

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0691283	(X3) Date Survey Completed 04/22/2022
Name of Provider or Supplier East Texas Hematology & Oncology Clinic Pa	Street Address, City, State 1202 West Frank Avenue, Lufkin, 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	. Based on a proficiency testing desk review survey performed on April 22, 2022, the laboratory was found to be out of compliance based on the following CONDITION LEVEL DEFICIENCIES : D2016 - 42 C.F.R. 493.803 Condition: Successful participation D6000 - 42 C.F.R. 493.1403 Condition: Laboratory Director, moderate complexity .
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 the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile and American Association of Bioanalysis (AAB) proficiency testing records, the facility failed to participate in</p>

	<p>proficiency testing in two of two consecutive testing events for the specialty hematology, resulting in unsuccessful performance. Refer to D2123. .</p>
<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 desk review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile, and American Association of Bioanalysis (AAB) proficiency testing records from 2021 and 2022, the laboratory failed to participate in a testing event resulting an unsatisfactory performance resulting in a score of 0 for the testing event for two out of two consecutive events. Two out of two overall testing event scores of unsatisfactory performance results in unsuccessful PT performance. Findings were: 1. A review of the CASPER Report 155 lists a score of "0" for the AAB PT Program Hematology 2021 3rd event and 2022 1st event. 2. A proficiency desk review of the AAB proficiency testing records from 2021 and 2022 confirmed that the laboratory failed to participate in the testing event resulting in an overall Hematology score of "0.0 NR" for the AAB PT TESTING Hematology 2021 3rd event, and 2022 1st event. .</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> <p>This CONDITION is not met as evidenced by: . Based on desk review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile and American Association of Bioanalysis (AAB) proficiency testing records, the laboratory director failed to ensure successful participation in a HHS approved proficiency testing program for the specialty of Hematology. Refer to D6016. .</p>
<p>D6016</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i)</p> <p>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</p>

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 desk review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile and American Association of Bioanalysts proficiency testing records, the laboratory director failed to ensure successful participation in a HHS approved proficiency testing program for the specialty Hematology for two of two consecutive events in 2021 and 2022. Refer to D2123 and D6000. .