

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D1017251	(X3) Date Survey Completed 03/17/2022
Name of Provider or Supplier Children's Healthcare Center	Street Address, City, State 3145 West Alberta, Edinburg, 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 March 17, 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 D6076 - 42 C.F.R. 493.1441 Condition: Laboratories performing high 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 the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile and American Proficiency Institute comparative evaluation records, the laboratory failed to achieve successful</p>

performance in two of three testing events for the specialty Hematology for the analyte Red Blood Cell (RBC), resulting in unsuccessful performance (refer to D2130).

D2121

HEMATOLOGY

CFR(s): 493.851(a)

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.

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 attain a score of at least 80 percent for the analyte Red Blood Cell (RBC) in two of three testing events in 2021. 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 scores (satisfactory is 80% or greater) for the analyte Red Blood Cell in the specialty of Hematology in two of three events: 2021 API 3rd event 60% 2021 API 1st event 0%

D2123

HEMATOLOGY

CFR(s): 493.851(c)

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 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 failed to participate in one out of three testing events for the specialty of Hematology, resulting in unsuccessful performance in the specialty of Hematology. The findings included: 1. Based on review of the American Proficiency Institute (API) proficiency evaluation reports, the laboratory failed to participate in the following event in 2021: For the 1st event of 2021, the laboratory failed to participate for the specialty of hematology, including the following analytes: HEMATOLOGY (analyte #0760) Failure to participate = 0 CELL I.D. OR WBC DIFF (analyte #0765) Failure to participate = 0 HCT (NON-WAIVED) (analyte #0785) Failure to participate = 0 HGB (NON-WAIVED) (analyte #0795) Failure to participate = 0 WBC (analyte #0805) Failure to participate = 0 PLATELETS (analyte #0815) Failure to participate = 0 2. Based on review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile, the laboratory received a score of 0 percent for each

	<p>event the laboratory failed to participate: For the 1st event of 2021, the laboratory failed to participate for the specialty of hematology, including the following analytes: HEMATOLOGY (analyte #0760) Failure to participate = 0 CELL I.D. OR WBC DIFF (analyte #0765) Failure to participate = 0 HCT (NON-WAIVED) (analyte #0785) Failure to participate = 0 HGB (NON-WAIVED) (analyte #0795) Failure to participate = 0 WBC (analyte #0805) Failure to participate = 0 PLATELETS (analyte #0815) Failure to participate = 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 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 analyte Red Blood Cell in two of three testing events in 2021, resulting in unsuccessful performance. 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 scores (satisfactory is 80% or greater) for the analyte Red Blood Cell in the specialty of Hematology in two of three events: 2021 API 3rd event 60% 2021 API 1st event 0% 2. Failure to achieve satisfactory performance for the same analyte in two of three 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) Comparative Evaluations proficiency testing records, the laboratory director failed to ensure successful participation in a HHS approved proficiency testing program for analytes specialty Hematology for the analyte Red Blood Cell (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</p>

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 Proficiency Institute (API) proficiency testing records, the laboratory director failed to ensure successful participation in a HHS approved proficiency testing program for specialty of Hematology (refer to D2130).