

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D0371059	(X3) Date Survey Completed 02/11/2020
Name of Provider or Supplier Comprehensive Healthcare Associates & Prevention	Street Address, City, State 15645 Farmington Road, Livonia, MI	
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
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with Testing Personnel #1 (TP1), the laboratory failed to maintain a copy of the Medical Laboratory Evaluation (MLE) final PT report, signed attestation statement sheets, review of the final graded PT reports, and the documentation of corrective action if indicated for 6 (MLE M1 - M3 for 2018 and 2019) of 6 events reviewed. Findings include: 1. Record review of the final graded MLE proficiency testing reports revealed the laboratory failed to maintain the following for 6 of 6 events: a. No documentation of review of the final graded report by the TP - MLE-M1-M3 2018 and M1 and M3 2019. b. No documentation of corrective action for the following: i. 80% score for platelet count for MLE-M1 2018 ii. 60% score for red blood cell count and 80% for hematocrit for MLE-M2 2018 iii. 20% score for hematocrit for MLE-M1 2019 iv. 80% score for platelet count for MLE-M3 2019 c. No copy of the final graded report for MLE-M2 2019 d. No signed attestation statement sheet for MLE-M1 and M2 2018 2. During the interview on 02/11/2020 at approximately 10:45 am, TP1 confirmed the laboratory did not maintain all the documentation listed above for 2018 and 2019. .</p>

D5293

GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT

CFR(s): 493.1239(b)(c)

(b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities.

This STANDARD is not met as evidenced by:

. Based on record review and interview with Testing Personnel #1 (TP1), the laboratory failed to follow written policies and procedures for an ongoing mechanism to monitor, assess, and correct problems as specified for the laboratory systems for 2 (2018 and 2019) of 2 years reviewed. Findings include: 1. Record review of the "Quality Assurance" policy revealed the laboratory was to perform a semi-annual check. 2. A review of the quality assurance records revealed the laboratory performed the check annually as follows: a. November 2018 b. November 2019 3. During the interview on 02/11/2020 at approximately 12:08 pm, TP1 confirmed the laboratory did not follow procedure and perform the quality checks semi-annually.