Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0893794	08/12/2019
Name of Provider or Supplier	**Street Address, City, State**	
Bakersfield Family Medical Center	4580 California Ave, Bakersfield, 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
D2003	ENROLLMENT CFR(s): 493.801(a)(2)(ii) For those tests performed by the laboratory that are not included in subpart I of this part, a laboratory must establish and maintain the accuracy of its testing procedures, in accordance with 493.1236(c)(1) This STANDARD is not met as evidenced by: Based on observation of Abbott i-STAT chemistry analyzers for Troponin, review of laboratory records, and interview with laboratory personnel, it was determined that the laboratory failed to maintain the accuracy of testing for Troponin. See D5217.
D2121	HEMATOLOGY CFR(s): 493.851(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 observation of analyzers, review of 2018 - 2019 proficiency testing reports from CMS (report 155D, Individual Laboratory Profile) and AAB (American Association of Bioanalysts), laboratory proficiency testing records, and patients results; and interview with laboratory personnel, it was revealed that the laboratory failed to attain scores of at least 80% for Prothrombin Time (Coagulation test) and Differentials. Findings included: a. Prothrombin Time 1) CMS and AAB reported the unsatisfactory score of 60% for event 3/2018. 2) Laboratory proficiency records revealed the laboratory obtained 2 unacceptable results out of 5 for Prothrombin Time using i-STAT. 3) Laboratory personnel affirmed (8/12/19 at 3pm) the aforementioned findings. 4) The reliability and quality of results reported could not be assured when

	proficiency testing scores indicated testing was unsatisfactory. The laboratory reported approximately 66 results annually, which was 5 or 6 per month. A few examples selected at random from the timeframe October 2018 - January 2019 were as follows: Date ID ---------- 10/26/18 MM 11/23/18 LT b. Differentials 1) CMS and AAB reported the unsatisfactory score of 0% for event 1/2019. 2) Laboratory proficiency records revealed the laboratory obtained 5 unacceptable results out of 5 for Differentials using the Abbott Celldyn Emerald, based on 5 unacceptable results out of 5 for Neut/Gran (Neutrophils/Granulocytes) and 5 unacceptable results out of 5 for Mixed/Mono (Monocytes). 3) Laboratory personnel affirmed (8/12/19 at 3pm) the aforementioned findings. 4) The laboratory reported approximately 2,554 results annually, which was approximately 212 per month during the timeframe January - April 2019. A few examples selected at random are as follows: Date ID ---------- 2/07/19 KM 2/17/19 EH 2/24/19 SC 2/28/19 CM 3/12/19 RR .
D2123	HEMATOLOGY CFR(s): 493.851(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events. This STANDARD is not met as evidenced by: Based on reviews of 2018 hematology proficiency testing reports from CMS (report 155D, Individual Laboratory Profile) and AAB (American Association of Bioanalysts), laboratory proficiency testing records, and patients results; and interview with laboratory personnel, it was revealed that the laboratory failed to participate in the 1st event of 2018. Findings included. a. CMS and AAB reported scores of 0% for all analytes in hematology: WBC Differential RBC (Red Blood Cell count) HCT (Hematocrit) HGB (Hemoglobin) WBC (White Blood Cell count) Platelets (Platelets count) b. Laboratory proficiency records revealed the laboratory failed to participate in the event. c. Laboratory personnel affirmed (8/12/19 at 4pm) the aforementioned findings. d. Although the laboratory failed to participate in hematology proficiency testing, it continued testing and reporting results. As a consequence, the reliability and quality of hematology results could not be assured during the timeframe March - April 2018. A few selected at random are as follows: Date ID ---------- 3/12/18 JM 3/13/18 BP 3/13/18 LE .
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).

	This STANDARD is not met as evidenced by: . Based on review of laboratory proficiency testing records and AAB proficiency testing reports for Troponin for 2018: event 3, the lack of laboratory records, and interview with laboratory personnel, it was determined that the laboratory failed to verify the accuracy of test results not graded by AAB. Findings included: a. For 4 out of 5 results reported by the laboratory for Troponin, AAB attached the code "#, This method was not graded due to an insufficient number of peer repondents...". b. The laboratory failed to provide for review documents evaluating reported results in comparison to intended results. c. Laboratory personnel affirmed (8/12/19 at 3pm) the aforementioned lack of laboratory records; and thus the failure to determine the accuracy of results not graded by AAB. d. The reliability and quality of results reported for Troponin could not be assured when the laboratory failed to determine the accuracy of Non-graded results. This included 4 out of 4 patients results randomly selected from the timeframe September to December 2018: Date ID ---------- ---------- 9/01/18 C, J 10/01/18 M, M 11/01/18 B, M 12/01/18 H, M .
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 laboratory proficiency testing records, AAB (American Association of Bioanalysts) proficiency testing reports for Cardiac Markers - Isoenzymes, 2018: 3rd event, and patients test records; the lack of laboratory records, and interview with laboratory personnel, it was determined that the laboratory failed to verify the accuracy of Troponin. Findings included: a. The laboratory chose to enroll in AAB's proficiency testing program to satisfy the requirement to at least twice annually verify the accuracy of testing for Troponin. b. Review of laboratory proficiency testing records and AAB's proficiency testing report for 3rd event, 2018, revealed that 4 out of 5 laboratory results failed to meet the acceptable range of intended results: PT Lab Intended Grading sample result result range ---------- 1 16.02 7.87 5.84 - 9.73 3 31.88 14.433 10.82 - 18.04 4 7.51 3.572 2.68 - 4.46 5 50 24.834 18.63 - 31.04 c. The laboratory was unable to provide other documents verifying the accuracy of testing during this timeframe. d. Laboratory personnel affirmed (8/12/19 at 3pm) the aforementioned findings and lack of alternate method for verifying testing accuracy; and thus, the accuracy of testing for Troponin failed to be verified. e. The reliability and quality of results reported for Troponin could not be assured when accuracy failed to verify. This included 4 out of 4 patients results randomly selected from the timeframe September to December 2018: Date ID ---------- ---------- 9/01/18 C, J 10/01/18 M, M 11/01/18 B, M 12/01/18 H, M
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) 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)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on survey findings and deficiency cited, the Laboratory Director is herein cited for deficient practice in providing overall administration of the laboratory to ensure that proficiency testing samples are tested as required. Findings included: a. Under the Laboratory Director's administration, the laboratory failed to participate in proficiency testing. b. See D2123.