Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D0385184	12/08/2021
Name of Provider or Supplier	**Street Address, City, State**	
Renal Associates, Pc	357 Tower Road, Dakota Dunes, SD	

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	A recertification survey for compliance with 42 CFR Part 493, Requirements for Laboratories, was conducted on 12/8/21. The Renal Associates laboratory was found not in compliance with the following requirements: D2009, D2015, D5215, D6018, and D6032.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to ensure the laboratory director and testing personnel had signed five of eight 2021 American Proficiency Institute (API) proficiency testing (PT) attestation statements (Hematology /Coagulation 1st event, Chemistry Core 1st, 2nd, and 3rd events, and Chemistry - Miscellaneous 1st event) that attested PT samples had been tested in the same manner as patient specimens. Findings include: 1. Review on 12/8/21 of 2021 API PT events revealed: *The Hematology/Coagulation 1st PT event attestation statement had not been signed by the laboratory director. *The Chemistry Core 1st PT event attestation statement had not been signed by the laboratory personnel who had performed the testing. *The Chemistry Core 2nd PT event attestation statement had not been signed by the laboratory director or the laboratory personnel who had performed the testing. *The Chemistry Core 3rd PT event attestation statement had not been signed by the laboratory director or the laboratory personnel who had performed the testing. *The Chemistry - Miscellaneous 1st event attestation statement had not been signed by the laboratory director. Review on 12/8/21 of the laboratory's Proficiency Testing policy, dated 2/1/17, revealed: *"The technical consultant/designated personnel will review the results of each proficiency test before the results are submitted." *"All PT records

	and testing must be kept for a period of 2 years." Interview on 12/8/21 at 11:50 a.m. with testing personnel A revealed: *She was not aware the "not graded" results had not been reviewed. *The testing had been performed before her being hired by the clinic in September 2021. *The testing had been performed by an employee who was no longer employed by the clinic.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to maintain a copy of required documentation related to the processing of seven of eight 2021 American Proficiency Testing Institute (API) proficiency testing (PT) events reviewed (Hematology/Coagulation 2nd and 3rd events; Chemistry Core 1st, 2nd, and 3rd events; and Chemistry - Miscellaneous 1st and 2nd events). This documentation would ensure the the results submitted for evaluation had been the results obtained by the laboratory processing the PT samples. Findings Include: 1. Review on 12/8/21 of the laboratory's 2021 API PT event records revealed: *The laboratory subscribed to PT events through the API. *PT specimens were processed and the results submitted via the company's website upon completion of testing. a. The laboratory had not retained copies of analyzer printouts documenting the results obtained from processing the PT samples for the following events: -Hematology/Coagulation 2nd testing event -Hematology/Coagulation 3rd testing event -Chemistry Core 1st testing event -Chemistry Core 3rd testing event b. The laboratory had not retained copies of results submitted electronically for evaluation for the following events: -Hematology /Coagulation 2nd testing event -Hematology/Coagulation 3rd testing event -Chemistry Core 1st testing event -Chemistry Core 2nd testing event -Chemistry Core 3rd testing event -Chemistry - Miscellaneous 1st event -Chemistry - Miscellaneous 2nd event Review on 12/8/21 of the Proficiency Testing policy, dated 2/1/17, revealed, "All PT records and testing must be kept for a period of 2 years." Interview on 12/8/21 at 11: 50 a.m. with laboratory personnel A revealed: *She was not aware the laboratory had not maintained the necessary documentation of PT processing. *The testing had been performed before her being hired by the clinic in September 2021. *The testing had been performed by an employee who was no longer employed by the clinic.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required

