

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  45D0871860	<b>(X3) Date Survey Completed</b>  09/25/2020
<b>Name of Provider or Supplier</b>  Emerald Pediatric Clinic	<b>Street Address, City, State</b>  11511 Veterans Memorial Drive # 300, Houston, 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>D2016</b>	<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: An unannounced revisit was performed on 9/25/20. Based on review of the CMS national database, 2019 and 2020 American Proficiency Institute proficiency testing records, and confirmed in interview, the laboratory failed to successfully participate in a proficiency testing program approved by CMS for the analytes: WBC (white blood cell), HGB (hemoglobin), HCT (hematocrit), PLT (platelet), RBC (red blood cells), and WBC (White blood cell) differential for 2 of 3 of the last proficiency testing events. Refer to D2121, D2130</p>
<b>D2121</b>	<b>HEMATOLOGY</b>

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:

An unannounced revisit was performed on 9/25/20. Based on review of the CMS national database, 2019 and 2020 American Proficiency Institute (API) proficiency testing records, and confirmed in interview, the laboratory failed to attain a score of at least 80% for the analytes: WBC (white blood cell), HGB (hemoglobin), HCT (hematocrit), PLT (platelet), RBC (red blood cells), and WBC (White blood cell) differential for 2 of 3 of the last proficiency testing events. Findings were: 1. Review of the CMS national database revealed the laboratory received "0" for all the analytes for 2 of 2 API testing events in 2020. 2020 1st event & 2nd event WBC - 0% RBC - 0% HGB - 0% HCT - 0% PLT - 0% WBC Diff - 0% 2. Review of the laboratory API test records revealed the laboratory received "0" for all analytes for 2 of 2 API testing events in 2020. 2020 1st event & 2nd event WBC - 0% RBC - 0% HGB - 0% HCT - 0% PLT - 0% WBC Diff - 0% 3. An interview with the primary testing person on 9/25/20 at 1000 hours in the nursing station confirmed the above findings. She was unaware the laboratory received 0 for their scores.

**D2122**

HEMATOLOGY

CFR(s): 493.851(b)

Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.

This STANDARD is not met as evidenced by:

An unannounced revisit was performed on 9/25/20. Based on review of the CMS national database, 2019 and 2020 American Proficiency Institute (API) proficiency testing records, and confirmed in interview, the laboratory failed to attain a score of at least 80% for 2 of 3 Hematology testing events in 2019 and 2020. Findings were: 1. Review of the CMS national database revealed the laboratory received "0" for Hematology in 2 of 2 API testing events in 2020. 2020 1st event & 2nd event Hematology - 0% 2. Review of the laboratory API test records revealed the laboratory received "0" for the specialty of Hematology for 2 of 2 API testing events in 2020. 2020 1st event & 2nd event Hematology - 0% 3. An interview with the primary testing person on 9/25/20 at 1000 hours in the nursing station confirmed the above findings. She was unaware the laboratory received "0" for their scores.

**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:

An unannounced revisit was performed on 9/25/20. Based on review of the CMS national database, 2019 and 2020 American Proficiency Institute (API) proficiency testing records, and confirmed in interview, the laboratory failed to participate in the specialty of hematology 2 of 3 of the last proficiency testing events. Findings were: 1. Review of the CMS national database revealed the laboratory received "0" for all the analytes for 2 of 2 API testing events in 2020. 2020 1st event & 2nd event WBC - 0% RBC - 0% HGB - 0% HCT - 0% PLT - 0% WBC Diff - 0% 2. Review of the laboratory API test records revealed the laboratory received "0" for Failure to Participate for all analytes for 2 of 2 API testing events in 2020. 2020 1st event & 2nd event WBC - 0% RBC - 0% HGB - 0% HCT - 0% PLT - 0% WBC Diff - 0% 3. An interview with the primary testing person on 9/25/20 at 1000 hours in the nursing station confirmed the above findings. She was unaware the laboratory received 0 for their scores.

**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:

An unannounced revisit was performed on 9/25/20. Based on review of the CMS national database, 2019 and 2020 American Proficiency Institute (API) proficiency testing records, and confirmed in interview, the laboratory failed to achieve satisfactory performance (80% or greater) for the analytes: WBC (white blood cell), HGB (hemoglobin), HCT (hematocrit), PLT (platelet), RBC (red blood cells), and WBC (White blood cell) differential for 2 of 3 of the last proficiency testing events. Findings were: 1. Review of the CMS national database revealed the laboratory received "0" for all the analytes for 2 of 2 API testing events in 2020. 2020 1st event & 2nd event WBC - 0% RBC - 0% HGB - 0% HCT - 0% PLT - 0% WBC Diff - 0% 2. Review of the laboratory API test records revealed the laboratory received "0" for all analytes for 2 of 2 API testing events in 2020. 2020 1st event & 2nd event WBC - 0% RBC - 0% HGB - 0% HCT - 0% PLT - 0% WBC Diff - 0% 3. An interview with the primary testing person on 9/25/20 at 1000 hours in the nursing station confirmed the above findings. She was unaware the laboratory received 0 for their scores.

