Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D2126610	05/23/2019
Name of Provider or Supplier	**Street Address, City, State**	
St Anthony Medical Laboratory	654 Avenue C, Suite #303, Bayonne, NJ	

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
D5018	URINALYSIS CFR(s): 493.1211 If the laboratory provides services in the subspecialty of Urinalysis, the laboratory must meet the requirements specified in 493.1230 through 493.1256, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on surveyor review of the Urinalysis Procedure Manual (UPM) and Work Records, lack of the Urine Microscopic Quality Control (QC) records and interview with the Technical Consultant (TC), the laboratory failed to meet the requirements of pre analytic, analytic and post analytic Urinalysis test procedures. The findings include: 1. The laboratory did not follow UPM procedures. Refer to D 5401 # 4 and (b) 2. The laboratory did not have manufacturer's procedure. Refer to D 5411(a) and (b) 3. The laboratory did not perform maintenance. Refer to D 5433 4. The laboratory did not run QC. Refer to D 5449 5. The laboratory did not report results accurately. Refer to D 5801 6. The laboratory did not report test name. Refer to D 5805
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: Based on lack of the Manufactures Package Insert (MPI) and interview with the Technical Consultant (TC), the laboratory failed to have written policy and procedure

	on maintaining an optimum integrity of a patients' specimens for tests performed on the Beckman Coulter DxI 600 chemistry analyzer from 12/20/17 to the date of the survey. The TC confirmed on 5/23/19 at 1:30 pm that the laboratory did not have a procedure for maintaining an integrity of patient samples.
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 surveyor review of the Competency Assessment (CA) records and interview with the Technical Supervisor (TS), the laboratory failed to evaluate competency accurately on two of two TP in 2018. The findings include: 1. The CA was not performed on each test method performed by testing personnel. 2. There were no records to substaniate how assessment was performedand what records were reviewed. 3. The TC confirmed on 5/23/19 at 11:00 am that CA was not done correctly.
D5309	TEST REQUEST CFR(s): 493.1241(e) If the laboratory transcribes or enters test requisition or authorization information into a record system or a laboratory information system, the laboratory must ensure the information is transcribed or entered accurately. This STANDARD is not met as evidenced by: Based on review of Test Requisition (TR), Laboratory Information System (LIS) and interview with the Technical Supervisor (TS), the laboratory failed to ensure that information from TR was transcribed accurately into the LIS for all tests from12/20 /17 to the date of the survey. The TS confirmed on 5/23/19nat 10:15 am that the laboratory did not ensure information was transcribed accurately.
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: a) Based on surveyor review of the Procedure Manual (PM), Laboratory's Records and interview with the Technical Consultant (TC) and Testing Personnel (TP), the laboratory personnel failed to follow all of the following procedures from 12/20 17 to the date of survey. The findings include: 1. The 'Laboratory Information System' procedure, step # 11, stated 'The interfaced results is verfied for accuracy bi-annually by random selection of five pateitns results' but the laboratory verified only once with

	less than five patients. 2. The 'Quality System Management' procedure, step # 8 stated "Assessment and Audits" reviewed once a month but there was no documented evidence that it was followed. 3. The 'New Reagent Lot Confirmation of Acceptability' procedure. step # 7 stated 'to perform lot to lot verification before new lot of reagent is put in use' but the laboartory did not follow Hemoglobin A1C test performed on the BioRad D 10 analyzer and for qualitative tests. 4. The 'Microscopic Examination' procedure, step # 4 stated to centrifuge the urine specimen @ 2000 rpm for five minutes but TP # 2 listed on CMS form 209 stated on the day of survey that she centrifuges for 15 minute @ around 3400 rpm. 5. The TC and TP comfirmed on 5 /23/19 at 1:30 pm that all above procedures were not followed. b) Based on surveyor review of ichem VELOCITY Operator Manual (OM) and interview with the Testing Personnel (TP), the laboratory failed to follow OM Urine Strips vial stability instructions to perform Urinalysis tests from 12/20/17 to the date of survey. The finding includes: 1. The OM stated open vial of strips stability was for five days but there was no new expiration date on the bottle of strips and TP # 2 listed in CMS form 209 stated she was not aware that it was good for only five days. 20464 c) Based on surveyor review of the Procedure Manual, and interview with Technical Consultant (TC), the laboratory failed to follow "Calibration Procedures & Calibration Verifications" (CPCV) procedure for chemistry test from 12/20/17 to the date of the survey. The findings include: 1. The PM stated "Linearity studies are performed twice a year and also when new assays are introduced to the test menu and after major maintenance.". 2. There was no evidence that linearity studies were performed on the Beckman coulter AU 680 and Unicel DxI 600 analyzers twice a year. 3. The TC confirmed on 5/23/19 at 11:40 am that the CPCV procedure was not followed.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: a. Based on surveyor review of the Procedure Manual (PM) and interview with the Technical Consultant (TC), the laboratory failed to have a procedure for Pathology Review of abnormal Manual Differentials from 12/20/17 to the date of the survey. The TC confirmed on 5/23/19 at 2:20 pm that laboratory did not have the above procedure. b. Based on surveyor review of the PM and interview with the TC, the