	for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to review proficiency testing (PT) results to ensure the accuracy of five of seven results not graded as acceptable 2021 American Proficiency Institute (API) PT samples reviewed (API 2021 Chemistry Core 1st and second events, Chemistry - Miscellaneous 1st event). Findings include: 1. Review on 12/8/21 of the 2021 API PT records revealed: * The evaluation and corrective action documentation was absent for the following PT events: a. Chemistry Core 1st event -The CH-02 alanine transaminase result was not graded due to lack of consensus. b. Chemistry Core 2nd testing event -The IAS-09 25-OH (hydroxy) Vitamin D result was graded unacceptable. -The laboratory reported 3,281 25-OH Vitamin D patient specimens between 1/1/21 and 11/30/21. c. Chemistry - Miscellaneous 1st testing event -The MA-01 microalbumin (semi-quantitative) result was not graded due to lack of consensus. -The MA-02 microalbumin (semi-quantitative) result was graded unacceptable. -The MA-03 microalbumin (semi-quantitative) result was graded unacceptable. -The laboratory reported 7,490 microalbumin patient specimens between 1/1/21 and 11/30/21. Review on 12/8/21 of the laboratory's Proficiency Testing policy, dated 2/1/17, revealed, "Review must be documented on ungraded samples as well as graded samples." Interview on 12/8/21 at 11:50 a.m. with laboratory personnel A revealed: *She was not aware the "not graded" results had not been reviewed. *The testing had been performed before her being hired by the clinic in September 2021. *The testing had been performed by an employee who was no longer employed by the clinic.
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 record review and interview, the laboratory director failed to ensure proficiency testing (PT) results had been reviewed, evaluated, and those activities documented for five of eight 2021 American Proficiency Testing (API) PT events reviewed (Hematology/Coagulation 2nd testing event, Chemistry Core 2nd testing event, and Chemistry - Miscellaneous 1st and 2nd testing events). PT samples are tested in the same manner as patient specimens, evaluation of PT results would ensure the accuracy of patient specimen results. Findings include: 1. Review on 12/8/21 of the completed API 2021 PT events records revealed: *A minimum score of 80% is required to pass the PT event. * The evaluation and corrective action documentation was absent for the following PT events: a. Hematology/Coagulation 2nd testing event - The laboratory received a score of 100% for this event. b. Chemistry Core 2nd testing event - The laboratory received a score of 80% for the 25-OH (hydroxy) Vitamin D analyte. -IAS-09 was graded unacceptable. -The laboratory reported 3,281 25-OH

	Vitamin D patient specimens between 1/1/21 and 11/30/21. c. Chemistry - Miscellaneous 1st testing event -The laboratory received a score of 33% for the microalbumin (semi-quantitative) analyte. -MA-01 was ungraded. -MA-02 was graded unacceptable. -MA-03 was graded unacceptable. -The laboratory reported 7,490 microalbumin patient specimens between 1/1/21 and 11/30/21. d. Chemistry - Miscellaneous 2nd testing event -The laboratory received a score of 100% for this event. Review on 12/8/21 of the laboratory's Proficiency Testing policy, dated 2/1/17, revealed: *"80% of all participant results in any method group must fall within the acceptable range established for the analyte." *"Review must be documented on ungraded as well as graded specimens." *"Both the technical consultant and the laboratory director will also review the results after they are scored and returned." *" All PT records and testing must be kept for a period of 2 years." Interview on 12/8/21 at 11:50 a.m. with laboratory personnel A revealed: *She was unaware the performance and corrective action documentation forms had not been retained. *The testing had been performed before her being hired by the clinic in September 2021. *The testing had been performed by an employee who was no longer employed by the clinic. The laboratory director was unavailable for interview at the time of the survey.
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 record review and interview, the laboratory director failed to specify the duties delegated to one of one consultant (the technical consultant) to ensure the individual was performing the required duties necessary for the proper operation and function of the laboratory. Findings Include: 1. Review on 12/8/21 of the CMS 209 Laboratory Personnel Report form revealed the technical consultant position was currently filled by a previous employee serving as a consultant. Review 12/8/21 of laboratory personnel records revealed: *There was no delegation of duties for the technical consultant. *There was no documentation of a competency assessment evaluation for the technical consultant performed in 2020 or 2021. There was no documentation available for review at the time of the survey of previous consultations with the technical consultant during 2020 and 2021. Interview on 12/8/21 at 11:50 a.m. with the clinical director revealed: *The laboratory did not have a written delegation of duties or contract with the technical consultant. *The technical consultant was available by phone, as necessary for consultation. *The technical consultant had been available for consultation since 2020. *The laboratory director had not assessed the competency of the technical consultant in 2020 or prior to 12/8/21. The laboratory director was unavailable for interview at the time of the survey.