Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D0369930	10/05/2022
Name of Provider or Supplier	**Street Address, City, State**	
Junction Clinic Pc	4771 Michigan Avenue, Detroit, MI	

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	During a recertification survey on October 5, 2022, the laboratory was found out of compliance with the following conditions: 42 CFR 493.1250 Condition: Analytic systems 42 CFR 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director
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 record review and an interview with the Technical Consultant (TC), the laboratory failed to establish policies and procedures to assess the competency of personnel serving the roles of Clinical Consultant and Technical Consultant for 2 (October 2020 to October 2022) of 2 years reviewed. Findings include: 1. A review of the laboratory's personnel records revealed the most recent competency assessments for the Clinical and Technical Consultants were dated 8/7/20 and 8/6/20 respectively. 2. The surveyor requested the laboratory's policy or procedure for assessing the competency of the Clinical and Technical Consultants on 10/5/22 at 11:28 am and it was not made available. 3. An interview on 10/5/22 at 11:36 am with the TC confirmed the laboratory had not established a policy or procedure for assessing competency of the Clinical and Technical Consultant.
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 record review, observations, and interviews, the laboratory failed to follow its policy to perform calibration verification at least every six months for Prostate Specific Antigen (PSA) and Testosterone analytes (Refer to D5401), failed to perform control testing each day of patient testing for Prostate Specific Antigen (PSA) and Testosterone analytes (Refer to D5445), and failed to ensure the results of Prostate Specific Antigen (PSA) and Complete Blood Count (CBC) control testing met the acceptability criteria before reporting patient results (Refer to D5481).
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 record review and observation, the laboratory failed to follow its policy to perform calibration verification at least every six months for Prostate Specific Antigen (PSA) and Testosterone analytes for 2 (October 2020 to October 2022) of 2 years reviewed. Findings include: 1. A review of the laboratory's "Lab Policies" revealed a section stating, "Calibration verification must be done every 6 months or as needed after service or change of reagents." 2. A review of the laboratory's "Calibration Verification" forms for PSA and Testosterone testing performed on the NanoEnTek Frend analyzer revealed handwritten documentation of calibration verification results for the following dates: a. 1/20/21 b. 10/21/21 c. 1/20/22 d. 7/20/22 3. The surveyor requested the instrument data from the calibration verification events listed above on 10/5/22 at 1:20 pm and the documents were not made available. 4. A review of the NanoEnTek Frend analyzer printouts revealed a lack of documentation for any PSA or Testosterone calibration verification testing performed on the dates listed above. 5. A review of the NanoEnTek Frend analyzer stored data revealed a lack of documentation for any PSA or Testosterone calibration verification testing performed on the dates listed above.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: . Based on observation and interview with specimen collection staff, the laboratory failed to ensure blood collection tubes had not exceeded their expiration date for 23 of

	23 sodium citrate BD Vacutainer tubes present in the laboratory's collection area. Findings include: 1. The surveyor observed 23 BD Vacutainer sodium citrate tubes in stock in the laboratory's collection area on 10/5/22 at 9:42 am and all had exceeded their expiration dates: a. Lot 9220387 with the expiration date of 5/31/20, three tubes present. b. Lot 0345722 with the expiration date of 9/30/21, three tubes present. c. Lot 1288649 with the expiration date of 7/31/22, 17 tubes present. 2. An interview with specimen collection staff on 10/5/22 at 9:56 am revealed the laboratory used the sodium citrate tubes to collect specimens for referral testing.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: . Based on record review, observation, and interview with the Technical Consultant (TC), the laboratory failed to perform control testing each day of patient testing for Prostate Specific Antigen (PSA) and Testosterone analytes for 20 (10/01/2020, 10/22/2020, 10/29/2020, 12/03/2020, 04/16/2020, 06/11/2021, 01/28/2022, 02/22/2022, 02/25/2022, 03/04/2022, 03/18/2022, 03/25/2022, 04/08/2022, 04/15/2022, 04/29/2022, 06/28/2022, 08/03/2022, 08/19/2022, 08/26/2022, and 09/30/2022) of 27 patient testing dates from October 2020 to October 2022. Findings include: 1. A review of the laboratory's "Lab Policies" revealed a section stating, "Chem, Hem, RIA- run minimum 2 controls each day of run. If both controls not in range, do corrective action. Rerun controls, recalibrate, or use new reagents or controls until acceptable results are obtained. If 3 controls run 2/3 must be in range." 2. An observation of the laboratory's NanoEnTek Frend Analyzer instrument memory on 10/5/22 at 1:36 pm revealed 20 of the 27 dates when two levels of quality control testing had not been performed each date of PSA and Testosterone patient testing from October 2020 to October 2022: a. 10/01/2020 b. 10/22/2020 c. 10/29/2020 d. 12/3/2020 e. 04/16/2020 f. 06/11/2021 g. 01/28/2022 h. 02/22/2022 i. 02/25/2022 j. 03/04/2022 k. 03/18/2022 l. 03/25/2022 m. 04/08/2022 n. 04/15/2022 o. 04/29/2022 p. 06/28/2022 q. 08/03/2022 r. 08/19/2022 s. 08/26/2022 t. 09/30/2022 3. A review of the laboratory's NanoEnTek Frend Analyzer instrument printed data revealed a lack of two levels of quality control testing on the dates listed above. 4. A review of the laboratory's NanoEnTek Frend Analyzer instrument memory and the instrument printed data revealed a total of 35 patients receiving PSA testing and a total of 14 patients receiving Testosterone testing had been tested on the dates listed above. 5. The surveyor observed Testing Personnel #1 (TP1) perform quality control testing for PSA on 10/5/2022 at 2:05 pm. TP1 manually entered the name for both control levels and performed testing. Once the instrument gave a result, TP1 pressed the "Print" button, and the instrument printed the results. The results of the quality control testing had automatically saved into the instrument's memory. 6. An interview on 10/5/22 at 2:05 pm with the TC revealed the laboratory had not implemented an Individualized Quality Control Plan (IQCP) for the NanoEnTek Frend analyzer for PSA and Testosterone testing.

