

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D1038982	(X3) Date Survey Completed 09/20/2021
Name of Provider or Supplier Medical Specialists Of Texarkana	Street Address, City, State 1002 Texas Blvd Suite 201, Texarkana, TX	
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	<p>The following deficiencies are a result of a desk review of proficiency testing scores obtained from the national database and verified with the proficiency testing company. The facility was found to be out of compliance with the conditions of participation of the CLIA program The following CONDITION LEVEL DEFICIENCIES were found to be out of compliance: D2016 - 42 C.F.R. 493.803 Condition: Successful participation [proficiency testing] D2017 - 42 C.F.R. 493.807 (a) - Reinstatement After Failure D6000 - 42 C.F.R. 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director;</p>
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:</p>

Based on a review of the CMS (Center for Medicare Services) national database and a proficiency desk review of the American Proficiency Institute (API) proficiency testing records from 2020 and 2021, it was determined the laboratory has not successfully participated in a proficiency testing program, for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. The laboratory did not successfully participate in the specialty of hematology for the analyte Red Cell Count (RBC) in three of five PT events in 2020 and 2021. Refer to D2130

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 a review of the CMS (Center for Medicare Services) national database, the 2020 and 2021 API (American Proficiency Institute) proficiency testing (PT) scores and confirmed in interview, the laboratory failed to participate successfully for the analyte Red Blood Cell (Hematology) for three of five consecutive testing events and has not demonstrated sustained satisfactory performance on two consecutive proficiency events since the unsuccessful scores. Findings were: 1. The laboratory received the following failing scores (passing = >80%) for the analyte Red Blood Cell (Hematology) for three of five PT events in 2020 and 2021: 2020 1st event RBC - 60 % 2020 3rd event RBC - 20% 2021 2nd event RBC - 40% The 2020 first and third testing event resulted in first time unsuccessful performance addressed on a proficiency testing desk review on 2/10/21. The 2021 second testing event constituted non-initial unsuccessful performance. 2. In an interview of the office manager on 09 /21/21 at 1105 hours via phone confirmed the above findings. The laboratory ceased hematology testing on 3/25/21.

D2130

HEMATOLOGY
CFR(s): 493.851(f)

Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:
Based on a review of the CMS (Center for Medicare Services) national database and a proficiency desk review of the American Proficiency Institute (API) proficiency

testing records from 2020, it was determined the laboratory failed to achieve satisfactory performance (at least 80%) in the specialty of hematology for the analyte Red Cell Count (RBC), for three of five consecutive testing events in 2020 and 2021, resulting in an unsuccessful PT performance for RBC. Findings were: 1. A review of the CMS national proficiency testing database revealed the following scores for the analyte RBC for three of five consecutive testing events in 2020 and 2021: 2020 API 1st event RBC - 60 % 2020 API 3rd event RBC - 20% 2021 API 2nd event RBC - 40% 2. A proficiency desk review of the API proficiency testing records from 2020 and 2021 confirmed that the laboratory received the following scores for the analyte RBC for three of five testing events in 2020 and 2021. 2020 API 1st event RBC - 60 % 2020 API 3rd event RBC - 20% 2021 API 2nd event RBC - 40% 3. Two out of three unsatisfactory scores of the same analyte result in unsuccessful PT performance.

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 a desk review of laboratory proficiency testing performance it was revealed that the laboratory director failed to provide overall management and direction of the laboratory services. Findings were: 1. A review of the laboratory proficiency testing results revealed that the laboratory director failed to ensure that the laboratory participated successfully. (refer to D6016) By not providing overall management and direction of the laboratory, the laboratory director could not ensure the accuracy or reliability of all laboratory services provided by the facility.

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 a desk review of proficiency testing results it was revealed that the laboratory director failed to ensure the overall quality of the laboratory services provided. The laboratory director failed to ensure successful participation in an approved proficiency testing program. (refer to D2130)