

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 15D2095759	(X3) Date Survey Completed 11/30/2022
Name of Provider or Supplier State Line Family Medicine	Street Address, City, State 535 West Eaton Pike, Richmond, IN	
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 record review and interview, the laboratory failed to perform remedial action for an unsuccessful score for one out of five analytes (platelet count (PLT)) tested using DxH 520 Automated Hematology Analyzer (SN: BD040304) for one (2022-A) of three proficiency testing (PT) for events in 2022. Findings include: 1. Review of PT testing evaluation from the American Academy of Family Physicians (AAFP) "EVENT: 2022-A Performance" indicated platelet count (PLT) had a score of 40% which is "unsatisfactory". 2. Review of laboratory "Policy # 3615LabAMB-SLFM-QA", signed by the laboratory director on 11/28/22, states: a. "Proficiency Testing for Moderate Complexity Testing is provided by American Academy of Family Physicians (AAFP)" on page 1 of 22. b. Under "Corrective Action for PT Failure" the "SLFM laboratory will have evidence of evaluation and corrective taken in response to unacceptable PT results" on page 16 of 22. 3. The "Review of Proficiency Survey Results" document for "EVENT: 2022A Performance", signed by the laboratory director on 11/22/22, states "Identification of Unacceptable Performance: Acceptable" and "Remedial Action Taken: None" for analysis date(s): 03/21/2022. 4. On 11/30/22 at 12:57AM, SP-1 (technical consultant) confirmed no</p>

remedial action was taken for unsatisfactory performance of analyte: platelet count (PLT) for event 2022A. 5. Annual Test Volume for the specialty of Hematology is approximately 3,786.

D3039

RETENTION REQUIREMENTS

CFR(s): 493.1105(a)(5)

Quality system assessment records. Retain all laboratory quality system assessment records for at least 2 years.

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory failed to retain documents for Quality Assessment (QA) for 2020 and 2021. Findings include: 1. Review of laboratory Policy #138-6084, under "13. Quality Assurance and Performance Improvement (QAPI)" states "quarterly reports are forwarded to the quality department where results are summarized in a report shared with the Quality Committee and Board." 2. On 11/30/22 at 2:00 PM, upon request for quality assessment documentation for 2020 and 2021, SP-1 (technical consultant) stated no Quality Assessments could be found for 2020 and 2021. 3. Review of laboratory "Policy # 3615LabAMB-SLFM-QA", signed by the laboratory director on 11/28/22, on page 14 of 22. Under, "VI. Documents and Records" reads. "documents and records are managed in accordance with national and local standards, maintained by: a. Retained as required b. Document and record storage can be assessed and tracked" 4. Review of laboratory "Policy # 3615LabAMB-SLFM-QA", signed by the laboratory director on 11/28/22, on page 15 of 22. Under, "VI. Assessments and Audits" reads, "the laboratory performs ongoing quality assessments for: a. Monitoring of determined quality indicators, corrective actions undertaken, and follow-up. b. Participation in proficiency testing program and review of the corresponding reports." 5. Annual Test Volume for the specialty of Hematology is approximately 3,786.

D5429

MAINTENANCE AND FUNCTION CHECKS

CFR(s): 493.1254(a)(1)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory failed to complete the monthly bleaching cycle for the DxH 520 Automated Hematology Analyzer (SN: BD040304) for six of 23 months (March 2021, May 2021, November 2021, February 2022, April 2022, and May 2022) reviewed. Findings include: 1. Review of the "DxH 520 Instrument Maintenance Checklist" for 2021 and 2022 indicated performance of the "Bleach Cycle" was not documented for the following months: March (2021), May (2021), November (2021), February (2022), April (2022), and May (2022). 2. Review of laboratory "Policy # 3615LabAMB-SLFM-QA", signed by the laboratory director on 11/28/22; under, "Preventative Maintenance and Repair" states the "appropriate maintenance and function checks performed and documented for all instruments (e.g., analyzers) and equipment, at least as frequent as specified by the manufacturer" on page 21 of 22. 3. Review of Beckman Coulter "DxH 520 Instructions for Use"

document published March 2019. Chapter 12 titled, "Cleaning Procedures" under Table 12.1 Matrix of Frequency for Cleaning Procedures requires the frequency for performing a bleach cycle is "Every 1,000 cycles or monthly, whichever comes first" on page 12-1. 4. Review of patient (PT#1-PT#8) medical records indicated testing was performed on four of eight patients with DxH 520 Automated Hematology Analyzer (SN: BD040304) without a bleach cycle being performed during the month samples were tested for the following: PT#1 on 03/02/21, Result: CBC (RHPA ONLY)- Abnormal PT#2 on 05/27/21, Result: CBC w/ Diff (RHPA ONLY) PT#3 on 11/12/21, Result: CBC (RHPA ONLY) PT#4 on 02/14/22, Result: CBC (RHPA ONLY) 5. On 11/30/22 at 12:50 PM and 1:10 PM, SP-2 (Testing Personnel) confirmed there was no documentation that the bleaching cycle where completed during March 2021, May 2021, November 2021, February 2022, April 2022, and May 2022. 6. Annual Test Volume for the specialty of Hematology is approximately 3,786.