D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: . Based on record review and interview with Testing Personnel #1 (TP1), the laboratory failed to ensure the results of Prostate Specific Antigen (PSA) and Complete Blood Count (CBC) control testing met the acceptability criteria before reporting patient results for 2 (4/6/2021 and 4/8/2022) of 15 patient testing dates reviewed. Findings include: 1. A review of the laboratory's "Lab Policies" revealed a section stating, "Chem, Hem, RIA- run minimum 2 controls each day of run. If both controls not in range, do corrective action. Rerun controls, recalibrate, or use new reagents or controls until acceptable results are obtained. If 3 controls run 2/3 must be in range." 2. A review of the laboratory's quality control records for 4/6/2021 revealed that out of the three controls performed, two controls for red blood cell counts were out of range. A total of 14 patients had CBC testing reported that date. a. The Normal Control Level range was 4.14 to 4.50 10^6/ul, the laboratory's result was 4.09 10^6/ul. b. The High Control Level range was 4.86 to 5.30 10^6/ul, the laboratory's result was 4.85 10^6/ul. 3. The surveyor requested documentation of corrective action performed for patients receiving CBC testing on 4/6/2021 on 10/5/22 at 1:00 pm and it was not made available. 4. An interview on 10/5/22 at 1:00 pm with Testing Personnel #1 indicated that the laboratory's process is to rerun quality control if it is out of range prior to reporting patient results and retain the rerun documentation. 5. A review of the laboratory's "Quality Control Chart" and the NanoTek Frend Analyzer instrument memory revealed the range for level 1 was less than or equal to 1.0 ng/mL. The laboratory had a result of 1.14 ng/mL for level 1 on 4/8/22. No reruns of the quality control testing were documented. 11 patients had PSA testing that date.
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 record review, observation, and interviews, the Laboratory Director failed to ensure the quality control program established was maintained (Refer to D6020), ensure the quality assessment program identified failures in quality as they occurred when quality control was not performed for Prostate Specific Antigen (PSA) and Testosterone analytes (Refer to D6022), and ensure patient test results were reported only when the test systems were functioning properly (Refer to D6025).
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 record review, observation, and interviews, the Laboratory Director failed to ensure the quality control program established was maintained. Refer to D5445.
D6022	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 and quality assessment programs are established and maintained to identify failures in quality as they occur. This STANDARD is not met as evidenced by: . Based on record review and observation, the Laboratory Director failed to ensure the quality assessment program identified failures in quality as they occurred when quality control was not performed each day of patient testing for Prostate Specific Antigen (PSA) and Testosterone analytes for 2 (October 2020 to October 2022) of 2 years reviewed. Findings include: 1. A review of the Laboratory Director's "Competency Evaluation for the Laboratory Director/Medical Director" dated 8/7 /2020 revealed a section stating, "The Laboratory Director of a high/moderate complexity laboratory is responsible for the overall operation and administration of the laboratory, including the employment of competent qualified personnel. Even though the option to delegate some responsibilities exists, the Laboratory Director is ultimately responsible and must ensure that all duties are properly performed and applicable CLIA regulations are met. It is the Laboratory Director's responsibility to ensure that the laboratory develops and uses a quality system approach to laboratory testing that provides accurate and reliable patient test results." 2. An observation of the laboratory's NanoEnTek Frend Analyzer instrument memory revealed 20 of the 27 dates when two levels of quality control testing had not been performed each date of patient testing from October 2020 to October 2022. Refer to D5445. 3. A review of the laboratory's quality assessment documentation revealed the laboratory assesses patient test management, quality control policies, laboratory safety policies, proficiency testing policies, personnel policies, and the quality assurance program during its reviews. The quality assessment reviews were documented monthly from October 2020 to September 2022 and had not identified the laboratory's failure to perform quality control testing for PSA and Testosterone testing each date of patient testing.
D6025	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(7) 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)(7) Ensure that patient test results are reported only when the system is functioning properly. This STANDARD is not met as evidenced by: . Based on record review and interview, the Laboratory Director failed to ensure patient test results were reported only when the test systems were functioning properly. Refer to D5481.