Lipoprotein 3. On February 1, 2019 at 15:00 hours, the laboratory was asked to provide documentation of verifying the calculations for 2017 and 2018. No documentation was provided. 4. An interview with the technical consultant on February 1, 2019 at 15:00 hours confirmed the facility had performed annual verifications for the calculations but the records could not be located.
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 surveyor observations, review of manufacturer's instructions, review of

	quality control records, review of calibration verification records, review of maintenance records, review of patient reports, and confirmed in interview of facility personnel, the laboratory director failed to provide overall management and direction of the laboratory. (refer to D6007, D6011, D6013, D6020, D6021, and D6028)
D6007	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(1) 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)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing; This STANDARD is not met as evidenced by: Based on direct observations, review of manufacturer's instructions, review of maintenance records, review of patient results, and confirmed in interview of laboratory personnel, the laboratory director failed to provide quality laboratory services for the analytic phase of testing. (refer to D5421, D5429, D5439, D5447, and D5469)
D6011	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(2) 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)(2) and provide a safe environment in which employees are protected from physical, chemical, and biological hazards. This STANDARD is not met as evidenced by: Based on surveyor observation, review of manufacturer's instructions, and confirmed in interview of facility personnel, the laboratory director failed to provide a safe physical environment that ensured the testing person followed laboratory safety polies to not pipette by mouth. (refer to D3011)
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 review of the laboratory's FREND chemistry analyzer verification records, and confirmed in interview of facility personnel, the laboratory director failed to ensure verification records were complete prior to patient testing. (refer to D5421)
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 review of manufacturer's instructions, review of quality control records from, and confirmed in interview of facility personnel, the laboratory director failed (a) to ensure two levels of quality control testing were performed on each day of patient testing, and (b) failed to follow the manufacturer's instructions for implementation of new lots of quality control on the MEDICA EasyRA. (refer to D5447 and D5469)
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 surveyor observations, review of laboratory policy, review of manufacturer's instructions, review of performance verification records, review of quality control records, review of calibration verification records, review of maintenance records, and confirmed in interview of facility personnel revealed the laboratory director failed to ensure the laboratory's quality assurance program was maintained. (refer to D5293 and D5793)
D6028	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(10) 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)(10) Employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate

	consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart; This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted CMS Form 209, review of the laboratory's submitted Form CMS 116, review of laboratory policies, review of proficiency testing records, review of verification records, review of quality control records, review of patient records, and confirmed in interview of facility personnel, the laboratory director failed to employ a sufficient number of laboratory personnel with appropriate education. The findings were: 1. Review of the laboratory's submitted CMS Form 209, signed by the laboratory director on February 1, 2019, revealed the laboratory identified 1 testing person. 2. Review of the laboratory's submitted CMS Form 116, signed by the laboratory director in February 1, 2019, revealed the laboratory documented the following test volumes: General Immunology: 2400 tests per year Routine Chemistry: 15,840 tests per year Hematology: 10,800 tests per year 3. The laboratory failed to verify accuracy of PT scores when the laboratory received a false score of 100% on a proficiency testing event. (refer to D215) 4. The laboratory failed to perform twice annual accuracy assessments for PSA in 2017 and Vitamin D in 2018. (refer to D5217) 5. The laboratory failed to perform performance specifications (precision, accuracy, reportable range, and normal range) for the FREND analyzer. (refer to D5421) 6. The laboratory failed to provide documentation of performing annual maintenance on the Drew 3 hematology analyzer in 2018 - repeat deficiency. (D5429) 7. The laboratory failed to perform calibration verification every six months in 2018 for the MEDICA EasyRA - repeat deficiency. (repeat D5439) 8. The laboratory failed to perform at least two levels of quality control each day of patient testing for the FREND analyzer when testing TSH, Vitamin D, and PSA. (refer to D5447) 9. The laboratory failed to follow the manufacturer's instructions for verification of new lots of quality control on the MEDICA EasyRA. (refer to D5469)