Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D2141229	07/23/2018
Name of Provider or Supplier	**Street Address, City, State**	
Dr Kordas Pediatric Health Care Center	3275 N Arlington Hts Rd, Arlington Heights, IL	

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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on the surveyor's direct observation, review of the laboratory's records, and an interview with the technical consultant (TC), the laboratory failed to enroll in an approved program for each of the specialties and subspecialties for which it seeks certification, affecting 164 patients. Findings: 1. The laboratory failed to enroll in an approved program for the subspecialty of Bacteriology for which it seeks certification. See D2001
D2001	ENROLLMENT CFR(s): 493.801(a)(1)(2)(i) The laboratory must-- (1) Notify HHS of the approved program or programs in which it chooses to participate to meet proficiency testing requirements of this subpart. (2)(i) Designate the program(s) to be used for each specialty, subspecialty, and analyte or test to determine compliance with this subpart if the laboratory participates in more than one proficiency testing program approved by CMS;

	This STANDARD is not met as evidenced by: Based on the surveyor's direct observation, review of the laboratory's proficiency testing (PT) documents, test volume worksheet, and an interview with the technical consultant (TC), the laboratory failed to enroll in an approved program for the subspecialty of Bacteriology for which it seeks certification, affecting 164 patients. Findings: 1. On 07/23/2018 at 11:30 AM during a tour of the laboratory, the surveyor observed media for both throat and urine cultures. 2. The PT documents presented showed that the laboratory is enrolled in the College of American Pathologists (CAP) PT program for the specialty of Hematology, but not Bacteriology. No other documented evidence was provided to show that the laboratory has enrolled in a CAP or any other PT program for the throat culture and Urine culture testing the laboratory performs. 3. The "Laboratory Non-waived CLIA Test Volume Worksheet" submitted by the laboratory documents that 4 patients have been tested for Urine culture colony counts, and 160 patients have been tested for Step Group A culture identification (ID) between the months of May and June of 2018. 4. On an Initial survey conducted on 07 /23/2018 at 1:45 PM, the TC and the laboratory director confirmed that the laboratory does perform Urine culture counts and Throat cultures for Strep Group A ID.
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 the surveyor's direct observations, manuals, records and an interview with the laboratory staff, the laboratory failed to meet the applicable analytic systems requirements in 493.1251 through 493.1283, that provides equivalent quality testing in the specialties of Hematology and Bacteriology. Findings: 1. The laboratory failed to have written procedures manual for all tests, assays, and examinations performed by the laboratory. See D5401. 2. The laboratory procedures' manual failed to include all the applicable requirements specified in 493.1251(b)(1) - (14), when using the operator's manual and the requirements are not provided by the manufacturer in the specialty of Hematology. See D5405. 3. The laboratory failed to establish control procedures that monitor the accuracy and precision of the complete analytic process for Bacteriology testing. See D5441. 4. The laboratory failed to perform checks for media and reagents used in Bacteriological testing. See D5471 and D5477.
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 the surveyor's review of the laboratory's procedures manual, direct observations, the Laboratory Non-waived CLIA Test Volume Worksheet, and an interview with the technical consultant (TC), the laboratory failed to have written procedures for all tests, assays, and examinations performed by the laboratory, affecting 164 patients. Findings: 1. On 07/23/2018 at 11:35 AM during a tour of the laboratory, the surveyor observed that the laboratory stored and stocked the following media and reagent: Selective Streptococcus Agar (SSA), Cystine-lactose-Electrolyte-Deficient (CLED) agar/ Eosin Methylene Blue (EMB) Agar paddles, and Bacitracin (Taxo A) Disks. 2. The laboratory's manual does not include the procedures for the Bacterial culture systems that uses the media and reagents listed in "Findings #1". 3. The laboratory documents on the "Laboratory Non-waived CLIA Test Volume Worksheet" that the laboratory has performed 4 Urine culture tests using the CLED /EMB agar, and 160 Strep Group A culture tests using the SSA agar and Taxo A disks. 4. On an Initial survey conducted on 07/23/2018 at 1:15 PM, the TC confirmed the above findings.
D5405	PROCEDURE MANUAL CFR(s): 493.1251(c) Manufacturer's test system instructions or operator manuals may be used, when applicable, to meet the requirements of paragraphs (b)(1) through (b)(12) of this section. Any of the items under paragraphs (b)(1) through (b)(12) of this section not provided by the manufacturer must be provided by the laboratory. This STANDARD is not met as evidenced by: Based on the surveyor's review of the laboratory's operator's manual, records, and an interview with the technical consultant (TC) and laboratory director (LD), the laboratory's procedures' manual failed to include all the applicable requirements specified in 493.1251(b)(1) - (14), when using the operator's manual and the requirements are not provided by the manufacturer, for tests performed in the specialty of Hematology, affecting 359 patients. Findings: 1. The laboratory uses the manufacturer's operators manual as it's procedure manual for Cellular Blood Count (CBC) analysis. Review of the operator's manual revealed that the manufacturer does not include the following procedure requirements: (b)(5). Calibration procedures. (b)(8). Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability; (b)(10). Reference intervals (normal values). (b)(11). Imminently life-threatening test results, or panic or alert values (b)(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. (b)(14). Description of the course of action to take if a test system becomes inoperable. 2. On an Initial survey conducted on 07/23/2018 at 1:15 PM, the TC and LD confirmed the above findings.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental

	conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on the surveyor's review of the laboratory's records, manuals and an interview with the technical consultant (TC) and laboratory director (LD), the laboratory failed to establish control procedures that monitor the accuracy and precision of the complete analytic process for Bacteriology testing, affecting 164 patients. Findings: 1. The laboratory's manual does not include a quality control plan for the Strep Group A culture identification and Urine Culture colony count testing performed in the laboratory. 2. No documentation was presented as evidence that control procedures were performed for throat and urine cultures each day of patient testing. 3. On an Initial survey conducted on 07/23/2018 at 1:30PM, the TC and LD confirmed the above findings.
D5471	CONTROL PROCEDURES CFR(s): 493.1256(e)(1)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(i) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on the surveyor's review of the laboratory's manuals, records, manufacturer's instructions, and an interview with the technical consultant (TC), the laboratory failed to check each lot of commercially prepared media when opened for positive and negative reactivity prior to testing with patients, affecting 164 patients. Findings: 1. The laboratory stores and stocks the following media and reagents: Selective Streptococcus Agar (SSA), Bacitricin (Taxo A) discs, and Cystine-lactose-Electrolyte-Deficient (CLED) agar/ Eosin Methylene Blue (EMB) Agar. 2. The manufacturer's instructions of both the agar and discs be tested for checked with positive and negative specified organisms. 3. The laboratory's manual does not include a procedure for checking the reactivity of its SSA, CLED/EMB agar and Taxo A Discs. 4. The media logs reveal that the laboratory does not check each lot/shipment of agar received for reactivity. 5. The laboratory documents on the "Laboratory Non-waived CLIA Test Volume Worksheet" that the laboratory has performed 4 Urine culture tests using the CLED/EMB agar, and 160 Strep Group A culture tests using the SSA agar. 6. On an Initial survey conducted on 07/23/2018 at 11:30 AM, the TC and the laboratory director confirmed the above findings.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for

	sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on the surveyor's review of the laboratory's records, manuals, the Laboratory Non-waived CLIA Test Volume Worksheet, and an interview with the laboratory staff, the laboratory failed to perform media checks for each batch of media; before, or concurrent with its' initial use for Bacteriology testing, affecting 164 patients. Findings: 1. The laboratory stores and stock the following media: Selective Streptococcus Agar (SSA) and Cystine-lactose-Electrolyte-Deficient (CLED) agar/ Eosin Methylene Blue (EMB) Agar. 2. The laboratory's manual does not include a procedure for checking its agar for sterility, if sterility is required for testing; for its ability to support growth; and its physical characteristics. 3. The media logs reveal that the laboratory does not document the sterility, ability to support growth, and physical characteristics of each lot/shipment of agar received before, or concurrent with its' initial use for patients. 4. The laboratory documents on the "Laboratory Non-waived CLIA Test Volume Worksheet" that the laboratory has performed 4 Urine culture tests using the CLED/EMB agar, and 160 Strep Group A culture tests using the SSA agar. 5. On an Initial survey conducted on 07/23/2018 at 1:30PM, the TC and the laboratory director confirmed the above findings.
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 the surveyor's review of the patients' test results, final report, laboratory's volume worksheet, and an interview with the technical consultant (TC) and the laboratory director (LD); the laboratory failed to ensure reference ranges or normal values are included in the final test report, affecting 359 patients. Findings: 1. The "final report" does not to include the "reference intervals" or "normal" values for the Cellular Blood Counts (CBC) tests the laboratory reports. 2. The laboratory documents on the "Laboratory Non-waived CLIA Test Volume Worksheet" that the laboratory has performed CBC analysis for 359 patients. 3. On an Initial survey conducted on 07/23/2018 at 1:45 PM, the TC and LD confirmed the above findings.
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 the surveyor's review of the laboratory personnel files, records, manuals, and an interview with the technical consultant (TC), the laboratory director (LD) failed to providing overall management and direction in accordance with 493.1407. Findings: 1. The LD failed to enroll the laboratory in an approved program for each of the specialties and subspecialties. See D6015. 2. The LD failed to ensure that quality control (QC) programs are established and maintained to assure the quality of laboratory services provided in the subspecialty. See D6020. 3. The LD failed to establish written policies and procedures that meet the personnel requirements in subpart M to assess employees performing moderately complex. See D6030. 4. The LD failed to ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. See D6033.
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) 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) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on the surveyor's review of the laboratory's proficiency testing (PT) records, and an interview with the technical consultant (TC) and the laboratory director (LD), the LD failed to enroll the laboratory in an approved proficiency testing (PT) program for the Bacteriology tests performed in the laboratory, affecting 164 patients. Findings: 1. The laboratory performs the following test systems: throat cultures (for Group Strep A) and Urine cultures (colony counts). 2. The LD failed to enroll the laboratory into an approved PT program for their bacterial testing, prior to testing patients. See D2000 and D2001.
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 the surveyor's review of the laboratory's records, and an interview with the laboratory director (LD); the LD failed to ensure that quality control (QC) procedures are established and maintained to assure the quality of laboratory services provided in the subspecialty of Bacteriology, affecting 164 patients. Findings: 1. The LD failed to establish written procedures for Group Strep A and Urine culture testing. 2. The LD failed to establish written procedures to check media and reagents used for the Group Strep A and Urine Colony count culture tests.

D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) 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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on the surveyor's review of the Laboratory Personnel Report (CMS 209), the laboratory's policies, procedures and records, and an interview with the technical consultant (TC), the laboratory director (LD) failed to establish written policies and procedures that meet the personnel requirements in subpart M to assess employees performing moderately complex testing, affecting 6 out of 6 testing personnel (TP). Findings: 1. The CMS 209 lists 6 employees conducting moderately complex testing in the laboratory as testing personnel (TP). 2. The personnel documents presented revealed that the training and competency procedures used to assess 6 out of 6 TP performing Cellular Blood Count (CBC) analysis, Strep Group A culture and Urine culture were from the manufacturer. 3. The laboratory's manual does not include a written competency policy and step-by-step procedure for assessing TP performing CBC analysis, Strep Group A identification, and Urine culture Colony count testing. 4. On an Initial survey conducted on 07/23/2018 at 1:45 PM, the TC and LD confirmed the above findings.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based on the surveyor's review of the laboratory's procedures manual, records, and an interview with the technical consultant (TC), the laboratory director (LD) failed to ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process, affecting 6 out of 6 testing personnel (TP). Findings: 1. The LD fail to establish written procedures for the Strep Group A culture and Urine culture the laboratory performs, prior to testing patients. 2. The LD failed to ensure the Cellular Blood Count (CBC) analysis manual included all the requirements specified in 493.1251(b)(1) - (14), prior to testing patients.
D6063	LABORATORY TESTING PERSONNEL

	CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on the surveyor's review of the Laboratory Personnel Report (CMS-209), employee files, and an interview with the technical consultant (TC), the laboratory failed to employ individuals who meet the qualification requirements of 493.1423 for testing personnel (TP). Finding: 1. The laboratory failed to ensure laboratory personnel meet the qualification requirements for performing moderately complex testing in the specialty of Hematology and the subspecialty of Bacteriology. See D6065.
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on the surveyor's review of the Laboratory Personnel Report (CMS-209), employee files, and an interview with the technical consultant (TC), the laboratory failed to ensure laboratory employees meet the qualification requirements for performing moderately complex testing in the subspecialty of Bacteriology and specialty of Hematology, affecting 1 out of 6 TP. Findings: 1. The CMS 209 lists 6 testing personnel (TP) performing Cell Blood Count (CBC) analysis and throat and urine culture in the laboratory. 2. Review of the education credentials revealed that employee C30 (listed on line 5) does not meet the education requirement as defined 493.1423(b) (1) - (4), due to non-evaluated education credentials. 3. On an Initial survey conducted on 07/23/2018 at 1:45 PM, the TC confirmed the above findings.