

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  45D0959698	<b>(X3) Date Survey Completed</b>  01/19/2023
<b>Name of Provider or Supplier</b>  Clear Lake Pediatric Clinic, Pa	<b>Street Address, City, State</b>  16 Professional Park Dr, Webster, TX	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	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 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] D6000 - 42 C.F.R. 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director;
<b>D2016</b>	<p><b>SUCCESSFUL PARTICIPATION</b> 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 a desk review of proficiency testing records obtained from the CMS national</p>

	<p>database and verified with the proficiency testing company American Proficiency Institute (API) found the laboratory had not successfully participated in a proficiency testing program approved by HHS, 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 and for six of six regulated analytes in two of three proficiency testing events in 2022. Cell I.D. or WBC Diff RBC HCT (Non-waived) HGB (Non-waived) WBC Platelets Key: CMS=Center for Medicare and Medicaid Services RBC=Red Blood Cell HCT=Hematocrits HGB=Hemoglobin WBC=White Blood Cell</p>
<p><b>D2121</b></p>	<p><b>HEMATOLOGY</b> 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 a desk review of proficiency testing records obtained from the CMS national database and verified with the proficiency testing company American Proficiency Institute (API) found the laboratory failed to attain a score of at least 80% of acceptable responses for six of six regulated analytes resulted in unsatisfactory performance for two of two American Proficiency Institute (API) proficiency testing events in 2022. The findings were: 1. API 2022 Hematology/Coagulation for the second event revealed the laboratory received unsatisfactory scores for the following: Hematology 0% Cell I.D. or WBC Diff 0% RBC 0% HCT (Non-waived) 0% HGB (Non-waived) 0% WBC 0% Platelets 0% 2. API 2022 Hematology/Coagulation for the third event revealed the laboratory received unsatisfactory scores of the following: Hematology 60% Cell I.D. or WBC Diff 60% RBC 60% HCT (Non-waived) 60% HGB (Non-waived) 60% WBC 60% Platelets 60% Key: CMS=Center for Medicare and Medicaid Services RBC=Red Blood Cell HCT=Hematocrits HGB=Hemoglobin WBC=White Blood Cell</p>
<p><b>D2122</b></p>	<p><b>HEMATOLOGY</b> CFR(s): 493.851(b)</p> <p>Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.</p> <p>This STANDARD is not met as evidenced by: Based on a desk review of proficiency testing records obtained from the CMS national database and verified with the proficiency testing company American Proficiency Institute (API) found the laboratory failed to attain an overall testing event score of at least 80% of acceptance responses for two of three API proficiency testing events in 2022. The findings were: 1. API 2022 Hematology/Coagulation for the second event revealed the laboratory received an overall unsatisfactory score for hematology specialty of 0%. 2. API 2022 Hematology/Coagulation for the third event revealed the laboratory received an overall unsatisfactory score for hematology specialty of 60%. Key: CMS=Center for Medicare and Medicaid Services</p>
<p><b>D2123</b></p>	<p><b>HEMATOLOGY</b> CFR(s): 493.851(c)</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.

This STANDARD is not met as evidenced by:  
Based on a desk review of proficiency testing records obtained from the CMS national database and verified with the proficiency testing company American Proficiency Institute (API) found the laboratory failed to participate in one of three testing events in 2022 resulted in unsatisfactory performance and a score of 0% for the testing event. API 2022 Hematology/Coagulation for the second event revealed the laboratory received an overall unsatisfactory score for hematology specialty of 0% due to failure to participate. Key: CMS=Center for Medicare and Medicaid Services

**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 desk review of proficiency testing records obtained from the CMS national database and verified with the proficiency testing company American Proficiency Institute (API) found the laboratory failed to achieve satisfactory performance (80% or greater) for the same analytes in two consecutive testing events in the specialty of Hematology for six of six regulated analytes for two of three proficiency testing events in 2022. Cell I.D. or WBC Diff RBC HCT (Non-waived) HGB (Non-waived) WBC Platelets Key: CMS=Center for Medicare and Medicaid Services RBC=Red Blood Cell HCT=Hematocrits HGB=Hemoglobin WBC=White Blood Cell

**D2131**

HEMATOLOGY  
CFR(s): 493.851(g)

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 a desk review of proficiency testing records obtained from the CMS national database and verified with the proficiency testing company American Proficiency Institute (API) found the laboratory failed to achieve an overall satisfactory performance (80% or greater) for two consecutive testing events in the specialty of Hematology for two of three proficiency testing events in 2022. (Refer to D2122) Key: CMS=Center for Medicare and Medicaid Services

**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 proficiency testing records obtained from the CMS national database and verified with the proficiency testing company American Proficiency Institute (API) found the laboratory director failed to provide overall management and direction of the laboratory services. (Refer to D6016) Key: CMS=Center for Medicare and Medicaid Services

**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 records obtained from the CMS national database and verified with the proficiency testing company American Proficiency Institute (API) found the laboratory director failed to ensure the overall quality of the laboratory services provided. The laboratory director failed to ensure successful testing performances in a HHS approved proficiency testing program. (Refer to D2130). Key: CMS=Center for Medicare and Medicaid Services