Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D0216885	04/05/2024
Name of Provider or Supplier	**Street Address, City, State**	
Gbmc Main Laboratory	6701 North Charles Street, 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
D2011	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(3) Laboratories that perform tests on proficiency testing samples must not engage in any inter-laboratory communications pertaining to the results of proficiency testing sample (s) until after the date by which the laboratory must report proficiency testing results to the program for the testing event in which the samples were sent. Laboratories with multiple testing sites or separate locations must not participate in any communications or discussions across sites/locations concerning proficiency testing sample results until after the date by which the laboratory must report proficiency testing results to the program. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records and interview with the histology and immunohistochemistry pathologist, the laboratory did not ensure that PT results were independently reviewed by the pathologists until after the PT results were submitted to the PT provider. Findings: 1. Records for the ISH-A 2023 PT event included a worksheet showing that six pathologists reviewed the PT samples and recorded their results. The worksheets did not include the date each pathologist reviewed the PT samples. 2. During the survey on 04/04/2024 at 3:20 PM, the histology and immunohistochemistry pathologist confirmed that the six pathologists reviewed the PT results independently prior to submitting the results to the PT provider.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for

specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:
Based on review of the standard operating procedure (SOP) manual, hematology and urinalysis reagent records, and interview with the core clinical laboratory manager (CCLM), the laboratory failed to have written instructions for documenting the lot number and expiration dates of reagents and stains used for manual testing. Findings: 1. The "Kleihauer-Betke Stain (fetal cell quantification)" SOP was reviewed. Section "V. Supplies and Reagents" lists the reagents as fetal cell fixing solution, fetal cell buffer solution, and fetal cell stain. The instructions state "check expiration and discard if reagent is expired." The SOP did not include instructions for documenting the lot numbers and expiration dates of the reagents used to ensure that they were not used past their expiration dates. Section "X. Quality Control (QC)" states "Two controls are run with the patient." The negative control is identified as a "Non-Mediterranean adult male with normal CBC [complete blood count] results." The "Mix Control" is prepared by "Dilution of equal volumes or cord blood (0.5 ml) and group compatible normal adult male blood." The SOP did not include instructions on how to identify the "Non-Mediterranean" negative control, source of the "cord blood" and the "group compatible normal adult male" for preparation of the "mix control." The SOP did not include instructions for documenting the patient identification numbers of the patients used for QC each day of testing. 2. The "Alcor ESR [erythrocyte sedimentation rate] procedure" SOP was reviewed. Section "IV. Supplies and Reagents" lists the needed products to perform the test. Review of the reagent records in the laboratory information system (LIS) showed that the lot numbers and expiration dates were not being captured for the "iWASH cleansing agent" used during the testing process. The SOP did not include instructions for documenting the lot numbers and expiration dates of the reagents used to ensure that they were not used past their expiration dates. 3. The "Blood Parasite Screen" SOP was reviewed. Section "V. Supplies and Reagents" lists the reagents as Giemsa stain, Wright stain buffer pH 7.15, and methanol. The SOP did not include instructions for documenting the lot numbers and expiration dates of the reagents used to ensure that they were not used past their expiration dates. 4. The "Body Fluid Manual Method" SOP was reviewed. "V. Supplies and Reagents" lists the reagents as normal saline and Wright's stain. The SOP did not include instructions for documenting the lot numbers and expiration dates of the reagents used to ensure that they were not used past their expiration dates. 5. The "Body Fluids Slide Preparation by Cytocentrifugation" SOP was reviewed. Section "III. Supplies and Reagents" lists "22% Bovine albumin" as a reagent needed for testing. The CCLM stated that the "22% Bovine albumin" was a reagent provided by the laboratory's blood bank. The SOP did not state that the "22%

