

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 25D0651762	(X3) Date Survey Completed 04/29/2021
Name of Provider or Supplier Alliance Healthcare System, Inc	Street Address, City, State 1430 Highway 4 East, Holly Springs, MS	
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
D2010	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2)</p> <p>The laboratory must test samples the same number of times that it routinely tests patient samples.</p> <p>This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records since the last survey on 8/30/18 for the Mindray BS480 analyzer and interview with testing personnel (TP) #7 listed on the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, the laboratory failed to test PT samples the same number of times they routinely test patient samples. Findings include: 1. Review of the Mindray BS480 analyzer PT printouts for Event 1, Event 2, and Event 3 of 2020 and Event 1 of 2021 revealed the laboratory tested all five PT samples twice prior to submitting the results to the PT provider. 2. Interview with TP #7 at 11:00 A.M. on 4/28/21 confirmed PT samples tested on the Mindray BS480 for Event 1, Event 2, and Event 3 of 2020 and Event 1 of 2021 were tested twice prior to submission to the PT provider while patient samples were only tested once prior to reporting results.</p>
D5411	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.</p> <p>This STANDARD is not met as evidenced by: Based on review of Sysmex CA-600 coagulation system manufacturer operator's</p>

manual, coagulation quality control (QC) records from 9/11/18 through 3/23/21, and confirmation with TC #2 (technical consultant) and GS #1 (general supervisor) at 11:00 am on 4/29/21, the laboratory failed to follow the manufacturer's instructions for establishing a normal patient mean (NPM) used in calculating the INR (international normalized ratio) when changing lot numbers of Innovin reagent. Findings include: 1. According to the CA-600 manufacturer's instructions, the NPM has to be entered into the analyzer along with the appropriate ISI value in order for the analyzer to calculate an accurate patient INR (international normalized ratio) which is included with the prothrombin result. 2. Based on review of the Coagulation QC records from 9/11/18 through 3/23/21, there was no documentation of the date the current lot of Innovin (lot #549730 expiration date 6/24/21) was put in use. 3. There was no documentation available the day of survey to indicate the laboratory had established a NPM (normal patient mean) with the new lot number of Innovin prior to testing and reporting patient samples according to the manufacturer's instructions. 4. Interview with GS #1 and TC #2 confirmed that an NPM was not established for the new lot of Innovin (#549730) in order to calculate an accurate INR.

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 review of the Mindray BS480 chemistry analyzer maintenance records from 8/30/18 until 4/29/21 and interview with the testing personnel (TP) #7 listed on the CMS (Center for Medicare & Medicaid Services) 209 personnel form at 2:30 pm on 4/28/21, the laboratory failed to document as performed the 3 month and 6 month maintenance on the Mindray BS 480 analyzer as required by the manufacturer. Findings include: 1. Review of the Mindray BS 480 records revealed the following maintenance was not being performed every 3 months and 6 months as required by the manufacturer: 3-Month maintenance: a. Clean DI water tank b. Replace Filter Core c. Replace Sample Syringe d. Replace Reagent Syringe 6-Month maintenance- a. Replace Lamp b. Replace Water Inlet Filter c. Replace Reference Electrode d. Replace Pump Tube 2. Review of the Mindray BS 480 3-month maintenance records from 10/30/18 through 4/29/21 revealed the 3 month maintenance had been performed on 1/29/19, 5/1/19, 9/29/19, 11/10/19, 12/31/19 and 1/4/21. The time periods from 5/1/19 - 9/29/19 and 12/31/19 - 1/4/21 exceed the 3 month maintenance requirement specified in the manufacturer's manual. 3. Review of the Mindray BS 480 6-month maintenance records form 10/1/18 through 4/29/21 revealed the 6 month maintenance had been performed on 1/29/19, 5/1/19 and 1/17/21. The time period from 5/1/19 - 1/17/21 exceeds the 6 month maintenance requirements specified in the manufacturer's manual. 4. Interview with TP #7 on 4/28/21 at 2:30 pm confirmed that maintenance on the Mindray BS 480 chemistry analyzer was not documented as performed every 3 or 6 months as required in the manufacturer's manual.

D6049

TECHNICAL CONSULTANT RESPONSIBILITIES
 CFR(s): 493.1413(b)(8)(iii)

The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records,

proficiency testing results, and preventive maintenance records.

This STANDARD is not met as evidenced by:

Based on review of the Mindray BS 480 chemistry analyzer records including maintenance, calibration, function checks, and quality control from 10/1/18 through 4/28/21 and interview with testing personnel (TP) #7 at 1:00 on 4/27/21, the records had not been documented as reviewed by a technical consultant as required. Findings Include: 1. Review of the Mindray BS 480 chemistry analyzer records from 10/1/18 through 4/28/21 revealed the following records were not documented as reviewed by a technical consultant: a. Mindray BS 480 maintenance records (daily, weekly, monthly, 3 month, 6 month, as needed) from 11/20/19 through 4/28/21. b. Mindray BS 480 calibration reports dated 12/22/19 through 4/28/21. c. Cuvette Blank Results from 12/29/19 through 4/26/21. d. Photometer Checks from 10/10/19 through 4/26/21. e. Quality control (QC) summaries from May 2020 through April 2021. 2. Interview with the TP #7 at 1:00 pm on 4/26/21 confirmed that the Mindray BS 480 records had not been documented as reviewed by a technical consultant.

D6123

TECHNICAL SUPERVISOR RESPONSIBILITIES

CFR(s): 493.1451(b)(8)(iii)

The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.

This STANDARD is not met as evidenced by:

Based on review of the Agilent Infinity II 1290/6460 LC/MS toxicology analyzer maintenance and quality control records from 1/28/19 through 4/26/21 and interview with staff at 1:00 pm, a TS (technical supervisor) failed to document review of the records. Findings include: 1. Review of the Agilent 6460 LC/MS records from 1/28/19 through 4/26/21 revealed the following records were not documented as reviewed by a TS. a. Agilent maintenance (daily weekly, monthly, as needed) from March 2020 through July 2020 and from August 2020 through April 2021. b. Quality Controls (QC) summary reports March 2020 through July 2020 and from August 2020 through April 2021. 2. Interview with the TP #7 at 1:00 pm 4/28/21 confirmed there was no documented review of the above listed maintenance and QC records.