

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 15D0356272	(X3) Date Survey Completed 05/14/2025
Name of Provider or Supplier Methodist Hospitals, Inc, The	Street Address, City, State 200 E 89th Ave, Suite 2a, Merrillville, 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
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>(a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on observation, record review and interview, the laboratory failed to perform and document preventative maintenance on one of one analyzer for ABX Pentra 60 C+ used for testing in the specialty of hematology for five of five analyte(s) (WBC, RBC, HGB, HCT, PLT) and eight of eight patients (PT-1 to PT-8) tested from 1/04/24 through 10/30/24. Findings included: 1. During a tour of the laboratory on 5-14-2025 at 10:15am, the analyzer, ABX Pentra 60 C+ (SN# 901PCP15208) was observed in use. The following analyte(s) in the subspecialty for hematology are listed below: White Blood Cells (WBC) Red Blood Cells, (RBC), Hemoglobin (HGB), Hematocrit (HCT), Platelet (PLT). 2. Review of the "Pentra 60 C+ User Manual" revision 24/09 /2003, section "2. Maintenance" under 2.1 Hydraulic cycle maintenance chart table states the "Frequency of maintenance cycles depends on the laboratory sample output ...according to the chart table beside:" The chart required once per month autoconcentrated cleaning for less than 100 samples ran or twice per month if greater than 100 samples ran on analyzer. 3. Review of the policy "Methodist Hospitals SL Oncology Hematology Infusion Center", under Autoclean procedures stated the laboratory will "perform auto clean twice a week (preferably Tuesdays and Fridays) and follow manufacturer's instructions." 4. In an interview on 5-14-2025 at 3:38 pm, SP-01 (Technical Consultant) and SP-2 (Practice Manager) acknowledged they do not document maintenance of analyzer or follow cleaning procedures outlined in the laboratory policy and instrument user manual. 5. Review of patients PT-1 to PT-8 indicated patient samples were run on analyzer, ABX Pentra 60 C+ without maintenance being documented as performed. Patient (PT) Collection date PT-1 1.04.24 PT-2 2.07.24 PT-3 3.14.24 PT-4 4.17.24 PT-5 5.23.24 PT-6 6.27.24 PT-7</p>

7.03.24 PT-8 10.30.24 6. The annual test volume for subspecialty in Hematology is 68,000.

D5441

CONTROL PROCEDURES

CFR(s): 493.1256(a)(b)(c)(g)

(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance.

This STANDARD is not met as evidenced by:

Based on observation, record review and interviews, the laboratory failed to monitor over time the accuracy and precision of the quality control (QC) test performance for one of one Hematology analyzer (Pentra 60 C+ serial number 901PCP15208) used to perform testing on five of five analyte(s) (WBC, RBC, HGB, HCT, PLT) on four (PT-4, PT-5, PT-6. and PT-8) of eight patients reviewed with testing from 1/04/24 through 10/30/24. Findings included: 1. During a tour of the laboratory on 5-14-2025 at 10:15am, the analyzer, ABX Pentra 60 C+ (SN# 901PCP15208) was observed in use. The following analyte(s) in the subspecialty for hematology are listed below: WBC, RBC, HGB, HCT, PLT. 2. Upon request for printed Quality Control (QC) reports on 5-14-2025 at 12:52 pm, SP-02 (Practice Manager) provided an excel spreadsheet of QC results saved from an external hard drive. Review of the QC report included control data and error flags that were not marked that they had been reviewed or monitored for accuracy, precision, trends or shifts. 3. Review of brochure for Hematology analyzer, ABX Pentra 60 C+ indicated Levy-Jennings graphs may be used to monitor and manage Quality Control (QC). 4. Upon request for QC evaluation documentation (e.g. review, trends and shifts), on 5-14-2025 at 12:52 pm, SP-01 (Technical Consultant) acknowledged that QC was not monitored or evaluated at the end of the lot to determine bias, trends, or shifts. 5. Review of patient PT-1 to PT-8 indicated patient samples were run on analyzer, ABX Pentra 60 C+ without QC evaluation being performed or documented. Patient (PT) Collection date PT-1 1.04.24 PT-2 2.07.24 PT-3 3.14.24 PT-4 4.17.24 PT-5 5.23.24 PT-6 6.27.24 PT-7 7.03.24 PT-8 10.30.24 6. The annual test volume for subspecialty in Hematology is 68,000.