Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D2086481	09/05/2019
Name of Provider or Supplier	**Street Address, City, State**	
San Carlos Center Laboratory, Pamf	301 Industrial Rd, San Carlos, CA	

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
D2005	ENROLLMENT CFR(s): 493.801(a)(4) Authorize the proficiency testing program to release to HHS all data required to-- (i) Determine the laboratory's compliance with this subpart; and (ii) Make PT results available to the public as required in section 353(f)(3)(F) of the Public Health Service Act. This STANDARD is not met as evidenced by: . Based on the lack of 2017 - 2019 proficiency testing reports from CMS (report 155D, Individual Laboratory Profile), review of laboratory proficiency testing records, proficiency testing reports from CAP (College of American Pathologists), and patients test records; and interview with the General Supervisor (Technical Supervisor-4) and a CAP representative, it was determined that the laboratory had failed to authorize the reporting of all proficiency test scores to HHS. Findings included: a. Patients test records revealed results were reported in bacteriology, mycology, parasitology, virology, immunology, chemistry, urinalysis, endocrinology, toxicology, and hematology. Based on the laboratory's CLIA Application (9/02/19) the laboratory reported approximately 1,354,088 results annually. b. Laboratory records revealed the laboratory had participated in CAP proficiency testing programs in 2017 - 2019 and was affirmed (9/05/19 at 12pm) by the General Supervisor (Technical Supervisor-4). c. However, the query (8/22/19) for the laboratory's CMS report 155D had revealed no information for review. d. A CAP representative affirmed (9/19/19 at 12:15pm) the laboratory's failure to authorize the release of all data; and thus: 1) the failure to make proficiency testing results available to the public as required in section 353(f)(3)(F) of the Public Health Service Act, and 2) disabling the CLIA process to determine the laboratory's compliance from 2017/event 3 to 2019/event 2 and continously monitor performance during the reporting of approximately 1,354,088 patients results annually. .

D2075	GENERAL IMMUNOLOGY CFR(s): 493.837(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Based on reviews of 2018/1st event proficiency testing reports from CAP (College of American Pathologists), laboratory proficiency testing records, and patients test reports; and interview with the General Supervisor (Technical Suprvisor-4), the laboratory failed to attain a score of at least 80% for Infectious Mononucleosis constituting unsatisfactory analyte performance. Findings included: a. CAP reported the score of 60% based on the laboratory's 2 unacceptable results out of 5. b. The General Supervisor (Technical Supervisor-4), affirmed (9/05/19 at 2pm) the aforementioned findings and that approximately 548 results had been reported annually. c. The reliability and quality of results reported could not be assured when testing was unsatisfactory. Based on the stated estimated annual test volume, the laboratory reported approximately 45 results each month during the timeframe March to August 2018. .
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: . Based on reviews of 2017 - 2018 proficiency testing reports from CAP (College of American Pathologists), laboratory proficiency testing records, and patients test records; the lack of documents, and interview with the General Supervisor (Technical Consultant-4), the laboratory failed to verify the accuracy of testing for Neonatal Direct Bilirubin, Urine Calcium, Urine Creatinine, Reticulocytes Absolute count, and Vitamin B12. Findings included: a. It was the laboratory's practice to participate in CAP proficiency testing programs as the means to satisfy the requirement to at least twice annually verify the accuracy of testing for Neonatal Direct Bilirubin, Urine Calcium, Urine Creatinine, Reticulocytes count, and Vitamin B12. b. The laboratory received unsatisfactory scores less than 80%; and thus, accuracy was not verified during those timeframes as follows: Analyte Year/Event Score ---------- Neonatal Direct Bilirubin .....2017 / B .....50% Urine Calcium .....2019 / B .....67% Urine Creatinine .....2019 / B .....67% Reticulocytes count .....2018 / A .....67% Vitamin B12. .....2018 / C .....67% c. The laboratory failed to provide for review documents for alternate means of verifying the accuracy of testing during the timeframes of the unsatisfactory testing performances. d. The General Supervisor (Technical Consultant-4) affirmed (9/05/19 at 4pm) the aforementioned findings and lack of alternate means; and thus, the laboratory failed to verify the accuracy of testing during the timeframes of unsatisfactory proficiency testing. e. The accuracy, reliability, and quality of results reported for patients could not be assured when accuracy failed to verify. Based on the stated annual test volumes (9/05/19), the number reported during the affected timeframes are as follows: Analyte Volume ---------- Neonatal Direct Bilirubin 31

	Urine Calcium ..... 525 Urine Creatinine .....9,677 Reticulocytes Absolute count.....295 Vitamin B12. ..... 5,852 .
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: . Based on observation of the Dimension Vista chemistry analyzers (serial numbers DV311238 and DV331057), review of laboratory training records for Ammonia (NH3), the lack of records, and interview with the General Supervisor/Technical Consultant-4, it was determined that the Laboratory Director was deficient in responsibility for ensuring that prior to testing patients specimens, all testing persons demonstrated that they can perform all testing operations reliably to provide and report accurate results. Findings included: a. In 2017, the laboratory added testing for Ammonia using the Dimension Vista analyzers. b. Laboratory records documented 9 persons completed training for the new test in October 2017. c. The laboratory was unable to provide for review records documenting each person demonstrating test performance to reliably provide and report accurate results for Ammonia. Also, none had participated in verifying Ammonia test performance specifications in July - September 2017. d. The General Supervisor/Technical Consultant-4 affirmed (9/05/19 at 5pm) the aforementioned findings; and thus, the deficient oversight of the Laboratory Director to have laboratory policy and practice requiring each person to demonstrate testing to complete their training prior to testing patients specimen. e. The reliability and quality of results reported for Ammonia could not be assured in the absence of personnel demonstrating accuracy prior to testing patients specimen. According to the CLIA Application (9/05/19) the labortory reported 68 results for Ammonia annually. .
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of personnel training records for Ammonia, the lack of laboratory policy and documents, and interview with Technical consultant-4/General Supervisor, it was determined that the Technical Consultants failed to evaluate and document competencies at least semiannually during the first year of testing for Ammonia. Findings included: a. Laboratory records documented 9 persons were trained to test for Ammonia, a new moderate complexity test, in October 2017. b. The laboratory

	was unable to provide for review documents evaluating personnel competencies within 6 months of their training to test for Ammonia. c. Technical consultant-4 /General Supervisor affirmed (9/05/19 at 5pm) that the laboratory policy and practice did not apply to new tests; and thus, the Technical Consultants failed in their responsibility to evaluate and document competencies at least semiannually during the first year of performing new tests. d. The reliability and quality of results reported for Ammonia during the first year could not be assured. The laboratory stated (Laboratory Testing Declaration, 9/05/19) that 68 Ammonia tests were performed annually.