Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	66D0662224	03/29/2019
Name of Provider or Supplier	**Street Address, City, State**	
Commonwealth Health Ctr - Laboratory	1178 Hinemu' St Garapan, Saipan Mariana Islands, MP	

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
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on proficiency testing record review and laboratory director and testing personnel interviews on March 28, 2019, the laboratory failed to ensure that proficiency testing samples were examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory. Findings include: a. The laboratory's bacteriology section has one fulltime lead microbiologist, one full time technologist and one backup technologist. b. The laboratory's copy of the attestation statements for all bacteriology proficiency testing (CAP D module) events for 2017 and 2018 indicated that the lead microbiologist performed all six proficiency testing events. c. The laboratory's copy of the attestation statements for all GC/Chlamydia proficiency testing (CAP GC/CHLAM HC7 module) events for 2017 and 2018 indicated that the lead microbiologist performed all six proficiency testing events. d. The laboratory's copy of the attestation statements for all mycobacteriology proficiency testing (API AFB module) events for 2017 and 2018 indicated that the lead microbiologist performed all four proficiency testing events. e. The laboratory director and the microbiology testing personnel confirmed by interview on March 28, 2019 at approximately 12:45 pm that all personnel listed at (a) routinely performed patient testing covered by proficiency testing modules listed at (b), (c) and (d).
D5543	HEMATOLOGY CFR(s): 493.1269(a)(d)

	(a) For manual cell counts performed using a hemocytometer-- (a)(1) One control material must be tested each 8 hours of operation; and (a)(2) Patient specimens and control materials must be tested in duplicate. (d) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on the laboratory's cerebral spinal fluid (CSF) hemocytometer patient testing record review and laboratory personnel interviews on March 29, 2019, the laboratory failed to perform quality control procedures as required for manual cell counts performed using a hemocytometer. Findings include: a. The laboratory performed manual CSF cell counts using a hemocytometer. b. For 11 of 11 randomly selected CSF patient records from March 2017 to January 2019, the laboratory maintained no documentation to indicate that quality control materials were tested on the days of patient testing. c. The laboratory staff and laboratory director confirmed by interview on March 29, 2019 at approximately 10:35 am that the laboratory did not maintain and test quality control materials for CSF hemocytometer body fluid testing. d. Based on record review the laboratory tested 4-5 CSF patient specimens monthly .
D5559	IMMUNOHEMATOLOGY CFR(s): 493.1271(e)(f) (e) Investigation of transfusion reactions. (e)(1) According to its established procedures, the laboratory that performs compatibility testing, or issues blood or blood products, must promptly investigate all transfusion reactions occurring in facilities for which it has investigational responsibility and make recommendations to the medical staff regarding improvements in transfusion procedures. (e)(2) The laboratory must document, as applicable, that all necessary remedial actions are taken to prevent recurrences of transfusion reactions and that all policies and procedures are reviewed to assure they are adequate to ensure the safety of individuals being transfused. (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 a random review of the laboratory's transfusion records from March 2017 through March 2019 and interview with the transfusion lead technologist and laboratory director on March 29, 2019, the laboratory failed, according to its established procedures, to promptly investigate all transfusion reactions occurring in facilities for which it has investigational responsibility, and make recommendations to the medical staff regarding improvements in transfusion procedures. Findings include: a. The laboratory performs compatibility testing for transfusion services. The laboratory and hospital policies define a transfusion reaction as "a change in blood pressure +/- 30 mmHg." Laboratory policy states that when the laboratory receives post-transfusion information indicating that a change of +/- 30 mmHg blood pressure occurred post-transfusion, and hospital staff did not declare a transfusion reaction had not occurred, the laboratory is to notify the nursing staff to initiate a transfusion reaction workup. b. For 1 (XBX9651 transfused on March 07, 2019) of 8 randomly selected patient transfusion records from March 2017 through March 2019, laboratory records indicated that the patient had a pre-transfusion blood pressure of 117/41 mmHg, and a post-transfusion blood pressure of 74/41 mmHg, a drop of 41 mmHg. c. The laboratory maintained no documentation that the laboratory had notified nursing

	staff to initiate a transfusion reaction workup for patient XBX9651. d. The laboratory director and the nursing director confirmed by interview on March 29, 2019 at approximately 12:30 pm, that the laboratory had not initiated a transfusion reaction workup for patient XBX9651. e. The laboratory reports performing approximately 134 transfusion compatibility tests annually.
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 laboratory record review and staff interviews on March 28, 2019, the laboratory failed to have a system in place that twice a year evaluates and defines the relationship between test results using different instruments. Findings include: a. The laboratory performed patient complete blood counts (CBC) on Penta ABX 60 and Penta ABX 80 hematology analyzers. The laboratory had no documentation of performing twice annual evaluations to determine the relationship between the two analyzers. b. The laboratory performed patient coagulation tests on two Siemens Sysmex 600 analyzers. The laboratory had no documentation of performing twice annual evaluations to determine the relationship between the two analyzers. c. By interview on March 28, 2019 at approximately 1:18 pm, the laboratory director and laboratory testing personnel confirmed the lack of such documentation between the analyzers listed in (a) and (b) . d. The laboratory reportedly tested approximately 24,313 patient CBC and coagulation specimens annually.
D6089	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(i) The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part. This STANDARD is not met as evidenced by: Based on the laboratory's proficiency testing record review for bacteriology and microbiology, and interview with testing personnel on March 28., 2019, the laboratory director failed to ensure that proficiency testing samples are tested by personnel who routinely perform the testing in the laboratory. Findings include: Proficiency record review for bacteriology and mycobacteriology indicates that the same individual performed all the proficiency testing for the bacteriology/mycobacteriology proficiency testing modules for 2017 and 2018. See D2007.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

	This STANDARD is not met as evidenced by: Based on laboratory's record review and staff interview on March 28-29, 2019, the laboratory director failed to ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. Findings include: The laboratory performs manual cerebral spinal fluid cell counts. The laboratory failed to provide evidence quality control material or documentation of quality control performed. See D5543.
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 laboratory's annual competency records for the years 2017 and 2018, and personnel interviews on March 28, 2019, the technical supervisor failed to ensure the procedures for evaluation of the competency of the staff included, but are not limited to, review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records and direct observation. Findings include: a. Although the laboratory had indicated on their annual competency form that all testing personnel were competent in preanalytical , analytical and postanalytical processes, the laboratory did not have documentation on how this competency was determined. b. The laboratory director and section lead personnel confirmed by interview on March 28, 2019 at approximately 10.35 am the lack of identification and documentation of how personnel competency was assessed. c. The laboratory reports testing approximately 92,391 patient specimens annually.