Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0187054	06/23/2021
Name of Provider or Supplier	**Street Address, City, State**	
Fulton County Medical Center	214 Peach Orchard Road, Mcconnellsburg, PA	

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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of the laboratory's competency and evaluation process policy, review of competency assessment (CA) records, and interview with the Laboratory Manager (LM), the laboratory failed to follow the Laboratory's written policies and procedures to assess the competency of 12 of 13 testing personnel (TP) for each test performed in the departments of Chemistry, Microbiology, Hematology, Immunology, and immunohematology in 2019, 2020 and 2021. Findings Include: 1. The laboratory's competency and evaluation process policy (page 2) states the following: - "Competency assessment, which includes the six procedures, must be performed for testing personnel for each test that the individual is approved by the laboratory director to perform." - "all new staff members will need to demonstrate competency at 6 months, 12 months and yearly thereafter." 2. On the day of survey, 06/22/2021 at 09: 00 am, the laboratory could not provide completed CA records for the following TP: a. - 1 of 9 TP (TP#11) in 2019. - 9 of 11 TP (TP #1, 2, 3, 4, 5, 7, 8, 10, and 11) in 2020. b. CA not performed for each test: - 8 of 9 TP (TP #1, 2, 3, 4, 5, 7, 8, and 9) in 2019. - 02 of 11 TP (TP #6 and #9) in 2020. - 10 of 13 TP (TP #1, 2, 4, 5, 6,7, 8, 10, and 13) in 2021. c. Incomplete CA records: - 2 of 2 new TP (TP#6 and TP#9) were not assessed for 5 of 6 competency assessment required procedures at 6 months from hired. 3. The LM confirmed the findings above on 06/23/2021 at 02:00 p.m.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)

	The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on review of the laboratory's Quality Assurance Plan procedure, review of Quality Assurance records, and interview with the Laboratory Manager (LM), the laboratory failed to follow the Laboratory's written policies and procedures for the completion of Quality Assessment (QA) forms in 2019, 2020, and 2021. Findings Include: 1. The laboratory's Quality Assurance Plan procedure (page 6) states: "A quality assessment form will be completed by the lab manager monthly." 2. On the day of survey, 06/22/2021 at 12:47 pm, review of the QA records revealed the LM did not complete the QA forms monthly in 2019, 2020, and 2021. - 2019: a. June QA form was completed on August 01, 2019. b. July, August, and September QA forms were completed on November 05, 2019. c. October and November QA forms were completed on January 12, 2020. - 2020: a. January and February QA forms were completed on May 22, 2020. b. March, April, and May QA forms were completed on July 29, 2020. c. July, August, and September QA forms were completed on May 2, 2021. d. October QA form was completed on May 18, 2021. e. November and December QA forms were completed on May 13, 2021. -2021: a. January and February QA forms were completed on April 27, 2021. 3. The LM confirmed the findings above on June 23 at 02:00 p.m.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of laboratory records and interview with the laboratory manager (LM) and testing personnel (TP), the laboratory failed to meet the applicable analytic systems requirements in 493.1251 through 493.1283, that provides equivalent quality testing and monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed for June 2019 to the day of survey. Refer to: D5401, D5403, D5421, D5421, D5429, D5445, D5449, D5555 and D5775.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

