Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	64D0724937	11/13/2019
Name of Provider or Supplier	**Street Address, City, State**	
Lbj Tropical Medical Center	1234 Paul Turner Dr, Pago Pago, AS	

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
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on review of the laboratory's College of America Pathologist (CAP) proficiency testing (PT) records, review of the CMS CASPER 155D reports for PT second quarter (Q2-2016), first quarter (Q1-2017), first quarter (Q1-2018), second quarter (Q2-2018) for parasitology and third quarter (Q3-2017), first quarter (Q1-2018) for AST(SGOT), and interview with the laboratory director and the laboratory technical supervisors on November 12, 2019, the laboratory failed to participate successfully for the subspecialty parasitology, and the analyte AST(SGOT). The findings included: a. The laboratory failed to achieve successfull participation in the subspeciatly parasitology PT which resulted in subsequent unsuccessful PT

	participation. See D2053 b. The laboratory failed to successfully participate and provide documentation of evaluation and remedial actions for unsatisfactory PT performance for two of three PT testing events in the subspecialty of routine chemistry for the analyte AST(SGOT), (unsuccessful PT performance). See D2094, D2096
D2053	PARASITOLOGY CFR(s): 492.829(d) (1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) Remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on review of analyte performance from the CMS CASPER 155D report for the years 2016 (Q2) , 2017 (Q1), 2018 (Q1, Q2), the laboratory's College of American Pathologists (CAP) proficiency records for second quarter (Q2-2016), first quarter (Q1-2017), first quarter (Q1-2018), second quarter (Q2-2018) and interview with the laboratory director and the department technical supervisor on November 12, 2019, the laboratory failed to achieve satisfactory scores in parasitology PT performance. The findings included: a. The laboratory is enrolled with College of American Pathology (CAP) for Microbiology (parasitology) PT testing since 2016. b. For the subspecialty of parasitology, the laboratory had unsuccessful PT performance for two of of three events in 2016, 2017 and 2018: CAP reported event for parasitology: Event Score % Q2 2016 60 Q1 2017 50 Q1 2018 66 Q2 2018 66 e. Patient test results review covering periods from January 22, 2018 through November 12, 2018. the laboratory had performed approximately 320 parasitology specimens. d. The laboratory director confirmed by interview on November 12, 2019 at approximately 10:30 a.m., that the laboratory had received the above unsatisfactory proficiency testing scores. f. The laboratory reports performing approximately 577 parasitology patient specimens annually.
D2094	ROUTINE CHEMISTRY CFR(s): 493.841(e) (1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on review of the laboratory's College of American Pathologist (CAP) Proficiency Testing (PT) records, CMS 0155D CASPER report and interview with the laboratory director and the laboratory chemistry department technical supervisor on November 12, 2019, the laboratory failed to (1) to undertake appropriate training and

	employ the technical assistance necessary to correct problems associated with proficiency testing failure and (2) The laboratory failed to take remedial action and document the action taken, and maintain documentation of the actions taken by the laboratory for two years from the date of participation in the failed proficiency testing event. The findings included: a. The laboratory is enrolled with CAP for chemistry proficiency testing since quarter 1 of 2016. b. In quarter two (Q2-2017) the laboratory failed PT testing for CK ISO), in quarter one (Q3-2017) the laboratory failed AST (SOGT) testing, in quarter one (Q1-2018) the laboratory failed AST (SGOT) testing, in quarter quarter three (Q3-2018) the laboratory failed CK, Total and LDH Total, in quarter one (Q1-2019) the laboratory failed glucose and BUN PT performance testing. Test Event Score CK ISO Q2 2017 0 AST(SOGT) Q3 2017 0 AST(SGOT) Q1 2018 0 CK Total Q3 2018 60 LDH Total Q3 2018 20 Glucose (NW) Q1 2019 60 BUN Q1 2019 40 c. For AST (SGOT)- Coding change error with CAP, event (Q3-2017) was documented as the issue for the initial unsatisfactory result. For (Q1-2018) AST (SGOT) failure, the laboratory documented the same response (clerical issue) as the reason for the second PT failure. d. The laboratory had no documentation of remedial actions taken for initial analyte unacceptable testing event scores, for the first or second unacceptable analyte testing event scores. e. A random patient review of (11) patient chemistry records and review of quality control logs and interview with the laboratory director and technical supervisor confirmed the testing of patient samples during the time of failed proficiency testing scores for the above analytes and during the period of unsuccessful analyte performance for AST(SGOT) (Q3 2017-Q1 2018). f. The laboratory reports performing a 478,556 routine chemistry tests annually which include (CK ISO, CK Total, AST (SGOT), LDH total, Glucose, BUN).
D2096	ROUTINE CHEMISTRY CFR(s): 493.841(f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on review of the laboratory College of American Pathologist (CAP) Proficiency Testing (PT) report, the CMS CASPER 0155D report, and interview with the laboratory director and chemistry technical supervisor on November 12, 2019, the laboratory failed to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events resulting in unsuccessful PT performance. The findings included: a. The laboratory is enrolled in CAP for the subspecialty of routine chemistry. Quarter three of 2017 (event 3) the laboratory recieved unaccaptable scores for the PT chemistry analyt AST(SGOT) and in quarter one (Q1-2018) 2018 the laboratory recieved unacceptable PT scores again for the chemistry analyte AST(SGOT). Event Score Q3 2017 0% Q1 2018 0% b. Based on interview, and a random sampling of patients from January 2018 through August of 2019, the laboratory director confirmed on November 12, 2019 at approximately 12:30 p.m. that the laboratory had continued testing patients for AST. c. The laboratory reports performing approximately 478,556 routine chemistry patient specimens annually which include AST(SGOT).
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 Chemistry verification data for the new chemistry analyzer (Beckman AU) installed on April 1st, 2019, and interview with the department technical supervisor on November 13, 2019, the laboratory failed to demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics, (accuracy, precision, reportable range for test result for the test system) and failed to verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. The findings included: a. The laboratory previously ran their chemistry patient specimens on a Siemens dimension analyzer. In 2019 the laboratory purchased a Beckman AU chemistry analyzer. b. The manufacturer performed comparison sampling for the laboratory on the two instruments during the implementation phase of the installation. The patient sampling results were entered into a program by the Beckman representative showing the linearity and bias of the Beckman analyzer. c. The laboratory did not have documentation of the Siemens chemistry analyzer"known" samples. The "known" samples results were no longer available in the Siemens analyzer memory and the print outs had been accidentally shredded. d. The laboratory did not have documentation summarizing the acceptability of the the validation report and its acceptability for implementing the new test methodology platform prior to testing and reporting patient results. e. The laboratory technical supervisor and laboratory director confirmed by interview on November 13, 2019 at approximately 1:15 p.m. that lack of proper validation of the new chemistry analyzer prior to testing patient specimens. f. The laboratory reports performing approximately 478,556 routine chemistry tests annually.
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 review of patient testing report logs and interview with testing personnel and the general supervisor on November 13, 2019, the laboratory failed to establish and perform quality control procedures in accordance with 493.1269(a) for manual cell counts performed using a hemocytometer--the laboratory failed to perform (a)(1) One control material tested each 8 hours of operation; and (d) The laboratory failed to document all control procedures performed. The findings included: a. The laboratory performs diluted and undiluted body fluid cell counts on a hemocytometer. b. The laboratory has no documentation of quality control materials being performed each

