Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D1032613	07/10/2024
Name of Provider or Supplier	**Street Address, City, State**	
Kd Medical Group Inc	400 W I St, Los Banos, CA	

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 the survey conducted on July 10, 2024, at approximately 12:30 p.m., review of the laboratory's policy and procedure, American Proficiency Institute (API) proficiency testing (PT) records, and interviews with the technical consultant (TC) and testing personnel (TP); it was determined that the laboratory failed to attain at least 80% of the acceptable score in routine chemistry for PSA analyte. The findings included: 1. Based on review of PT records for the first event of 2024 (Q1-2024), API reported an unsatisfactory score report as follow: PSA PT Q1-2024 Overall score 50% Specimen Reported Expected IA-01 *3.16 3.19 - 4.07 IA-02 6.00 5.80 - 7.54 2. The TC and TP affirmed on July 10, 2024, at approximately 12:30 p.m. that the laboratory obtained PT scores in statement #1. 3. According to the laboratory testing declaration submitted on the day of the survey, the laboratory performed approximately 105,000 routine chemistry test samples including PSA during the time the laboratory had unsatisfactory proficiency testing results. Thus, the reliability and quality of chemistry patient results reported could not be assured.
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: Based on the interviews with the laboratory's technical consultant (TC), and testing personnel (TP), review of policies and procedures, proficiency test records, and nine (9) randomly chosen patient records on July 10, 2024, the laboratory failed to establish a written and approved policies and procedure for all tests performed in Cepheid Gene Xpert for Virology. Findings included: 1. Based on the survey on July 10, 2024 at approximately 12:00 p.m., it was determined that no policies and procedures were found for Chlamydia trachomatis (CT), Neisseria gonorrheae (GC), Covid-19 (SARS-CoV-2), Respiratory Syncytial Virus (RSV) and Influenza A/B testing and only a reference manual from Cepheid was found at the time of survey. 2. During an interview at approximately 12:00 p.m. on July 10, 2024, the TC and TP affirmed that no policies and procedure for testing and reporting of results to CalRedie was ever established. 3. According to the submitted laboratory declaration of test volume, the laboratory performed 3,600 Virology tests that included CT, GC, SARS-CoV-2, RSV and Influenza A/B.
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 the lack of a complete laboratory verification of performance specifications for Virology and interviews with the technical consultant (TC) and testing personnel (TP) on July 10, 2024, the laboratory failed to provide an established performance specifications documentation comparable to those established by the manufacturer. The findings included: 1. Based on review of the laboratory's documentation for verification procedure for Virology, at the time of survey, it was found that the documentation was incomplete. Performance specifications for accuracy, precision, reportable range, and method validation for the Cepheid Gene Xpert instrument in Virology were incomplete. 2. The TC and TP affirmed at the time of the survey on July 10, 2024, at approximately 2:30 p. m. that the testing and documentation for

	verification provided at the time of the survey were only performed by the manufacturer. 3. Based on the review of the incomplete verification of performance, only Chlamydia trachomatis (CT) and Neisseria gonorrheae (GC) set-up were documented but none were found for Covid-19 (SARS-CoV-2), Respiratory Syncytial Virus (RSV) and Influenza A/B 4. Based on the testing declaration submitted at the time of survey, the laboratory performed and reported approximately 3,600 tests for Virology annually that included CT, GC, SARS-CoV-2, RSV, and Influenza A/B. .
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 the surveyor's review of the laboratory's policy and procedure, nine (9) randomly chosen patient records and interviews with the technical consultant (TC) and testing personnel (TP), it was determined that the laboratory failed to perform and document preventive maintenance (PM) as defined by the manufacturer and with at least the frequency specified by the manufacturer for the laboratory's Hematology, and Virology analyzers. The findings included: 1. At the time of survey, based upon the review of records and documentation at approximately 2:00 p.m. on July 10, 2024, it was determined that the laboratory failed to record any PM performed for Cepheid Gene Xpert for Virology and Sysmex XN-550 for Hematology. 2. The TC and TP affirmed on July 10, 2024, at approximately 2:00 p.m. that maintenance performed was missed to be recorded for November 2023 and January 2024 for Cepheid and June 2024 for Sysmex. 3. Based on the review of three (3) out of 9 randomly chosen patient records, 3 had missing record of PM performed for months of November 2023 and January 2024 for Cepheid and June 2024 for Sysmex. Therefore, the quality of patient testing was not assured. 4. According to the laboratory's testing declaration submitted by the laboratory on July 10, 2024, the laboratory performed approximately 3,600 Virology and 105,000 Chemistry tests annually.
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 laboratory's policy and procedure manual, nine (9) randomly chosen patient testing records, quality control documentation, and interviews with the technical consultant (TC) and testing personnel (TP), the laboratory failed to include two levels of quantitative quality control (QC) for each day of testing patient specimen for chemistry and virology. Findings include: 1. Based on the review of 9 randomly chosen patient test reports, four (4) out of nine had no quality control documentation found at the time of the survey. 2. Both the TC and TP affirmed on

