

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 36D0904493	<b>(X3) Date Survey Completed</b> 03/27/2019
<b>Name of Provider or Supplier</b> Clinical Hematology And Oncology Svcs	<b>Street Address, City, State</b> 155 5th Street Ne, Parkview Center, Barberton, OH	
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>D2007</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's Medical Laboratory Evaluation (MLE) proficiency testing (PT) records and interviews with Testing Personnel (TP) #1 and TP#2, the laboratory failed to examine or test complete blood cell (CBC) count PT samples by TP#1 and TP#3 who routinely performed patient testing. This deficient practice had the potential to affect 18,635 patients tested under the specialty of hematology. Findings Include: 1. Review of three out of three of the laboratory's 2018 MLE CBC PT events did not find any record that TP#1 or TP#3 participated in testing CBC PT samples. 2. TP#1 and TP#2 confirmed TP#1 and TP#3 did not participate in CBC PT events or re-analyze previously tested specimens in 2018. The interviews occurred on 03/27/2019 at 11:04 AM.</p>
<b>D2016</b>	<p><b>SUCCESSFUL PARTICIPATION</b> 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-</p>

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.

This CONDITION is not met as evidenced by:  
Based on record review, an interview with Testing Personnel (TP), and the lack of 2019 Medical Laboratory Evaluation (MLE) complete blood count Proficiency Testing (PT) records, the laboratory failed to successfully participate in a proficiency testing program for the nonwaived specialty of hematology, for which the laboratory is certified under CLIA. This deficient practice had the potential to affect 18, 635 patients tested in the specialty of hematology. Findings Include: 1. Review of 2017-2019 complete blood count MLE PT records revealed no PT records for 2019. 2. The surveyor requested the 2019 MLE PT records from TP#2. TP#2 stated the laboratory had not received the 2019 MLE 1st event samples yet. The surveyor requested MLE PT documentation from the laboratory regarding enrollment and late shipment of the PT samples. The laboratory was unable to provide the requested documentation on the date of the survey. The interview occurred 03/27/2019 at 11:30 AM. 3. On 03/29/2019 at 4:42 PM TP#2 had sent an email stating the 2019 MLE PT samples for the 1st event had been received by the laboratory, but were never submitted to MLE for evaluation.

**D5401**

**PROCEDURE MANUAL**  
CFR(s): 493.1251(a)

A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

This STANDARD is not met as evidenced by:  
Based on policy and procedure review and an interview with Test Personnel (TP), the laboratory failed to follow written policies and procedures for hematology proficiency testing during 2018. This deficient practice had the potential to affect 18,635 patients tested under the specialty of hematology. Findings Include: 1. Review of the laboratory's policies and procedures, provided on the date of the inspection, found a "Tab 2: Proficiency Testing (PT)" policy and procedure which contained the following statement: "Test proficiency samples in the same way as patient samples, i. e., run them with the regular patient workload using a staff member who routinely performs hematology testing on the AcT analyzer." 2. Review of the laboratory's Medical Laboratory Evaluation (MLE) attestation pages from 2018 MLE-M1, 2018 MLE-M2, and 2018 MLE-M3 found PT had only been completed by TP#2. TP#2 verified PT testing for 2018 was not rotated through staff routinely testing on the AcT analyzer. The interview occurred on 03/27/2019 at 11:20 AM.

**D6017**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(4)(ii)

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)(ii) Ensure that results are returned within the timeframes established by the proficiency testing program.

This STANDARD is not met as evidenced by:  
REPEAT Based on review of the laboratory's Medical Laboratory Evaluation (MLE) proficiency testing (PT) records and interviews with Testing Personnel (TP), the Laboratory Director failed to ensure the complete blood cell (CBC) PT results were submitted to the PT provider within the timeframe established by the PT program. This deficient practice had the potential to affect 18,635 patients tested in the specialty of hematology. Findings Include: 1. Review of the laboratory's 2017-2019 MLE PT records revealed no records for 2019 MLE PT 1st event. 2. TP#2 confirmed the laboratory did not submit the CBC PT results by the due date for the 1st event in 2019. The interviews occurred on 03/27/2019 at 11:30 AM.

**D6029**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(11)

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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:  
Based on review of Laboratory Personnel Report (CLIA) Form CMS-209 signed by the Laboratory Director March 19, 2019, lack of education documentation, and an interview with Testing Personnel (TP), the Laboratory Director failed to ensure prior to testing patients' specimens, Testing Personnel have the appropriate education and experience to perform all testing operations reliably to provide and report accurate results. This deficient practice had the potential to affect 18,635 patients tested under the specialty of hematology. Findings Include: 1. Review of Laboratory Personnel Report (CLIA) Form CMS-209 signed by the Laboratory Director March 19, 2019 revealed one testing personnel identified as Testing Personnel #3. 2. Upon request for education documentation for Testing Personnel #3 on the date of survey, TP#1 confirmed no documentation of education was available for review. The interview occurred 03/27/2019 at 10:15 AM.