

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D0077174	(X3) Date Survey Completed 11/12/2020
Name of Provider or Supplier Tlc Pediatrics Everett	Street Address, City, State 391 Broadway Ste 301, Everett, MA	
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 evidence of unsuccessful proficiency testing performance for the White Blood Cell Differential, Red Blood Count, Hematocrit, Hemoglobin, and White Blood Count analytes as well as the specialty of Hematology, the following Condition level deficiency was deemed to be not met: Condition 42 CFR 493.803 - Proficiency Testing - Successful Participation. .
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 an off-site proficiency testing desk review for calendar year 20, the laboratory failed to successfully participate (achieve a score of 80 percent or more) in the American Proficiency Institute (API) proficiency testing program for the the white</p>

blood cell differential, red blood count, hematocrit, hemoglobin, and white blood cell count analytes resulting in ongoing unsuccessful proficiency testing performance in the specialty of Hematology. Refer to D2123, D2130, and D2131. .

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 record review of calendar year 2020 American Proficiency Institute (API) proficiency testing results, the laboratory failed to attain a testing event score of at least 80 percent for all hematology analytes as evidenced by the following testing event scores: White Blood Cell Differential Analyte: 1. 2020 API testing event 1 - score of 60 %. 2. 2020 API testing event 2 - score of 73 %. Red Blood Count: 1. 2020 API testing event 1 - score of 40 %. 2. 2020 API testing event 2 - score of 60 %. Hematocrit: 1. 2020 API testing event 1 - score of 40 %. 2. 2020 API testing event 2 - score of 60 %. Hemoglobin: 1. 2020 API testing event 1 - score of 40 %. 2. 2020 API testing event 2 - score of 60 %. White Blood Count: 1. 2020 API testing event 1 - score of 40 %. 2. 2020 API testing event 2 - score of 60 %. The overall hematology scores were confirmed in a telephone interview with the laboratory director on 11/12/20 at 9:24 AM. .

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 American Proficiency Institute (API) proficiency testing performance review for calendar year 2020, the laboratory failed to achieve an overall testing event score of satisfactory performance for two out of two testing events for the specialty area of Hematology leading to unsuccessful performance as evidenced by the following scores obtained: The specialty of Hematology: 1. 2020 API testing event 1 - score of 43 %. 2. 2020 API testing event 2 - score of 68 %. The overall hematology scores were confirmed in a telephone interview with the laboratory director on 11/12/20 at 9:24 AM. .