	This STANDARD is not met as evidenced by: Based on review of the laboratory procedure manual and interview with Testing Personnel (TP) #3, the laboratory failed to have written procedures for bacteriology culture examinations analyzed from 06/23/2019 to the day of survey. Findings include: 1. On the day of survey, 06/23/2021 at 12:00 am, the laboratory could not provide written procedures for urine, sputum, wounds, stool, and cerebral spinal fluid (CSF) culture examination performed in 2019, 2020 and 2021. 2. The following bacteriology culture examinations were performed: - 2019: 3,818 specimens. - 2020: 3,943 specimens. - 2021: 1,627 specimens. 3. TP#3 confirmed the findings above on 06/23/2019 around 12:15 p.m.
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 pin worm procedure, review of quality control (QC) records, and interview with Testing Personnel (TP)#3, the laboratory failed to establish a complete procedure to assess QC for pin worm examinations performed in 2020. Findings Include: 1. On the day of survey, 06/23/2021 at 09:20 am, reviewed of the pin worm examination procedure revealed QC was not included in the procedure. 2. The laboratory could not provide QC records for pin worm examinations performed in 2020. 3. 1 Pin worm examination was performed in 2020. 4. TP#3 confirmed the findings above on 06/23/2021 around 09:25 a.m.
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 review of the laboratory's validation records and interview with the laboratory manager (LM) and testing personnel (TP), the laboratory failed to demonstrate and document the performance specifications for accuracy, precision, reportable range and reference ranges for the 2 of 2 Siemens Vista Dimension 500 chemistry analyzers, 2 of 2 Ortho Vision immunohematology analyzers, 1 of 1 Cepheid GeneXpert System Microbiology analyzer, and for the Giardia /Cryptosporidium quick check kit before reporting patient test results in 2020 and 2021. Findings Include: 1. The New Test Implementation, under purpose states, "CLIA requires the lab to verify the manufacturer's performance specifications provided in the package insert for accuracy, precision reportable range and reference ranges for each new moderate complexity test the laboratory performed before reporting patient test results". 2. On the days of survey 06/22/201 to 06/23/2021, review of validation records revealed, the following validation studies were not evaluated for their performance specifications for accuracy, precision, reportable range and reference ranges before reporting patient test results: - 2 of 2 Siemens Vista Dimension 500 chemistry analyzers. - 2 of 2 Ortho Vision immunohematology analyzers. - Cepheid GeneXpert System: SARS-CoV-2 cartridge. 4 plex (SARS-CoV-2, Flu A, Flu B and RSV) cartridge. Giardia/Cryptosporidium quick check kit. 3. The LM and TP confirmed the findings above on 06/23/2021 around 2:00 p.m.
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 observation of the laboratory and interview the Laboratory Manager (LM), the laboratory failed to assess the maintenance/ function checks for a sampling of Fisher Scientific timers (3 of 3) used for time specific testing in the laboratory from 2019 to the day of survey. Findings Include: 1. On the day of survey, 06/22/2021, the laboratory could not provide maintenance/function check records for the following Fisher Scientific timers used from 06/22/2019 to 06/23/2021: - S/N: 09119790 - Due: 09/14/2001. - S/N: 181390295 - Due:06/25/2020. - S/N: 151876321 - Due:11/23 /2017. 2. The laboratory preventative maintenance procedure did not include maintenance/ function checks for timers used in the laboratory. 3. The LM confirmed the findings above on 06/23/2021 around 2:00 pm.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when

	they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's Individualized Quality Control Plans (IQCP) and interview with the Laboratory manager (LM), the laboratory failed to include 2 of 3 parts for IQCP's established for the Med Tox meter and Cepheid GeneXpert System when implementing an individualized quality control plan. Findings include: 1. On the days of survey, 06/22/2021 and 06/23/2021, review of the laboratory's individualized quality control plan revealed, the laboratory failed to include a Quality Control Plan (QCP) and a Quality Assessment Plan (QAP) which is 2 of 3 parts of an IQCP for the following tests: - Med Tox Meter: used to analyze Triage drugs for abuse. - Cepheid GeneXpert System: - SARS-CoV-2 cartridge. - 4 plex (SARS-CoV-2, Flu A, Flu B and RSV) cartridge. - MRSA cartridge. - SSTI/MRSA/S cartridge. - Clostridium Difficile Toxin cartridge. 2. The LM confirmed the findings above on 06/23/2021 around 2:00 p.m.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of Giardia/ Cryptosporidium quick check quality control (QC) records and interview with Testing Personnel (TP) #3, the laboratory failed to include a negative and positive control material, each day of patient testing for Giardia/ Cryptosporidium quick check kit analyzed in 2021. Findings Include: 1. On the day of survey, 06/23/2021 at 09:20 a.m., reviewed of the Giardia/ Cryptosporidium quick check QC records, revealed the laboratory did not include a negative and positive control materials each day of patient testing from 01/01/2021 to the day of survey. 2. 20 test for Giardia/Cryptosporidium were performed in 2021. 3. The TP#3 confirmed the findings above on 06/23/2021 around 09:25 a.m.
D5555	IMMUNOHEMATOLOGY CFR(s): 493.1271(c)(f) (c) Blood and blood products storage. Blood and Blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on observation of the immunohematology laboratory and interview with testing personnel (TP) #2, the laboratory failed to establish and label a segregated area for

	quarantine blood products from 06/22/2019 to the day of survey. Findings include: 1. On the day of survey, 06/22/2021, observation of the immunohematology laboratory revealed, the refrigerator storing blood products did not have an area labeled for quarantine blood products. 2. TP #2 confirmed the finding above on 06/22/2021 and 1: 10 p.m.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on review of the laboratory's records and interview with the laboratory manager (LM) and testing personnel (TP) #5, the laboratory failed to evaluate and document the relationship between the 2 of 2 Siemens Vista Dimension 500 chemistry analyzers and 2 of 2 ACL TOP 350 coagulation analyzers at least twice in 2019, 2020 and 2021. Findings Include: 1. On the days of survey,06/22/2021 and 06/23/2021, review of laboratory records revealed, the comparison of test results between 2 of 2 Siemens Vista Dimension 500 analyzers and 2 of 2 ACL TOP 350 were not evaluated and documented twice annually in 2019, 2020 and 2021. 2. The Correlation Testing on Back Up Instrumentation procedure, did not state the acceptable ranges for the comparison of analyzers. 3. The LM and TP#5 confirmed the findings above around 12:00 pm.