	Bovine albumin" was provided by the blood bank as needed. 6. The "Bone Marrow Collection Procedure" SOP was reviewed. Section "III. Supplies and Reagents" lists the reagents as Wright stain, Heparinized tubes, Aerobic and Anaerobic blood culture bottles, and Lavender EDTA tubes. The SOP did not include instructions for documenting the lot numbers and expiration dates of the reagents used to ensure that they were not used past their expiration dates. 7. The CSF [cerebrospinal fluid] Cell Count" SOP was reviewed. "V. Supplies and Reagents" lists the reagents as normal saline and Wright's stain. The SOP did not include instructions for documenting the lot numbers and expiration dates of the reagents used to ensure that they were not used past their expiration dates. 8. The "Synovial Fluid Cell Count and Crystal Examination" SOP was reviewed. "V. Supplies and Reagents" lists the reagents as saline and Hyaluronidase (Type-1-S), Sigma Chemical Co. The SOP did not include instructions for documenting the lot numbers and expiration dates of the reagents used to ensure that they were not used past their expiration dates. 9. Review of the urinalysis records for the two Iris urinalysis analyzers showed that there was no instructions for the documentation of the lot number and expiration date of the urine dipsticks used on the analyzer prior to December 2023. 10. Review of the hematology reagent records within the two Sysmex analyzers showed that there was no documentation of the lot numbers and expiration dates of the Wright stain used for slide preparation. Review of the records for the manual stainer showed that there was no documentation of the lot numbers and expiration dates of the Wright stain used for slide preparation. 11. Review of the "Iris" (urinalysis analyzer) records within the analyzer system showed that the lot numbers and expiration dates of the dipstick chemical reagent strip was not being retained. The analyzer records showed that the lot numbers and expiration dates were not available prior to December 2023. 12. During the exit interview on 04/05/2024 at 2:00 PM, the CCLM confirmed that the SOP's failed to include written instructions for how to identify patient controls used for the Kleihauer-Betke test and documenting the lot number and expiration dates of reagents and stains used for manual testing to ensure that they were not used past the manufacturer's expiration date.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on review of the hematology and urinalysis reagent, stain and quality control (QC) records and interview with the core clinical laboratory manager (CCLM), the laboratory failed to ensure that reagents, stains and QC materials were not used after their expiration date. Findings: 1. Cross refer to Tag D5403 for details. 2. During the exit interview on 04/05/2024 at 2:00 PM, the CCLM confirmed that the laboratory records for manual and automated testing failed to include the lot number and expiration dates of reagents and stains used for manual testing to ensure that they were not used past the manufacturer's expiration date.
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 microbiology instrument maintenance record review and interview with the laboratory director (LD), the laboratory did not ensure that monthly maintenance on the Phoenix AP (Automatic Processor) instrument was performed and documented as defined by the manufacturer and with at least the frequency specified by the manufacturer. Findings: 1. The laboratory uses a Phoenix AP Instrument to standardize a broth inoculum of organisms used in the Phoenix identification and susceptibility panels. The "Phoenix AP Instrument Maintenance Log" includes a column to check off when the maintenance, "TUBING CHANGE 30 Days" and "WASTE TIP CHUTE 30 Days" is performed. 2. A review of monthly "Phoenix AP Instrument Maintenance Logs" from January through December 2022 showed that "TUBING CHANGE 30 Days" was not documented for five out of twelve months, and "WASTE TIP CHUTE 30 Days" was not documented for six out of twelve months in 2022. 3. During an interview on 04/05/2024 at 1:50 PM, the LD confirmed that monthly microbiology analyzer maintenance was not performed and documented as recommended by the manufacturer.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on review of the microbiology quality control (QC) procedure and QC records and interview with microbiology supervisor (MS), the laboratory failed to document repeat testing and corrective actions taken when QC results were unacceptable or out of acceptable range. Findings: 1. The procedure titled "Microbiology Quality Control Overview" stated that for media "If acceptable quality control results are not obtained, repeat the QC using a standardized suspension of the quality control organism" and for susceptibility testing "If failed QC results are due to a random error, document the error and retest the antimicrobial disk/susceptibility panel on the day the error is observed" and "If the failed QC results are due to a system error, correct the error and document it in the Microbiology Quality Control log." 2. The 2022 "Kirby-Bauer/E-Test Quality Control" log showed that the acceptable range for Minocycline with "EC 25922" was 19-25. The laboratory recorded a result of 26 on 02/18/2022. 3. The 2022 "Gram Negative Rod Kirby-Bauer Quality Control" log showed that the acceptable range for Ampicillin was 16-22 mm. The laboratory recorded a result of 2 on 03/09 /2022. 4. The 2022 "Pseudomonas Kirby-Bauer Quality Control" log showed that the acceptable range for Ceftriaxone was 17-23 mm. The laboratory recorded a result of 28 on 06/25/2022. 5. The 2022 "MDRO Gram Negative Bacillus Quality Control" log showed that the acceptable range for Vabomere with Klebsiella pneumoniae was 0.008-0.06. The laboratory recorded a result of 0.94 on 11/10/2022 and 12/02/2022. 6.

	The 2023 "Haemophilus Influenza Kirby-Bauer Quality Control" log showed that the acceptable range for Azithromycin was 13-21 mm. The laboratory recorded a result of 22 on 01/13/2023. 7. The 2023 "Staphylococcus Kirby-Bauer Quality control" log was reviewed. a. The acceptable range for Cefoxitin was listed as 23-29 mm. The laboratory recorded a result of 18 on 08/11/2023. b. The acceptable range for Clindamycin was listed as 24-30 mm. The laboratory recorded a result of 21 on 08/11 /2023. c. The acceptable range for Erythromycin was listed as 22-30 mm. The laboratory recorded a result of 8 on 08/11/2023. d. The acceptable range for Penicillin was listed as 26-37 mm. The laboratory recorded a result of 12 on 08/11/2023. e. The acceptable range for Rifampin was listed as 26-34 mm. The laboratory recorded a result of 35 on 08/24/2023. 8. The 2023 "Medium/Biochemical: Rapid Anaerobe Panel" log showed that the expected results were positive for both "Clos. Perfringens" with "AGL" and for "Clos. Perfringens" with "ARG." The recorded results for the panel performed on 10/13/2023 for lot B1017-2 were negative for both "Clos. Perfringens" with "AGL" and for "Clos. Perfringens" with "ARG". 9. There was no documentation of repeat testing or corrective actions for the unacceptable and out of range QC results listed above. 10. During the survey on 04/04/2024 at 2:10 PM, the MS confirmed that the unacceptable and out of range QC results did not have documentation of repeat testing or corrective actions.