Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D1002851	(X3) Date Survey Completed 04/28/2022
Name of Provider or Supplier Hematology And Oncology Of Lima Inc	**Street Address, City, State** 825 West Market Street Suite 203, Lima, OH	

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
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) 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 This STANDARD is not met as evidenced by: Based on record review and an interview with Testing Personnel (TP) #1, the laboratory failed to examine or test proficiency testing samples by all personnel who routinely perform testing in the laboratory. Two out of four TP failed to participate in seven out of seven proficiency testing events reviewed in the speciality of hematology. Findings Included: 1. Review of the laboratory's CMS-209 form found four individuals listed as TP, qualified by the LD, to perfordm moderate complexity hematology procedures. 2. Review of proficiency testing event documentation and data found that TP #3 and TP #4 failed to participate in seven out of seven proficiency testing events in the specialty of hematology. Event TP Date 1 #1 02//4/2020 2 #2 05 /12/2020 3 #1 09/05/2020 4 #2 02/02/2021 5 #1 05/11/2021 6 #2 09/15/2021 7 #2 02 /27/2022 3. An interview with TP #1, on 04/28/2022 at 2:48 PM, confirmed that TP #3 and TP #4 failed to participate in seven out of seven proficiency testing events reviewed in the speciality of hematology.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.

	This STANDARD is not met as evidenced by: Based on record review and an interview with Testing Personnel (TP) #1, the laboratory failed to follow policies and procedures for the competency assessment for two out of two newly hired TP performing moderate complexity testing in the specialty of hematology. Findings include: 1. Review of the laboratory's manual found a competency assessment policy, approved by the Laboratory Director (LD) on 04/05 /2022. The policy stated the following:"...New employees shall have performance evaluation using the check off sheet and the competency assessment form 6 months after the initial training and at the 1 year mark..." 2. Review of the laboratory's CMS-209 form found four individuals listed as TP, qualified by the LD, to perform moderate complexity hematology procedures. 3. Review of training records and competency assessment documentation found that TP #3 and TP #4 were newly hired. TP #3 hire date: 09/03/2019 TP #4 hire date: 08/05/2020 4. Further review of competency assessment documentation failed to find a competency assessment performed at six months after initial training for TP #3 and TP #4, as stated in the policy. TP #3 TP#4 Initial 10/01/19 09/02/2020 6 month [none] [none] 5. An interview with TP #1, on 04/28/2022 at 2:39 PM, confirmed that the lab failed to follow the approved policy and failed perform competency assessment on the newly hired TP #3 and TP #4 six months after initial training.