**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:

An unannounced revisit was performed on 9/25/20. Based on review of the CMS national database, 2019 and 2020 American Proficiency Institute (API) proficiency testing records, and confirmed in interview, the laboratory failed to achieve

satisfactory performance (80% or greater) for specialty of hematology for 2 of 3 Hematology testing events in 2019 and 2020. Two out of three overall testing event scores of unsatisfactory performance results in unsuccessful PT performance. Findings were: 1. Review of the CMS national database revealed the laboratory received "0" for Hematology in 2 of 2 API testing events in 2020. 2020 1st event & 2nd event Hematology - 0% 2. Review of the laboratory API test records revealed the laboratory received "0" for the specialty of Hematology for 2 of 2 API testing events in 2020. 2020 1st event & 2nd event Hematology - 0% 3. An interview with the primary testing person on 9/25/20 at 1000 hours in the nursing station confirmed the above findings. She was unaware the laboratory received "0" for their scores.

**D5215**

**EVALUATION OF PROFICIENCY TESTING PERFORMANCE**  
CFR(s): 493.1236(b)(2)

The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).

This STANDARD is not met as evidenced by:

An unannounced revisit was performed on 9/25/20. Based on review of the CMS national database, 2020 American Proficiency Institute (API) proficiency testing records, and confirmed in interview, the laboratory failed to verify the accuracy of the analytes: WBC (white blood cell), HGB (hemoglobin), HCT (hematocrit), PLT (platelet), RBC (red blood cells), and WBC (White blood cell) differential for 1 testing event in 2020. Findings were: 1. Review of the laboratory API test records revealed the laboratory received "0" for all analytes for the 1st test event in 2020. 2020 1st event WBC - 0% RBC - 0% HGB - 0% HCT - 0% PLT - 0% WBC Diff - 0% 2. Review of the laboratory records revealed the laboratory performed the 2020 API 1st event on 3/27/20. 3. Review of the test records revealed no documentation of the laboratory verifying the accuracy of the above analytes for the 2020 1st event. 4. An interview with the primary testing person on 9/25/20 at 1000 hours in the nursing station confirmed the above findings. She was unaware the laboratory did not send the laboratory results to API. She was also unaware the laboratory could self evaluate their performance.

**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:

An unannounced revisit was performed on 9/25/20. Based on review of the CMS

	<p>national database, American Proficiency Institute proficiency testing records, and confirmed in interview, the laboratory director failed to ensure that the proficiency testing samples are tested as required. Refer to D2121, D2130, D2131</p>
<b>D6033</b>	<p><b>TECHNICAL CONSULTANT-MODERATE COMPLEXITY</b> CFR(s): 493.1409</p> <p>The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.</p> <p>This CONDITION is not met as evidenced by: An unannounced revisit was performed on 9/25/20. Based on review of the laboratory verification records, laboratory test records, and confirmed in interview, the technical consultant failed to provide technical oversight for the hematology testing on the QBC Star hematology analyzer. Refer to D6036, D6040, D6042, D6053</p>
<b>D6036</b>	<p><b>TECHNICAL CONSULTANT RESPONSIBILITIES</b> CFR(s): 493.1413</p> <p>The technical consultant is responsible for the technical and scientific oversight of the laboratory.</p> <p>This STANDARD is not met as evidenced by: An unannounced revisit was performed on 9/25/20. Review of manufacturer's instructions, laboratory records, quality control records, and patient test reports, the Technical Consultant failed to provide technical and scientific oversight of the laboratory as evidenced by: 1. The laboratory failed to document the verification studies for Complete Blood Count (CBC) testing on the QBC Star hematology analyzer. Refer to D5421 2. The laboratory failed to monitor laboratory temperature and humidity, ensuring accurate and reliable test system operation for the QBC Star hematology analyzer. Refer to D5413 3. The laboratory failed to document acceptable quality control prior to patient testing. Refer to D5447</p>
<b>D6040</b>	<p><b>TECHNICAL CONSULTANT RESPONSIBILITIES</b> CFR(s): 493.1413(b)(2)</p> <p>The technical consultant is responsible for-- (b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system.</p> <p>This STANDARD is not met as evidenced by: An unannounced revisit was performed on 9/25/20. Based on review of the laboratory verification records and confirmed in interview, the technical consultant failed to ensure the laboratory documented complete verification studies for the QBC Star hematology analyzers prior to start of patient testing. (Refer to D5421)</p>
<b>D6042</b>	<p><b>TECHNICAL CONSULTANT RESPONSIBILITIES</b> CFR(s): 493.1413(b)(4)</p>

(b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results;

This STANDARD is not met as evidenced by:

An unannounced revisit was performed on 9/25/20. Based on review of the laboratory quality control (QC) records and confirmed in interview, the technical consultant failed to ensure the laboratory had documentation of performing quality control testing on the QBC Star hematology analyzer each day of patient testing . Refer to D5447

**D6053**

**TECHNICAL CONSULTANT RESPONSIBILITIES**

CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

An unannounced revisit was performed on 9/25/20. Based on a review of the laboratory's personnel records and interview of facility personnel, the technical consultant failed to document semiannual competency evaluations during the first year of all personnel performing hematology patient testing. Findings were: 1. A review of the facility's personnel files revealed no documentation of a semiannual competency evaluation relating to laboratory testing for 4 of 4 testing personnel. 2. The laboratory was asked for documentation of the semiannual competencies for all testing personnel. No documentation was provided. 3. An interview with the primary testing person on 9/25/20 at 1015 hours in the nursing station confirmed the above findings.