Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D0696888	07/27/2022
Name of Provider or Supplier	**Street Address, City, State**	
Sinai Hospital Department Of Pathology	2401 W Belvedere Ave, Baltimore, MD	

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
D5213	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1) The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program. This STANDARD is not met as evidenced by: Based on review of the "Proficiency Testing (PT) for Point of Care Testing-LBH" procedures that included whole blood (WB) human chorionic gonadotropin (hCG) and interview with the general supervisor (GS) of point of care (POC) testing, the laboratory failed to provide instructions for verifying the accuracy of the of WB-hCG that was not listed in subpart I. Findings: 1. The "Proficiency Testing (PT) for Point of Care Testing-LBH" procedures states, "For Fingerstick hCG: The POCC has collaborated with the medical director to determine a suitable alternate PT assessment to be run semi-annually." 2. During the survey on 07/25/2022 at 11:00 AM, the GS of POC testing confirmed that the alternate PT procedure for fingerstick WB-hCG did not provide instructions for how to select specimens from the POC lab to be compared with hCG results from the main lab, document the findings for review, and corrective actions when the results failed to correspond.
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:

	A. Based on hematology slide stainer maintenance record review and interview with the laboratory staff, the laboratory did not ensure that monthly maintenance was performed and documented on the hematology slide stainer as recommended by the manufacturer. Findings: 1. The laboratory uses a Hematek slide stainer to stain peripheral blood smears for analysis. The "Hematek Stainer Maintenance Log" states that monthly the lab must "Inspect pump tubing, replace if needed." 2. A review of monthly Hematek slide stainer maintenance records from January 2021 to June 2022 showed that monthly slide stainer maintenance was not documented 10 out of 18 months. 3. During an interview on 07/26/2022 at 1:30 PM, the laboratory staff confirmed that monthly hematology slide stainer maintenance was not documented as defined by the manufacturer and with at least the frequency specified by the manufacturer. B. Based on chemistry analyzer maintenance record review and interview with the general supervisor (GS) for automated chemistry, the laboratory did not ensure that maintenance was performed and documented on the Advia XPT chemistry analyzers as recommended by the manufacturer. Findings: 1. The laboratory uses 2 Advia XPT chemistry analyzers to perform chemistry testing. The monthly maintenance log lists 2 maintenance tasks to be completed under "2 months" and "3 months" and 3 maintenance tasks to be completed under "4 months" maintenance. 2. A review of monthly "Advia Chemistry XPT Maintenance Logs" from June 2021 to June 2022 showed that on the "Advia 1" chemistry analyzer, "2 month" maintenance was not documented 12 out of 13 months; "3 month" maintenance was documented September 2021 and March 2022 but not documented during the 6 months in between; and "4 month" maintenance was documented 2 out of 13 months reviewed. 3. A review of "Advia 2" monthly maintenance logs for the same time period showed that the second page of the maintenance log which lists "2 month," "3 month," and "4 month" maintenance for July and September 2021 was not present at the time of the survey. 4. One of 2 tasks were documented for "2 month" maintenance for 5 out of 11 months; "3 month" maintenance was documented for 2 out of 11 months and 1 of 2 tasks were documented for 1 out of 11 months; and "4 month" maintenance was documented 1 out of 11 months and 2 of 3 tasks were documented for 1 out of 11 months reviewed. 5. During an interview on 07/26/2022 at 2:30 PM, the GS for automated chemistry confirmed that monthly chemistry analyzer maintenance was not documented as defined by the manufacturer and with at least the frequency specified by the manufacturer.
D6072	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(3) Each individual performing moderate complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed. This STANDARD is not met as evidenced by: Based on review of the "Quality Control Guidelines" for the automated lab, cumulative quality control (QC) printouts for carbamazepine (CARB), "SHB Automated Lab Corrective Action Log" and interview with the general supervisor (GS) of automated chemistry, the testing person (TP) failed to ensure that the corrective actions for QC failures were documented as required. Findings: 1. The "Quality Control Guidelines" procedure states, " Any data point which falls outside +/- 2 SD [standard deviation] units from the mean requires corrective action. Corrective action taken will be documented in LIS [laboratory information system] or on the Corrective Action Log." 2. The QC printouts for CARB level 1 and 2 for the

	month of September 2021 were reviewed. The LIS printout showed that CARB level 2 had failed the programmed Westgard rules for QC on 09/01/21 once, 09/03/21 two times, 09/07/21 once, 09/13/21 once, between 09/15/21 and 09/16/21 four times, 09/17 /21 two times, 09/23/21 once, and 09/24/21 four times. 3. The "SHB Automated Lab Corrective Action Log" for the Adiva 1 chemistry analyzer from January 2021 through July 2022 was reviewed. The worksheets that were reviewed showed that in 2021 there were no corrective actions recorded after 01/12/21. The first date recorded in 2022 was 01/23/22 and ended with 04/12/22. 4. The GS stated that when a QC result violates one of the programmed Westgard rules for QC failure, the rule that was violated will be printed in the last column of the QC printout from the LIS. The GS stated that according to the QC guidelines, the TP can record the corrective actions taken in the LIS or the corrective action log. 5. During the survey on 07/26/2022 at 9: 30 AM, the GS confirmed that the QC printout from the LIS and the "SHB Automated Lab Corrective Action Log" failed to include the corrective actions taken by the TP when QC results failed to meet the programmed Westgard rules for acceptability.
D6148	GENERAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1463(a)(4) The general supervisor is responsible for monitoring test analyses and specimen examinations to ensure that acceptable levels of analytic performance are maintained. This STANDARD is not met as evidenced by: Based on review of the "Quality Control Guidelines" for the automated lab, cumulative quality control (QC) printouts for carbamazepine (CARB), and interview with the quality assurance (QA) manager, the general supervisor (GS) for automated chemistry failed to ensure that the weekly QC review was documented as required. Findings: 1. The "Quality Control Guidelines" procedure states, "Weekly: QC results are reviewed by the Team Leader. Evidence of review may be in the form of printed reports, dated and initialed, or by utilizing the "Marked as Reviewed" function through the LIS [laboratory information system] QC Inquiry application." 2. The cumulative QC printouts for September 2021 for carbamazepine (CARB) showed that the monthly review was performed by the QA manager. There were no additional weekly reviews documented by the GS on the monthly report. 3. When interviewed, the QA manager accessed the LIS QC application and showed that QC had not been electronically reviewed for the Advia chemistry analyzer for the month of September 2021 and was not being used to document weekly QC review for the Advia chemistry analyzer. 4. During the survey on 07/27/2022 at 2:30 PM, the QA manager confirmed that the QC the "Marked as Reviewed" statement was not in the LIS system showing that the GS has performed the weekly QA review as required.
D6149	GENERAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1463(b)(1) The director or technical supervisor may delegate to the general supervisor the responsibility for assuring that all remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications. This STANDARD is not met as evidenced by: Based on review of the "Quality Control Guidelines" for the automated lab, cumulative quality control (QC) printouts for carbamazepine (CARB), "SHB

	Automated Lab Corrective Action Log" and interview with the quality assurance (QA) manager, the general supervisor (GS) of automated chemistry failed to ensure that the testing personnel were documenting the corrective actions as required. Cross refer to Tag D6072.