	laboratory failed to have a procedure for the speed and time needed to spin Coagulation samples from 12/20/17 to the date of the survey. The CS confirmed on 5 /23/19 at 2:30 pm that laboratory did not have the above procedure.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: a) Based on lack of Centrifuge procedure manual, observation of Centrifuge and interview with the Technical Consultant (TC), the laboratory failed to know the speed of centrifuge used for preparing Urine Microscopic tests from 12/20/17 to the date of survey. The TC confirmed on 5/23/19 at 1:00 pm that speed of centrifuge was not known. b) Based on surveyor review of the Procedure Manual (PM) and interview with the TC, the laboratory failed to have Urine Strips package insert from 12/20/17 to the date of survey. The TC confirmed on 5/23/19 at 1:10 pm that the laboratory did not have manufacturer's insert. 20464 c) Based on surveyor observation of Quality Control material (QC) in use, review of the Liquicheck Immunoassay Plus Control Manufacture Package Insert (MPI) and interview with the Testing Personnel (TP), the laboratory Failed to follow MPI for the Beckman Coulter DXI 600 from 12/20/17 to the date of survey. The findings include: 1. The MPI stated "Once thawed, do not refreeze this product. Discard remaining Material. This product is shipped under frozen conditions"". 2. The TP stated "QC was thawed aliquoted and then frozen." 3. The QC material was observed in the freezer aliquoted into cuvettes. 4. Approximately 1300 patients were run and reported. 5. The TP confirmed on 5/23/19 at 11:00 am that the laboratory did not follow the MPI
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on surveyor observation of the Quality Control (QC) material and interview with the Technical Consultant (TC), the laboratory failed to put new expiration dates on controls used on the DxH 600, Biorad D10, ichem Velocity, Immulite 2000, IL ACL Elite and AU 680 analyzers on the date of survey. The TC confirmed on 5/23/19 at 2:00 pm the laboratory failed to put new expiration dates on the control material.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially

	available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM), laboratory records and interview with the Technical Consultant (TC), the laboratory failed to perform and document maintenance of Microscope, Centrifuge and Pipettes in 2018. The TC confirmed on 5/23/19 at 12:20 pm that the laboratory did not perform and document maintenance on equipments.
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 lack of Calibration Verification (CV) records and interview with the Technical Consultant (TC), the laboratory failed to perform and document CV procedures at least once every six months for Hematology Tests performed on the Beckman Coulter Unicell DxH 600 analyzer from 12/20/17 to the date of the surveyor. The TC confirmed on 5/23/19 at 2:10 pm CV was not performed every six months.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(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 qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on lack of Urine Microscopic Quality Control records and interview with the Technical Consultant (TC), the laboratory failed to perform and document urine microscopic controls on each day of patient testing from 12/20/17 to the date of the survey. The TC confirmed on 5/23/19 at 1:00 pm that the laboratory did not perform and document quality control on each day of patient testing.
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 surveyor review of the Quality Control (QC) records and interview with the Technical Consultant (TC), the laboratory failed to verify that the assayed QC materials were within the acceptable ranges before they were put into use for tests performed on the Beckman Coulter AU 680, Beckman Coulter DxI 600, Immuilite 2000, iChem VELOCITY, IL ACL Elite analyzers from 12/20/17 to the date of survey. The TC confirmed on 5/23/19 at 1:00 pm that the laboratory did not verify QC materials.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on surveyor review of the Quality Control (QC) records and interview with the

