

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 07D0994636	(X3) Date Survey Completed 12/23/2021
Name of Provider or Supplier Oncology Hematology Care Of Connecticut	Street Address, City, State 849 Boston Post Road, Suite 100, Milford, CT	
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	A proficiency testing desk review of the Oncology & Hematology Care of Connecticut LLC Laboratory was conducted pursuant to 42CFR Part 493 of the Clinical Laboratory Improvement Amendments (CLIA) of 1988.
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 record review of proficiency testing (PT) data report (Report 155) and graded results from Medical Laboratory Evaluation (MLE), the laboratory failed to achieve successful participation in PT for the regulated analyte of cell identification or</p>

white blood cell differential (cell id/wbc diff) in the specialty of hematology. The laboratory received unsatisfactory scores for events 1 and 3 of 2021. Refer to D2127, D2128, D2130.

D2127

HEMATOLOGY
CFR(s): 493.851(d)

Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

This STANDARD is not met as evidenced by:

Based on record review and phone interview with the technical consultant (TC), the laboratory failed to submit proficiency testing (PT) results on time during event 3 of 2021 for the specialty of hematology. Findings include: 1) Record review on 12/23/21 of the CMS CASPER PT report, 155D, revealed a score of 0 for analyte 765, cell identification or white blood cell differential (cell id/wbc diff), for event 3, 2021. 2) Record review on 12/23/21 of the Medical Laboratory Evaluation (MLE) instructions accompanying event 3 (ME3) revealed results had to be returned by the deadline 10/1/21. 3) Record review on 12/23/21 of 'Boule (DCS) Medonic M series' instrument print out for MLE-ME3 revealed specimens HD11-HD15 were run on 9/28/21. 4) Phone interview on 12/20/21 at 11:20 AM with the TC revealed specimen results were not submitted to MLE.

D2128

HEMATOLOGY
CFR(s): 493.851(e)

(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

This STANDARD is not met as evidenced by:

Based on record review and phone interviews, the laboratory failed to undertake appropriate action necessary to correct unsatisfactory performance during proficiency testing (PT) for the analyte of cell identification or white blood cell differential (cell id/wbc diff) for events 1 and 3 of 2021 in the specialty of hematology. Findings include: 1) Record review on 12/23/21 of the CMS CASPER PT report, 155D, revealed the following: a. Event 1 2021: score 66 for the analyte 765 cell id/wbc diff. b. Event 3 2021: score 0 for analytes 765 Cell Id/WBC Diff, 775 RBC, 785 HCT (Non-waived), 795 HGB (Non-waived), 805 WBC, and 815 Platelets 2) Record review on 12/23/21 of the "Proficiency Testing Evaluation 2021 MLE-ME1" revealed the following: a. Samples HD1-HD5 had unacceptable results for granulocyte/neut (percent). b. The analyte cell id/wbc diff received an overall score of 66% resulting in unsatisfactory performance for the analyte. c. No corrective action with the summary not signed and dated by laboratory director as being reviewed 3) Record review on 12/23/21 of the "Proficiency Testing Evaluation 2021 MLE-ME3" revealed 0% scores for the following analytes a. Cell Identification or WBC Differential b. Erythrocyte Count c.

Hematocrit d. Hemoglobin e. Leukocyte Count f. Platelet Count 4) Record review on 12.23.21 of email dated 12.21.21 at 6:35 PM from the technical consultant revealed the following: a. "Plans of correction" document was created on 12.21.21 at 4:37pm. b. No documentation of an investigation report for MLE-ME1 or MLE-ME3 was submitted. 5) Phone interview on 12/16/21 at 1:52 PM with testing personnel revealed he/she was unaware of unsatisfactory score of 66% for cell id/wbc diff for event 1 2021. 6) Phone interview on 12/21/21 at 12:05pm with technical consultant stated, "still developing spreadsheet to make sure PTs are returned on time."

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 and phone interview, the laboratory failed to achieve a satisfactory score in the analyte of cell identification or white blood cell differential (cell id/wbc diff) in 2 out of 3 events in 2021 in the specialty of hematology. Findings include: 1) Record review on 12/23/21 of CMS CASPER PT report, 155D, revealed the following: a. Analyte 765, with a score or 66 for event 1 of 2021 for cell id/wbc diff. b. Score of 0 for cell id/wbc diff for event 3 2021. 2) Record review on 12/23/21 of the "Proficiency Testing Evaluation 2021 MLE-ME1" revealed the following: a. Samples HD1-HD5 had unacceptable results for granulocyte/neut (percent). b. The analyte cell id/wbc diff received an overall score of 66% resulting in unsatisfactory performance for the analyte. 3) Phone interview on 12/20/2021 at 11:20 AM with TC revealed the following: a. The unsatisfactory score for event 1 2021 was due to a transcription error. b. Specimens for event 3 2021 were not submitted.