

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D1023920	(X3) Date Survey Completed 12/12/2019
Name of Provider or Supplier Winnsboro Medical Clinic	Street Address, City, State 3326 Front Street, Suite B, Winnsboro, 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 December 12, 2019. Winnsboro Medical Clinic - 19D1023920 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 Association of Bioanalysts (AAB), the laboratory failed to successfully</p>

participate in proficiency testing as evidence by: 1. The laboratory failed to achieve a score of at least 80% for Hematology analytes in three of four testing events. Refer to D2130 2. The laboratory failed to achieve an overall score of at least 80% for two of three consecutive testing events in the specialty of Hematology. Refer to D2131 3. The laboratory failed to achieve a satisfactory score for Free Thyroxine (Free TY) for two of three proficiency testing events resulting in initial unsuccessful performance in Endocrinology. Refer to D2107

D2017

REINSTATEMENT OF NONWAIVED LABORATORIES
CFR(s): 493.807(a)(b)

(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.

This CONDITION is not met as evidenced by:
Based on review of proficiency testing results from the CMS-153, CMS-155D and American Association of Bioanalysts (AAB), the laboratory failed to achieve a score of at least 80% for Red Blood Cells in three of four testing events. 1. Review of proficiency testing records and the CMS 155D Report revealed the laboratory received a score of 0% for three of four proficiency testing events resulting in non initial unsuccessful performance for Red Blood Cell: a. 2019 Event 2: Score of 0% for Red Blood Cell (RBC) b. 2019 Event 1: Score of 100% for Red Blood Cell (RBC) b. 2018 Event 3: Score of 0% for Red Blood Cell (RBC) e. 2018 Event 2: Score of 0% for Red Blood Cell (RBC)

D2107

ENDOCRINOLOGY
CFR(s): 493.843(f)

Failure to achieve satisfactory performance for the same analyte or test in 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 record review, the laboratory failed to achieve a satisfactory score for Free Thyroxine (Free TY) for two of three proficiency testing events resulting in initial unsuccessful performance in Endocrinology. Findings: 1. Review of the CMS 0155D and American Proficiency Institute (API) records revealed the laboratory received the following results for Free TY testing: a) Event 1 2019: Score of 20% b) Event 2 2019: Score of 80% b) Event 3 2019: Score of 60%

<p>D2123</p>	<p>HEMATOLOGY CFR(s): 493.851(c)</p> <p>Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events.</p> <p>This STANDARD is not met as evidenced by: Based on a review of proficiency testing (PT) results, the laboratory failed to participate in Event 2 of 2019 resulting in an unsatisfactory performance and a score of zero for White Blood Cell Differential (WBC Diff), Red Blood Cell (RBC), Hematocrit (HCT), Hemoglobin (HGB), White Blood Cell (WBC) and Platelets. The findings are as follows: 1. Review of American Proficiency Institute (API) proficiency testing records and CASPER 155D report revealed the laboratory did not participate in Event 2 of 2019 for Hematology testing resulting in the following unsatisfactory scores: Event 2 of 2019 WBC Diff score of 0%. RBC score of 0%. HCT score of 0%. HGB score of 0%. WBC score of 0%. Platelets score of 0%.</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 testing events. Findings: 1. Review of proficiency testing records and the CMS 155D Report revealed the laboratory received a score of 0% for three of four proficiency testing events resulting in non initial unsuccessful performance for Red Blood Cell: a. 2019 Event 2: Score of 0% for Red Blood Cell (RBC) b. 2019 Event 1: Score of 100% for Red Blood Cell (RBC) b. 2018 Event 3: Score of 0% for Red Blood Cell (RBC) e. 2018 Event 2: Score of 0% for Red Blood Cell (RBC) 2. Review of proficiency testing records and the CMS 155D Report revealed the laboratory received a score of less than 80% for the following two of three proficiency testing events resulting in initial unsuccessful performance for Hematocrit: a. 2019 Event 2: Score of 0% for Hematocrit b. 2019 Event 1: Score of 100% for Hematocrit c. 2018 Event 3: Score of 40% for Hematocrit</p>
<p>D2131</p>	<p>HEMATOLOGY CFR(s): 493.851(g)</p> <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.</p>

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 consecutive testing events in the specialty of Hematology. Findings: 1. Review of proficiency testing records and Casper Report 0155D revealed the laboratory received an overall score of 0% for the following two consecutive events in Hematology: a. 2019 Event 2: Score of 0% for Hematology b. 2018 Event 3: Score of 70% for Hematology

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 participate in Event 2 of 2019 resulting in an unsatisfactory performance and a score of zero for White Blood Cell Differential (WBC Diff), Red Blood Cell (RBC), Hematocrit (HCT), Hemoglobin (HGB), White Blood Cell (WBC) and Platelets. Refer to D2123 2. The laboratory failed to achieve a score of at least 80% for Hematology analytes in three of four testing events. Refer to D2130 3. The laboratory failed to achieve an overall score of at least 80% for two of three consecutive testing events in the specialty of Hematology. Refer to D2131 4. The laboratory failed to achieve a satisfactory score for Free Thyroxine (Free TY) for two of three proficiency testing events resulting in initial unsuccessful performance in Endocrinology. Refer to D2107