	Technical Consultant (TC), the laboratory failed to perform corrective action when the Standard Deviation Index (SDI) was above acceptable limits for the Beckman Coulter Unicell DXH 600 Hematology analyzer in March 2019. The findings include: 1. The QC plan stated the SDI must be below 2.0 but the Hemoglobin Assay SDI was 3.0 and 2.50 for QC level 2 and 3 respectively. 2. There was no documented evidence corrective action was taken. 3. The TC confirmed on 5/23/19 at 2:10 pm that corrective action was not performed.
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 Urinalysis Final Report (UFR) and interview with the Technical Consultant (TC), the laboratory failed to ensure that Urine Clarity results were interfaced accurately from 12/20/17 to the date of survey. The finding includes: 1. Five of five UFR were reviewed and revealed that Slightly-Cloudy results were reported as 'Slightly' on UFR. 2. The TC confirmed on 5/23/19 at 1:20 pm that results were not interfaced accurately.
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 surveyor review of the Final Reports (FR) and interview with the Technical Consultant (TC), the laboratory failed to include 'The Test performed on the FR from 12/20/17 to the date of survey. The finding includes: 1. There was no Urine Microscopic test name for microscopice test results reported on the FR. 2. The TC confirmed on 5/23/19 at 1:00 pm that the laboratory did not test name on the FR.
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 surveyor review of the Final Report (FR), Operator Manual (OM), Procedure Manual (PM), the lack of Manufacturer Package Insert (MPI) and interview with the Technical Consultant (TC), the laboratory failed to identify the source of the Reference Intervals (RI) used for Endocrinology and Special Chemistry from 12/20 /17 to the date of survey. The finding includes: 1. The TC stated the laboratory used the RI listed on MPI but there was no MPI available for review.. 2. The TC confirmed on 5/23/19 at 1:00 pm that the laboratory did not have a source for the RI's.
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 surveyor review of the Procedure Manual (PM) and interview with the Technical Consultant (TC), the laboratory failed to establish a procedure for verifying manually entered and calculated results from 12/20/17 to the date of survey. The TC confirmed on 5/23/19 at 11:30 am that the laboratory did not have the procedure mentioned above.
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 surveyors review of the laboratory's records and interview with the Technical Consultant (TC), the Laboratory Director failed to provide overall management and direction to the laboratory to ensure that laboratory testing is performed satisfactorily and in compliance with the CLIA regulations from 12/20/17 to the date of the survey. 1. The (LD) failed to ensure that Testing Personnel were performing and reporting reliable patient tests results. Refer to D6014. 2. The LD failed to ensure trends and /or shifts were monitored. Refer to 6074
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the

	test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on surveyor review of the Final Reports (FR), observation of the instruments, Analyzer Records (AR), interview with the Testing Personnel (TP) and Technical Consultant (TC), the Laboratory Director (LD) failed to ensure that TP were performing and reporting reliable patient tests results from January 2019 to the date of the survey. The findings include: 1. A review of three AR from the Beckman Coulter Unicell DXH analyzer with Hemoglobin/Hematocrit failures revealed the failed results were reported on the FR in May 2019. 2. A review of the Immulite (IM) 2000 AR revealed: a. The instrument had a warning from May 9 to the date of the survey "Incubation Temperature Out" but 11 patients were run and reported. b. Results were reported on the FR when calibration was expired from: 1. 3/19/19 to 4/6/19 - Five patients were run 2. 4/30/19 to 5/9/19 - 7 patients were run c. Quality Control for Thyroxine (T4) and Cortisol failed on the IM and results were reported on the FR as below: 1. 3/2/19, 3/29/19, 4/4/19, 5/8/19, 5/15/19 and 5/22/19 - 17 patients were reported d. On 5/22/19 the Cortisol reagent was expired but two patients were resulted. 3. A review of the AR for the IL ACL Elite coagulation analyzer revealed on 5/7/19 eight patient results had an "Incubation temperature out" warning but the results were on the FR. 4. The TC confirmed on 5/23/19 at 2:00 pm that the laboratory did not report reliable results.
D6074	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(5) Each individual performing moderate complexity testing must be capable of identifying problems that may adversely affect test performance or reporting of test results and either must correct the problems or immediately notify the technical consultant, clinical consultant or director. This STANDARD is not met as evidenced by: Based on surveyor review of the Quality Control (QC) records and interview with the Technical Consultant (TC), the Testing Personal (TP) failed to identify problems that may affect test performance by not reviewing and evaluating trends and/or shifts for tests performed on the Beckman Coulter Unicell DxH 600 analyzer from 1/25/19 to 3 /31/19. The TC confirmed on 5/23/19 at 1:45 pm that trends and shifts were not reviewed.