

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 15D0356272	(X3) Date Survey Completed 11/22/2021
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
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on record review, observation, and interview, the laboratory failed to retain quality control records for one of one hematology analyzers (Horiba Medical PENTRA 60/C+) for at least two years and eight of eight patients reviewed. Findings include: 1. Review of eight medical records indicated that patient #1 through patient # 8 had testing performed with the hematology analyzer. There were no printouts of quality control on the reviewed dates of patient testing. Patient # 1 on 9/21/20 Patient # 2 on 10/21/20 Patient # 3 on 11/17/20 Patient # 4 on 12/20/20 Patient # 5 on 1/20/21 Patient # 6 on 2/23/21 Patient # 7 on 3/17/21 Patient # 8 on 4/1/21 2. On 11/22/2021 at 12:14 PM, observation of the hematology analyzer for quality control records indicated quality control records were present on the hematology analyzer for the current lot number, but SP2 could not review historical quality control on the analyzer. 3. Review of policy and procedure for quality control that was reviewed and dated by the laboratory director on 4/19/17 read when to run controls, which included: "After calibration. After daily start up is complete. After a reagent lot number change. After a service call or component replacement. If there is an unusual trend or shift in patient results. After 8 hours of patient testing." 4. On 11/22/2021 at 3:15 PM, SP1 confirmed that the Horiba Medical PENTRA 60/C+ deletes previous documentation of quality control, and printouts of daily quality control are not available. 5. The annual test volume for hematology testing is approximately 69,500.</p>
D5407	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p>

Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.

This STANDARD is not met as evidenced by:

Based on record review, observation, and interview, the laboratory director failed to sign and date the manufacturer's instructions that were being used as the procedures for one of one hematology analyzers (Horiba Medical PENTRA 60/C+) before initial patient testing on 3/11/2020. Findings include: 1. On 11/22/21 at 12:39 pm, upon request for policies and procedures for the Horiba Medical PENTRA 60/C+ hematology analyzer, SP1 indicated the policies for the step-by-step instructions, maintenance, QC, and calibration were located within the hematology analyzer interface. 2. On 11/22/21 at 2:21 pm, review of the manuals found on the Horiba Medical PENTRA 60/C+ indicated the step-by-step procedures were on the instrument, but there was no place for the laboratory director to sign and date their approval. 3. On 11/22/21 at 10:39 am, SP1 indicated that the first day of patient testing with the Horiba Medical PENTRA 60/C+ was on 3/11/2020. On 11/22/2021 at 2:33 pm, SP1 confirmed that there was no additional signoff sheet in the instrument manual to indicate that the laboratory director had reviewed and dated their approval for the current manufacturer's instructions revision. 4. The annual test volume for hematology testing is approximately 69,500.

D5421

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE
CFR(s): 493.1253(b)(1)

Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory failed to document review and approval by the laboratory director on the performance specifications for one of one hematology analyzers (Horiba Medical PENTRA 60/C+) before initial testing on 3/11/2020. Findings include: 1. Review of the instrument performance analysis for the Horiba Medical PENTRA 60/C+ completed on 3/11/2020 indicated that there was no signature or date from the laboratory director indicating their review and approval. 2. Review of eight medical records indicated that patient #1 through patient # 8 had testing performed on the hematology analyzer. Patient # 1 on 9/21/20 Patient # 2 on 10/21/20 Patient # 3 on 11/17/20 Patient # 4 on 12/30/20 Patient # 5 on 1/20/21 Patient # 6 on 2/23/21 Patient # 7 on 3/17/21 Patient # 8 on 4/1/21 3. On 11/22/21 at 10:39 am, SP1 indicated that the first day of patient testing with the Horiba Medical PENTRA 60/C+ was on 3/11/2020. Upon request on 11/22/21 at 2:21 pm, SP1 confirmed there was no additional documentation to show that the laboratory director signed off on the performance specifications. 4. The annual test volume for hematology testing is approximately 69,500.