

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D1082475	(X3) Date Survey Completed 09/16/2022
Name of Provider or Supplier All Childrens Pediatric Clinic Pa	Street Address, City, State 4221 North Conway Suite D, Palmhurst, 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 September 16, 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 a desk review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile and American Proficiency Institute (API) proficiency testing records, the facility failed to achieve successful</p>

performance in four of four overall consecutive testing events for Hematology in 2021 (events 1, 2, and 3) and 2022 (event 1) resulting in unsuccessful performance (refer to D2131) and failed to achieve successful performance in three or more consecutive testing events for the analytes White Blood Cell Differential, Erythrocyte Count, Hemoglobin, Hematocrit, White Blood Cell Count, and Platelets resulting in unsuccessful participation (refer to D2130).

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 review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile and the American Proficiency Institute (API) Comparative Evaluations, the laboratory failed to achieve satisfactory performance for the analytes White Blood Cell Differential, Erythrocyte Count, Hemoglobin, Hematocrit, White Blood Cell Count, and Platelets in three or more consecutive testing events in 2021 and 2022. The findings included: 1. Based on review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile and the American Proficiency Institute (API) Comparative Evaluations, the laboratory received the following unsatisfactory analyte scores (satisfactory is 80% or greater): White Blood Cell Differential 2021 (event 1) 0% 2021 (event 2) 0% 2021 (event 3) 0% Red Blood Cell Count 2021 (event 1) 0% 2021 (event 2) 0% 2021 (event 3) 0% 2022 (event 1) 60% Hemoglobin 2021 (event 1) 0% 2021 (event 2) 0% 2021 (event 3) 0% 2022 (event 1) 60% Hematocrit 2021 (event 1) 0% 2021 (event 2) 0% 2021 (event 3) 0% 2022 (event 1) 60% White Blood Cell Count 2021 (event 1) 0% 2021 (event 2) 0% 2021 (event 3) 0% Platelets 2021 (event 1) 0% 2021 (event 2) 0% 2021 (event 3) 0% Failure to achieve satisfactory performance for the same analyte in two consecutive events or three out of three consecutive testing events is unsuccessful performance.

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 review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile and the American Proficiency Institute (API) Comparative Evaluations, the laboratory failed to achieve satisfactory performance for the overall specialty of Hematology in four of four consecutive testing events in 2021 (events 1, 2, and 3) and 2022 (event 1). The findings included: 1. Review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile, the laboratory received the following unsatisfactory scores (satisfactory is 80% or greater) for specialty of Hematology in four of four consecutive events: 2021 API 1st event 0% 2021 API 2nd event 0% 2021 API 3rd event 0% 2022 API 1st event 76% 2. Review of the American Proficiency

	<p>Institute (API) Comparative Evaluations, the laboratory received the following unsatisfactory scores (satisfactory is 80% or greater) for specialty of Hematology in four of four consecutive events: 2021 API 1st event 0% 2021 API 2nd event 0% 2021 API 3rd event 0% 2022 API 1st event 76% Failure to achieve satisfactory performance for an overall testing event in two consecutive events or four out of four consecutive testing events is unsuccessful performance.</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 Proficiency Institute (API) proficiency testing records, the laboratory director failed to ensure successful participation in an 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 director must-- (e)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;</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 Proficiency Institute (API) proficiency testing records, the laboratory director failed to ensure successful participation in an HHS approved proficiency testing program for the specialty Hematology (refer to D2130 and D2131).</p>