	eight hours of patient testing. c. The laboratory has no documentation of an individualized quality control plan (IQCP) in place for establishing alternative quality control procedures. d. The hematology general supervisor confirmed by interview on November 13, 2019 at approximately 09:00 a.m. that the laboratory did not have a quality control plan for hemocytometer body fluid cell counts and do not perform quality control or document quality control procedures for body fluid cell counts. e. The laboratory reports performing approximately 370 body fluid patient specimens annually.
D5809	TEST REPORT CFR(s): 493.1291(e) The laboratory must, upon request, make available to clients a list of test methods employed by the laboratory and, as applicable, the performance specifications established or verified as specified in 493.1253. In addition, information that may affect the interpretation of test results, for example test interferences, must be provided upon request. Pertinent updates on testing information must be provided to clients whenever changes occur that affect the test results or interpretation of test results. This STANDARD is not met as evidenced by: Based on review of patient test reports, the Cobas Elecsys Total PSA product insert and interview with department technical supervisor and testing personnel on November 13, 2019, the laboratory failed to make available to clients information that may affect the interpretation of test results for Total Prostate-Specific Antigen testing. The findings included: a. The laboratory performs Total PSA on the Cobas immunoassay analyzer using the Elecsys total PSA reagent. b. The product insert states "the laboratory finding must therefore always contain a statement on the tPSA assay method used. tPSA values determined on patient samples by different testing procedures cannot be directly compared with one another and could be the cause of erroneous medical interpretations". c. A random sampling of (11) patients from January 2018 to August 2019 indicated that the patient test reports did not contain this statement. The laboratory had changed laboratory information systems and that comment had been dropped from the patient tPSA reports. d. The laboratory director and technical supervisor confirmed by interview on November 13, 2019 at approximately 16:15 p.m. that the patient tests reports for tPSA did not contain the required interpretive statement. e. The laboratory reports performing approximately 726 tPSA patients in 2018, and approximately 968 tPSA patients in 2019.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on the severity of the deficiecies cited herin, the Condition: Laboratoriories performing High Complexity testin: Laboratory director failed to meet the requirements of 493.1445 of this subpart in providing overall management and direction for high complexity testing. The findings included: a. Failure to ensure

	satisfactory Proficiency Testing, See D2016, D2096, D6089 b. Failure to ensure verification of Performance procedures and characteristics for new methodologies are performed prior to testing and releasing of patient results, See D5421, D6092 c. Failure to ensure corrective actions are taken when proficiency testing fail to meet acceptable criteria. See D2094
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method. This STANDARD is not met as evidenced by: Based on review of the laboratory's verification records for the implementation of the new chemistry analyzer, and interview with the technical supervisor and the laboratory director on November 13, 2019, the laboratory director failed to ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method. See D5421
D6092	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iv) The laboratory director must ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on review of the laboratory's Proficiency Testing (PT) records, the CMS CASPER 0155D and interview with the laboratory laboratory director and technical supervisor on November 12, 2019, the laboratory director failed to ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory. The findings included: a. The laboratory had initial PT unsuccessful performance in parasitology in which initial remedial training activities did not correct the deficiency leading to subsequent unsuccessful PT performance. See D2016 b. The laboratory had unsatisfactory AST(SGOT) performance in Q3 2017 due to clerical change in CAP report form, due to lack of remedial corrective action this unsatisfactory performance was repeated in Q1 2018 leading to an unsuccessful PT performance with no remedial or corrective action documented. See D2016, D2094, D2096
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 review of patient reports and interview with the hematology technical supervisor on November 13, 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. The findings included: a. The laboratory hematology department performs diluted and undiluted body fluid analysis on a hemocytometer. b The laboratory has no quality control process for the body fluid analysis for hemocytometer. See D5543