

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D0710641	(X3) Date Survey Completed 02/11/2019
Name of Provider or Supplier Albert G Kerr Md	Street Address, City, State 121 Christian Drive, Rayville, 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 SURVEY was performed on February 11, 2019. Albert G Kerr - 19D0710641 was found not in compliance with the following CONDITION LEVEL DEFICIENCIES: 42 CFR 493.803 CONDITION: Successful Participation 42 CFR 493.807 CONDITION: Reinstatement of Nonwaived Testing 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 results from the CMS-153, CMS-155D and American Proficiency Institute (API), the laboratory failed to successfully participate</p>

	<p>in proficiency testing as evidence by: 1. The laboratory failed to achieve satisfactory performance for Red Blood Cells (RBC) in three of four consecutive events resulting in non-initial unsuccessful participation. Refer to D2017 2. The laboratory failed to achieve a score of at least 80% for Hematology analytes in three of four consecutive events. Refer to D2130. 3. The laboratory failed to achieve an overall score of at least 80% for two of three events in the specialty of Hematology. Refer to D2131</p>
<p>D2017</p>	<p>REINSTATEMENT OF NONWAIVED LABORATORIES CFR(s): 493.807(a)(b)</p> <p>(a) If a laboratory's certificate is suspended or limited or its Medicare or Medicaid approval is cancelled or its Medicare or Medicaid payments are suspended because it fails to participate successfully in proficiency testing for one or more specialties, subspecialties, analyte or test, or voluntarily withdraws its certification under CLIA for the failed specialty, subspecialty, or analyte, the laboratory must then demonstrate sustained satisfactory performance on two consecutive proficiency testing events, one of which may be on site, before CMS will consider it for reinstatement for certification and Medicare or Medicaid approval in that specialty, subspecialty, analyte or test. (b) The cancellation period for Medicare and Medicaid approval or period for suspension of Medicare or Medicaid payments or suspension or limitation of certification under CLIA for the failed specialty, subspecialty, or analyte or test is for a period of not less than six months from the date of cancellation, limitation or suspension of the CLIA certificate.</p> <p>This CONDITION is not met as evidenced by: Based on review of proficiency testing results from the CMS-153, CMS-155D and American Proficiency Institute (API), the laboratory failed to achieve satisfactory performance for Red Blood Cells (RBC) in three of four consecutive events resulting in non-initial unsuccessful participation. See D2130</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: Based on review of proficiency testing results from the CMS-155D and American Proficiency Institute (API), the laboratory failed to achieve a score of at least 80% for Hematology analytes in three of four consecutive events. Findings: 1. Review of proficiency testing records and the CMS 155D Report revealed the following proficiency testing scores for Red Blood Cells (RBC) resulting in non-initial unsuccessful performance: a. 2017 Event 3: Score of 60% for RBC b. 2018 Event 2: Score of 0% for RBC c. 2018 Event 3: Score of 0% for RBC 2. Review of proficiency testing records and the CMS 155D Report revealed the following proficiency testing scores for Hematocrit (Hct) resulting in initial unsuccessful performance: a. 2018 Event 2: Score of 20% for Hct b. 2018 Event 3: Score of 40% for Hct</p>
<p>D2131</p>	<p>HEMATOLOGY CFR(s): 493.851(g)</p>

Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:

Based on review of proficiency testing records and CMS Report 0155D, the laboratory failed to achieve an overall score of at least 80% for two of three events in the specialty of Hematology. Findings: 1. Review of proficiency testing records and Casper Report 0155D revealed the laboratory did not score at least 80% for the following two out of three events in Hematology: a. 2018 Event 2: Score of 70% b. 2018 Event 3: Score of 73%

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 record review and interview with personnel, 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:

The laboratory director failed to ensure that proficiency testing samples are satisfactory as required. Findings: 1. The laboratory failed to achieve satisfactory performance for Red Blood Cells (RBC) in three of four consecutive events resulting in non-initial unsuccessful participation. Refer to D2017 2. The laboratory failed to achieve a score of at least 80% for Hematology analytes in three of four consecutive events. Refer to D2130. 3. The laboratory failed to achieve an overall score of at least 80% for two of three events in the specialty of Hematology. Refer to D2131