

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  23D0993677	<b>(X3) Date Survey Completed</b>  02/03/2020
<b>Name of Provider or Supplier</b>  Ascension Bright Futures Pediatrics	<b>Street Address, City, State</b>  714 N 9th Street, Kalamazoo, MI	
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:                      . . Based on record review and interview with Testing Personnel #1 (TP1), the laboratory failed to successfully participate in a CMS approved proficiency testing program for the specialty of hematology for 2 (events 1 and 3 of 2019) of 3 testing events. Findings include: The laboratory failed to achieve satisfactory performance for the specialty of hematology. Refer to D2123 and D2131. .</p>
<b>D2123</b>	<p>HEMATOLOGY CFR(s): 493.851(c)</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.

This STANDARD is not met as evidenced by:  
. Based on record review and interview with Testing Personnel #1 (TP1), the laboratory failed to participate in proficiency testing for the specialty of hematology for 2 (events 1 and 3 of 2019) of 3 testing events. Findings include: 1. A record review of the laboratory's American Proficiency Institute (API) proficiency testing records revealed a lack of final reports submitted to API. 2. A record review of the CMS database revealed the laboratory failed to participate for two out of three consecutive PT events constituting unsuccessful performance for the specialty of hematology. Hematology PT Event Score 1st event 2019 0% 3rd event 2019 0% 3. An interview on 2/3/2020 at 10:25 am with TP1 confirmed the laboratory did not submit their proficiency testing results to API for events 1 and 3 of 2019.

**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 record review and interview with Testing Personnel #1 (TP1), the laboratory failed to achieve satisfactory performance for the specialty of hematology for 2 (events 1 and 3 of 2019) of 3 testing events. Findings include: 1. A record review of the laboratory's American Proficiency Institute (API) proficiency testing records revealed a lack of final reports submitted to API. 2. A record review of the CMS database revealed unsatisfactory performance for two out of three consecutive PT events constituting unsuccessful performance for the specialty of hematology. Hematology PT Event Score 1st event 2019 0% 3rd event 2019 0% 3. An interview on 2/3/2020 at 10:25 am with TP1 confirmed the laboratory did not submit their proficiency testing results to API for events 1 and 3 of 2019.

**D6046**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:  
. Based on record review and interview with Testing Personnel #1 (TP1), the

Technical Consultant failed to evaluate the competency of testing personnel performing hematology testing for 1 (Testing Personnel #1) of 7 testing personnel listed on the CMS-209 form. Findings include: 1. A record review of the laboratory's established "Lab Personnel: Responsibilities, by Position" revealed a section stating, "The technical consultant is responsible for technical and scientific oversight of the laboratory. This person is not required to be on-site at all times, but must be available to provide consultation either on-site, by telephone, or electronically in addition, the technical consultant evaluates the competency of all testing personnel on an ongoing basis." 2. A record review of testing personnel competency assessments revealed TP1 had self-evaluated their annual competency for 2018, dated 3/3/2018. 3. An interview on 2/3/2020 at 10:05 am with the TP1 confirmed their competency evaluation was not performed by the Technical Consultant.