Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D0932353	07/02/2019
Name of Provider or Supplier	**Street Address, City, State**	
Amit H Sheth Md Pc	22878 Three Notch Road, California, MD	

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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on proficiency testing (PT) record review and interview with the laboratory staff, the laboratory failed to ensure that the laboratory director (LD) signed PT attestation statements, attesting that PT specimens were run in the same way as patient samples. Findings: 1. A review of hematology PT records from 6 events from 2017 to 2019 showed that the LD did not sign the attestation statements for the 1st hematology PT event, 2019. 2. During an interview on 4/11/19 at 3:00 PM, the laboratory staff confirmed that the attestation statement was not signed by the LD.
D2128	HEMATOLOGY CFR(s): 493.851(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 proficiency testing (PT) record review and interview with the laboratory

	staff, the laboratory failed to ensure that corrective action was taken and documented for failed PT. Findings: 1. The laboratory failed Hematology "Cell ID or WBC Diff" PT (66%) for 2nd event, 2017. 2. No corrective action was documented for the failed PT. 3. During an interview on 4/11/19 at 3:00 PM, the laboratory staff confirmed that there was no corrective action taken or documented for the failed PT.
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 standard operating procedure manual (SOPM) review and interview with the laboratory staff, the laboratory did not ensure that the SOPM included a list of imminently life-threatening test results, or panic or alert values. Findings: 1. The laboratory uses a procedure manual that was provided by Beckman Coulter with its AcT diff2 hematology analyzer. The laboratory is required to fill in information from its own laboratory to complete the procedure manual. 2. The procedure, "Panic/Alert Value Procedures" states to "Insert this laboratory's patient test values that require immediate notification of the provider." The laboratory failed to document its "Critical /Panic/Alert Values" for hematology testing. 3. During an interview on 4/11/19 at 3: 00 PM, the laboratory staff confirmed that the SOPM did not include a list of panic or alert values.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on standard operating procedure manual (SOPM) review and interview with the laboratory staff, the laboratory did not ensure that the SOPM was approved, signed, and dated by the laboratory director (LD). Findings: 1. A review of the current SOPM showed that the procedures were not approved (signed and dated) by the LD. 2.

	During an interview on 4/11/19 at 3:00 PM, the laboratory staff confirmed that the current SOPM was not signed and dated by the LD.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on quality control (QC) record review, observation, and interview with the laboratory staff, the laboratory failed to ensure that hematology QC was not used before it exceeded its expiration date. Findings: 1. During a tour of the laboratory at 9: 30 AM, it was observed that the in-use hematology QC, lot # 068800 (low), 078800 (normal), and 088800 (high) had expired 3/25/19. During an interview, testing person #2 stated that the QC was still in use and that they "need to change to the new ones." 2. A review of QC records showed that lot # 068000 (low), 078000 (normal), and 088000 (high) expired 12/3/18 but was run on 12/4/18; and 3. Lot # 067900 (low), 077900 (normal), and 087900 (high) expired 12/18/17 but was run on the analyzer from 1/2/18 to 6/12/18. 4. During an interview on 4/11/19 at 3:00 PM, the laboratory staff confirmed that hematology QC was run after controls had expired.
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: Note: This is a repeat deficiency. The laboratory was cited during the re-certification survey on 6/20/2017 for not performing and documenting monthly cleaning of the hematology analyzer. The plan of correction stated that this would be corrected. Based on hematology instrument maintenance record review and interview with laboratory staff, the laboratory did not ensure that monthly maintenance was performed on the hematology analyzer as recommended by the manufacturer. Findings: 1. The laboratory uses a Beckman Coulter AcT diff2 hematology analyzer to perform CBC analysis. The instrument maintenance worksheet lists "clean baths" under monthly maintenance. 2. A review of monthly hematology analyzer maintenance records from January, 2018 to March, 2019 showed that monthly instrument cleaning was not documented. 3. During an interview on 4/11/19 at 3:00 PM, the laboratory staff confirmed that monthly hematology analyzer maintenance was not performed.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that

	perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on temperature and humidity log record review and interview with laboratory staff, the laboratory failed to document corrective action when humidity readings were out of range. Findings: 1. The humidity range for the laboratory is "30 - 85% without condensation"; and 2. From February to March, 2019 the laboratory's humidity readings were out of range 8 out of 40 times recorded. 3. There were no corrective actions documented for these dates. 4. During an interview on 4/11/19 at 3:00 PM, the laboratory staff confirmed that there were no corrective actions documented for the days that the humidity readings were out of range.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) 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)(3) Ensure that-- (e)(3)(ii) 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 hematology instrument validation records and interview with the laboratory staff, the laboratory director (LD) failed to ensure that the correlation study between the old and new hematology analyzer was acceptable before putting the new analyzer into use. Findings: 1. The laboratory began using a new hematology analyzer in June, 2018. The installation technician performed a method comparison between the old and the new analyzer as part of the new instrument's verification procedure. 2. A review of hematology instrument validation records showed that the LD did not sign the method comparison study, approving the instrument for use in the laboratory. 3. During an interview on 4/11/19 at 3:00 PM, laboratory staff confirmed that the LD failed to ensure that all verification procedures were reviewed and signed before using the new hematology analyzer.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) 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)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory.

	This STANDARD is not met as evidenced by: Based on proficiency testing (PT) record review and interview with laboratory staff, the laboratory director acting as technical consultant did not ensure that corrective action was taken and documented for failed hematology PT for 2nd event, 2017. Refer to D2128.
D6022	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of the quality assurance (QA) plan and interview with the laboratory director (LD), the LD failed to ensure that quality control (QC) and QA procedures monitored overall operation of the laboratory to identify immediate QC failures and ensure that effective corrective actions are taken when failures are identified. Findings: 1. Record review showed that the laboratory had a blank "Monthly QA Checklist" but there were no QA reviews present at the time of the survey. During an interview at 1:45 PM, laboratory staff confirmed that no QA reviews had been performed. 2. Corrective actions were not performed on failed hematology proficiency testing. Refer to D2128. 3. Hematology QC was run on control material which had exceeded its expiration date. Refer to D5417. 4. Monthly maintenance was not performed and documented on the hematology analyzer as recommended by the manufacturer. Refer to D5429. 5. Corrective actions were not performed and documented when laboratory humidity readings were out of range. Refer to D5781. 6. During an interview on 4/11/19 at 3:00 PM, the laboratory staff confirmed that the LD failed to ensure that QC and QA programs are established and maintained to identify failures in quality as they occur.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Note: This is a repeat deficiency. The laboratory was cited during the re-certification survey on 6/20/2017 for not performing competency check assessments on laboratory staff. The plan of correction stated that this would be corrected. Based on record review and interview with the laboratory staff, the laboratory director acting as the technical consultant failed to perform and document the competency reviews on all testing personnel. Findings: 1. The laboratory currently has 3 testing personnel listed on the "Laboratory Personnel Report (CLIA) (CMS-209)." 2. During the survey on 4 /11/19 at 3:00 PM the laboratory staff confirmed that there were no competency evaluations for 3 of 3 testing personnel for 2017 and 2018.

D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on record review and interview with the laboratory staff, the laboratory did not ensure that all testing personnel were qualified to perform patient testing. Findings: 1. Record review showed that at the time of the survey there were no credentials or transcripts available for 3 of 3 testing personnel. 2. During an interview on 4/11/19 at 3:00 PM, the laboratory staff confirmed that there were no documents available to verify that 3 of the 3 testing personnel listed on the Laboratory Personnel Report (CLIA-209) met the minimum requirement for performing testing, e.g., have earned a high school diploma or equivalent.