Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0930454	10/11/2018
Name of Provider or Supplier	**Street Address, City, State**	
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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
D2087	ROUTINE CHEMISTRY CFR(s): 493.841(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency (PT) testing result reports, and interview with the testing personnel, it was determined that the laboratory failed to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. The findings included: a. The laboratory performed routine chemistry including, but are not limited to the followings: Total Bili (T Bili), total Cholesterol (Chol), Triglycerides (TG), b. The laboratory enrolled its proficiency testing programs with API (American Proficiency Institute). c. The laboratory attained scores of 60 % for the following analyte T Bili, Chol, and TG in the 2nd 2017 PT, 1st 2018 PT, and 1st 2018 PT, respectively, which were unsatisfactory analyte performance for the testing event. d. the laboratory performed routine chemistry in approximately 50 patient samples weekly. e. The testing personnel affirmed (10/11/18 @ 11:43 am) that the laboratory failed to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event was unsatisfactory analyte performance for the testing event.
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 the laboratory's proficiency (PT) testing result reports, and interview with the testing personnel, it was determined that the laboratory failed, at least twice annually, to verify the accuracy of any test or procedure it performs that is not included in subpart I of 42 CFR part 493. The findings included: a. The laboratory performed Progesterone (Prog) , Insulin (Ins), Vit B12 (B12), Folate (Fol) , Testosterone (TST), which are not listed in the subpart I of 42 CFR part 493 CLIA regulations. b. The laboratory enrolled with API (American Proficiency Institute) PT provider, to verify the accuracy of the test procedures listed in item (a) it performed. c. At the time of survey (10/11/18 @121:35) there were no evidences of evaluation records for the test mentioned above in itewm (a), at least twice annually to verify the accuracy of the testing systems which are not listed in the subpart I of 42 CFR part 493.
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 review of the laboratory records, and interview with the testing personnel, it was determined that the laboratory director failed to approve, sign, and date the current laboratory procedures. The findings included: a. No evidence of the current laboratory director's has approved, signed and dated the procedure current procedure manuals. b. The laboratory has no system in place for "DATA AUDIT TRAIL" in the procedure manual. c. According to the procedure manual for "DATA AUDIT TRAIL", the laboratory must perform: "The Audit Report" on a monthly basis and reviewed by the technical supervisor and/or Director.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on review of the temperature records, and interview with the testing personnel, it was determined that the laboratory failed to define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. The laboratory failed to monitor and document the following, but is not limited to temperature. The findings included: a. Review a laboratory's temperature chart for both Fridge (refrigerator) and Freezer from Sept 3, 2018 thru Sept 28, 2018. b. The laboratory did not define the acceptable temperature ranges for refrigerator and freezer and indicated on the records. c. Temperature recorded for refrigerator were between 0 and -1 with no unit of oC or oF

	identified.. d. Temperature recorded for freezer were between -14 and -17 with no unit of oC or oF identified.. e. The personnel who monitored the temperature signed its initials ditto beyond September 28, 2018 with NC.
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 review of the laboratory records, and interview with the testing personnel, it was determined that the laboratory failed to follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems. The findings included: See D-5407 and D-5413
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of the patient's test result reports, and interview with the laboratory director, it was determined that the laboratory failed to provide a complete final reports including, but are not limited to the patient demography, the full names of the anlyte in the test results plus the result unit or interpretation appropriately. The findings included: The laboratory's patient final test result reports must indicate and include the followings but not limited to the test performed, the test result and, if applicable, the units of measurement or interpretation, or both. I. a. The laboratory performed urine drug screen by Beckman AU for AMPH, BARB, BENZO, COC, OP, THC and METH. b. The laboratory must provide appropriate nomenclatures of the test names of the drugs clearly, not by abbreviation and the test result interpretations. c. For a qualitative drug screen testing, the laboratory failed to use a "cut off" but a "normal range" for the above mentioned drugs. d. The laboratory's final drug screen test report provided name in abbreviations, and "cut off" listed under "normal range" in its qualitative testing system as follows: Name Normal Range AMPH, 999.99 1000.00 BARB 199.99 200.00 BENZO 199.99 200.00 COC 299.99 300.00 OP 1999.99 2000.00 THC 49.99 50.00 METH 299.99 300.00 d. The laboratory failed to provide the test result under "Detected" or "Positive" and "non Detected" or "Negative" for the test results in a qualitative drug screen testing system, instead of in quantitative results. II. a. The laboratory performed routine chemistry including, but are not limited to the following analyte, HDL, LDL, Na, K etc. b. The laboratory's

	patient chemistry testing result reports indicated the Normal Ranges for HDL, LDL, B /C, CRF, AGAP, GLOB, OSMO as follows: Name Normal Range HDL 40.0 41.0 LDL -99999 99999 B/C -9999999 9999999 CRF -9999999 9999999 AGAP -9999999 9999999 GLOB -9999999 9999999 OSMO -9999999 9999999 c. The laboratory failed to provide proper interpretation information for its chemistry test results reports. III. a. The laboratory provided incomplete patient test results reports. b. Review of three CBC hematology test reports, ACC# 23937 (run on 08-21-2018), ACC# 24139 (run on 09-06-18) , ACC# 23865 (run on 08-17-18). c. The laboratory patient test result reports provided "Patient Limits" between 00.0 to 99.9 for all the CBC parameters. b. The laboratory failed to provide a completed patient "Patient Limits" or "Reference Ranges" based on the gender difference.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(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 postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on review of the laboratory records, and interview with the testing personnel, it was determined that the laboratory failed to follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the postanalytic systems. The findings included: a. See D-5805 b. The laboratory printed out a report for patient ID #23936, drawdate of 08/21/18 at the date of survey (10/11/18), T3 Free test was ordered along with other male hormones. c. The physician ordered "Male Hormones" panel which including, but are limited to the followings: Insulin level, LH, T3 Free, T4 Free, Testosterone for his patients. d. This report indicated that T3 Free is still PENDING and Date Reported: PENDING" on the date of survey/print-out (10/11/18) e. More incomplete and/or pending results reports were noted for the following patients with similar "PENDING " reports. f. There were patient result reports still with "Date Reported: PENDING" at the date of survey (10 /11/18): ID DrawDate Test Pending 23544 07/09/18 LH T3 Free 23864 08/17/18 T3 Free 23821 08/13/18 T3 Free g. The laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems
D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b) 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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by:

	Based on observation of the facility, review of the laboratory's records, and interview with the laboratory director, and the testing personnel, it was determined that the laboratory director failed to be 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. The findings included: See D-6016, D-6018, and D-6021
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency (PT) testing result reports, and interview with the testing personnel, it was determined that the laboratory director failed to ensure that the proficiency testing samples were tested as required under Subpart H of 42 CFR part 493. The findings included: See D-2087
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on review of the laboratory proficiency testing (PT) result reports, and interview with the testing personnel (TP), it was determined that the laboratory director failed to ensure that all proficiency testing reports received were reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. The findings included: a. The laboratory enrolled its proficiency testing (PT) programs with API (American Proficiency Institute). b. The laboratory failed to ensure that all proficiency testing reports received were reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; c. No evidence of reviewing the scored PT reports were noted.
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 the laboratory's proficiency (PT) testing result reports, and interview with the testing person, it was determined that the laboratory director failed to ensure that the quality control program was established and maintained to assure the quality of laboratory services provided. The findings included: See D-5407, D-5413
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 review of the laboratory's proficiency (PT) testing result reports, and interview with the testing person, it was determined that the laboratory director failed to ensure that quality assessment programs were established and maintained to assure the quality of laboratory services provided. The findings included: See D-5891