

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D0719604	(X3) Date Survey Completed 08/17/2020
Name of Provider or Supplier Renal Associates Of Baton Rouge	Street Address, City, State 5131 O'Donovan, First Floor, Baton Rouge, LA	
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 PT Desk Review was performed on August 17, 2020. Renal Associates of Baton Rouge, CLIA ID 19D0719604, was found not in compliance with the following CONDITION LEVEL DEFICIENCIES: 42 CFR 493.803 CONDITION: Successful Participation 42 CFR 493.1403 CONDITION: Laboratories Performing Moderate Complexity Testing; Laboratory Director
D2016	<p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.</p> <p>This CONDITION is not met as evidenced by: Based on review of proficiency testing (PT) results from the CASPER 155D report, the laboratory failed to successfully participate in proficiency testing for Hematology. Findings: 1. The laboratory failed to attain a score of at least 80% for Red Blood Cells</p>

	<p>(RBC) and Hematocrit (HCT) for two (2) events in 2020. Refer to D2121. 2. The laboratory failed to achieve a score of at least 80% for Red Blood Cells (RBC) in two consecutive events, resulting in an initial unsuccessful performance. Refer to D2130 I. 3. The laboratory failed to achieve a score of at least 80% for Hematocrit (HCT) in two consecutive events, resulting in an initial unsuccessful performance. Refer to D2130 II.</p>
<p>D2121</p>	<p>HEMATOLOGY CFR(s): 493.851(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the proficiency testing results from the CASPER 155D report, the laboratory failed to attain a score of at least 80% for Red Blood Cells (RBC) and Hematocrit (HCT) for two (2) events in 2020. Findings: 1. Review of CASPER Report 155D proficiency test results revealed the laboratory did not achieve a score of at least 80% for the specialty of Hematology for the following two (2) events and analytes: 2020 1st Event RBC score received 60% 2020 2nd Event RBC score received 40% 2020 1st Event HCT score received 40% 2020 2nd Event HCT score received 40% .</p>
<p>D2130</p>	<p>HEMATOLOGY CFR(s): 493.851(f)</p> <p>Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance.</p> <p>This STANDARD is not met as evidenced by: I. Based on review of proficiency testing (PT) results from the CASPER 155D report, the laboratory failed to achieve a score of at least 80% for Red Blood Cells (RBC) in two consecutive events, resulting in an initial unsuccessful performance. Findings: 1. Review of the CASPER 155D report for PT results revealed the laboratory received the following scores for RBC resulting in an initial unsuccessful performance: a) 2020 1st Event RBC score received 60% b) 2020 2nd Event RBC score received 40% II. Based on review of proficiency testing (PT) results from the CASPER 155D report, the laboratory failed to achieve a score of at least 80% for Hematocrit (HCT) in two consecutive events, resulting in an initial unsuccessful performance. Findings: 1. Review of the CASPER 155D report for PT results revealed the laboratory received the following scores for HCT resulting in an initial unsuccessful performance: a) 2020 1st Event HCT score received 40% b) 2020 2nd Event HCT score received 40%</p>
<p>D6000</p>	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p> <p>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.</p>

This CONDITION is not met as evidenced by:
Based on record review, the Laboratory Director failed to provide overall management and direction for the laboratory. Refer to D6016.

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 record review, the Laboratory Director failed to ensure that proficiency testing results are satisfactory as required. Findings: 1. The laboratory failed to attain a score of at least 80% for Red Blood Cells (RBC) and Hematocrit (HCT) for two (2) events in 2020. Refer to D2121. 2. The laboratory failed to achieve a score of at least 80% for Red Blood Cells (RBC) in two consecutive events, resulting in an initial unsuccessful performance. Refer to D2130 I. 3. The laboratory failed to achieve a score of at least 80% for Hematocrit (HCT) in two consecutive events, resulting in an initial unsuccessful performance. Refer to D2130 II.