	July 10, 2024, at approximately 2:00 p.m. that the laboratory does not have an Individualized Quality Control Plan (IQCP) to support the claim of batch testing on days when volume is low. Thus, the missing QC records during patient documentation review for the 4 out 9 patients that were performed cannot be assured on the reliability and quality of the test results reported. 3. Based on the laboratory's testing declaration submitted on July 10, 2024, the laboratory performed approximately 3,600 Virology tests and 105,000 Routine Chemistry tests annually.
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 patient test results records, laboratory's policy and procedure manual, proficiency testing (PT) records, and interviews with the technical consultant (TC) and testing personnel (TP); it was determined that the laboratory failed to follow the established written policies and procedures (P&P) for corrective actions of each test results and an incomplete P&P for quality assessment (QA) as part of an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the post analytic systems. The findings included: 1. The laboratory had an established written policy or procedure for corrective action reporting but failed to follow when unacceptable scores for PT were received. 2. Based on the review of PT records and laboratory's policy and procedure for corrective action, in 2021 and 2022, no corrective action report were performed for all PT results that received an unacceptable score that included ALT, Amylase, and Cholesterol analytes. 3. Based on the review of the laboratory's policies and procedure, the laboratory failed to have a complete written P&P for QA when performing a random check of one patient record per month ensuring information, assessment, turn-around times, quality control review, etc. are correct. 4. The TC and TP affirmed on July 10, 2024, at approximately 12:30 p.m. that the laboratory failed to perform a corrective action report as declared on statements #1 and #2. Both also affirmed that the current P&P for QA is incomplete. 5. Based on the laboratory's annual test declaration submitted and signed by the laboratory director on July 10, 2024; the laboratory performed 161,900 tests at the time when no corrective action report were performed for all PT results that received an unacceptable score that included ALT, Amylase, and Cholesterol analytes..
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 the deficiencies cited, the Laboratory Director is herein cited for deficient practice in responsibility to ensure that systems for the preanalytic, analytic and postanalytic phases of laboratory were monitored and followed. Findings include: 1. The laboratory received unsatisfactory performance results for PSA. See D2087 2. The laboratory failed to have a complete Quality Assessment policy and procedure and missed to conduct and document a corrective action for proficiency testing results in 2021 and 2022. See D5891. 3. The laboratory failed to provide an approved and establish policy and procedure for Cepheid Gene Xpert in Virology. See D5403. 4. The laboratory failed to provide a complete verification of performance documentation. See D5421 5. The laboratory missed to record preventive maintenance. See. D5429 6. The laboratory missed to perform Quality Control. See. D5447 7. The Technical Consultant missed to conduct competency assessement. See D6053
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) 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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on the review of the laboratory's policies and procedure, job qualifications and descriptions, and interviews with the technical consultant (TC) and testing personnel (TP), it was determined that the laboratory failed to specify in writing the responsibilities and duties of each personnel. Findings included: 1. Based on the surveyor's review of the laboratory's policies and procedure manual on July 10, 2024 at approximately 12:15 p.m., the only duties and responsibilities found at the time of survey was for the TC. 2. The TC and TP affirmed that it was the practice of the laboratory to have the TP handle the duties and responsibilities of the laboratory director (LD) in his absence but none was placed in writing. 3. The reliability and quality of test results performed by the testing personnel without specified written duties and responsibilities cannot be assured. 4. According the laboratory testing declaration submitted on July 10, 2024, the laboratory performed approximately 161,900 tests annually.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

	This STANDARD is not met as evidenced by: Based on review of personnel competency assessment records, policies and procedures, nine (9) randomly chosen patient records, and interviews with technical consultant (TC) and testing personnel (TP), it was determined that the Technical Consultant failed to evaluate and document competencies at least semiannually during the first year of testing for Chlamydia trachomatis (CT), Neisseria gonorrheae (GC), Covid-19 (SARS-CoV-2), Respiratory Syncytial Virus (RSV) , and Influenza A/B in Cepheid Gene Xpert. Findings included: 1. The laboratory declared one clinical laboratory scientist (CLS) as testing personnel in CMS-209 form. Upon review of competency assessment records for the last two years, no initial nor annual competencies were performed for operating Cepheid Gene Xpert since the start of testing was found. 2. Based on the review of 9 randomly chosen patient records, two (2) out of 9 were resulted for SARS-CoV-2, RSV and Influenza A/B tests without competency assessment for TP. 3. The TC and TP affirmed by interview on July 10, 2024 at approximately 12:55 p.m. that no competency assessment was performed for operating and testing on Cepheid Gene Xpert. Thus, the reliability and accuracy of test reports performed since 2023 is not assured. 4. According to the annual laboratory testing declaration submitted at the time of survey, the laboratory performed 3,600 Virology tests that included CT, GC, SARS-CoV-2, RSV and Influenza A/B.