

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 48D1076688	(X3) Date Survey Completed 09/09/2021
Name of Provider or Supplier Yacht Haven Family Practice	Street Address, City, State 5302 Yacht Haven Grande Suite 124, St Thomas, VI	
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
D2128	<p>HEMATOLOGY CFR(s): 493.851(e)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on review of proficiency testing results and laboratory director interview, the laboratory failed to take and document remedial action for proficiency testing (PT) failures for 5 of 16 test analytes reviewed on the AAFP 2021-A testing event for Hematology. Findings include: 1) Review of the AAFP 2021-A shows the following PT failures: a) Sample HD5- Lymphocyte in percent- result submitted- 1.2. PT evaluation- Fail b) Sample HD2- Monocyte/Mixed in percent- result submitted- 0.5. PT evaluation- Fail c) Sample HD2- Red Blood Cell Count- result submitted- 2.23. PT evaluation- Fail d) Sample HD2- Hemoglobin- result submitted- 6.5. PT evaluation- Fail e) Sample HD2- Hematocrit- result submitted- 16.7. PT evaluation- Fail 2) Surveyor requested remedial and or corrective action for the proficiency testing failures for the AAFP-2021 A testing event for Hematology. No remedial action was provided. 3) In an e-mail communication dated September 9, 2021 at 11:24 AM, the laboratory director confirmed the following: a) Were not aware of any corrective action taken-but will check.</p>
D5447	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g)</p>

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on review of patient test records, quality control records and laboratory interview, the laboratory failed to perform two control materials of different concentrations at least once a day patient specimens are assayed for complete blood cell count (CBC) testing in the specialty of Hematology for three of three test reports reviewed. Findings include: 1) Review of CBC test reports shows patient testing performed on November 10, 2020 for the following three test reports: a) XX778 performed at 3:10 PM b) XX778 performed at 3:02 PM c) XX287 performed at 11:58 AM 2) The surveyor requested two control materials of different concentrations for CBC test reports assayed on November 10, 2020. a) The laboratory provided quality control statistics for MX-410 with an expiration date of May 5, 2018. b) No documentation was provided of the requested two control materials of different concentrations that were assayed for CBC test reports on November 10, 2020. 3) In an e-mail correspondence dated September 9, 2021 at 11:24 AM confirmed the following: a) Current IT issue-will be provided b) No documentation was provided of the requested two control materials of different concentrations that were assayed for CBC test reports on November 10, 2020.