Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D1015025	03/17/2020
Name of Provider or Supplier	**Street Address, City, State**	
Stockton Hematology Oncology Medical Group	2316 Orchard Parkway, Ste 110, Tracy, 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
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 the number and severity of the deficiency cited herein, the Condition: Successful [Proficiency Testing] Participation was not met. The laboratory failed to achieve an overall testing event score of satisfactory performance for two of three consecutive testing events of unsuccessful performance for Hematology RBC (Erythrocytes), HCT (Hematocrit) and PLT (Platelets). (see D2130).
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 review of the third quarter (Q3-2020) of the American Association of Bioanalysts (AAB) proficiency testing (PT) records, ten (10) randomly selected patient test results from 01/16/2018 to 02/25/2020 and interview with a testing person, it was determined that the laboratory failed to participate in a testing event is unsatisfactory performance and results in a score of 0% for the testing event. The findings included: a. AAB reported an unsatisfactory score of 0% for the Hematology PT performance summary of Q3-2020, which included: Automated Erythrocyte (RBC), Hemoglobin (HGB), Hematocrit (HCT), Leukocyte (WBC) count, Platelet count and White Blood (WBC) Differential analysis. b. The testing person affirmed (03/17/2020) that laboratory failed to submit the proficiency challenges for ABB Q3-2020. c. The laboratory's testing declaration form, signed by the laboratory director on 03/16/2020, stated that the laboratory performs 2,500 automated CBCD tests annually.
D2130	HEMATOLOGY CFR(s): 493.851(f) Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: 1. Based on CMS PT records (CMS CASPER Report 0155D and 0153D), it was determined that the laboratory failed to achieve satisfactory performance for the same analyte or test in two out of three consecutive PT events for the analyte, Erythrocyte count (RBC), resulting in a subsequent unsuccessful performance. Findings include: RBC Q2-2016 Q3-2016 Q2-2019 Q3-2019 40% 60% 60% 0% Q1 - First Testing Event Q2 = Second Testing Event Q3 = Third Testing Event b. Failure to achieve satisfory performance fro the same analyte or test in two out of thre consecutive PT results in an initial unsuccessful performance for the analyte, RBC. 2. The laboratory failed to maintain successful performance with the PT program by failing to obtain a score of 80% of acceptable response in two out of three consecutive PT events for the analytes RBC (Erythrocytes), HCT (Hematocrit) and PLT (Platelets). Q2-2019 Q3-2019 HCT 60% 0% PLTS 60% 0% b. The testing person confirmed (03/17/2020) that laboratory failed two consecutive testing events of unsuccessful performance for HCT (Hematocrit) and PLT (Platelets) 2019 and subsequent unsuccessful performance for Hematology RBC (Erythrocytes) 2016 and 2019. c. The laboratory's testing declaration form, signed by the laboratory Director on 03/16/2020, stated that the laboratory performs 2,500 automated CBCD tests annually.
D5469	CONTROL PROCEDURES

	CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on Surveyor review of quality control, ten (10) patient test records from 1/16 /2018 to 02/25/2020, policies and procedures, verification data, and an interview with a laboratory testing personnel, the laboratory failed to verify the criteria for acceptability of hematology CBC quality control QC materials for Abbott quality control materials (Lot L0041, Exp. Date 2020-05-29) performed on the Cell-Dyn Emerald analyzer . The findings include: a. The laboratory used the Abbott QC materials reference ranges for automated hematology CBCD (Complete Blood Count with Differential) performed on the Cell-Dyn Emerald analyzer. The normal QC(Lot N0041) manufacturer's assay value for WBC (White Blood count) was manually incorrectly enter with the analyzer. The manufacturer's package insert for the normal QC WBC assay value was 8.2 (Lot N0041) but was manually enter as 8.3. b. The laboratory testing personnel on 3/17/2010 at 11:30 am, confirmed that the manufacturer's assay value for QC material normal was incorrectly manually entered in the Cell-Dyn Emerald analyzer. c. The laboratory's testing declaration form, signed by the laboratory Director on 03/16/2020, stated that the laboratory performs 2,500 automated CBCD tests annually.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on the severity of the deficiencies cited herein, the Condition: Laboratories Performing Moderate Complexity Testing: Laboratory director was not met. The laboratory director, moderate complexity testing, failed to ensure that PT samples were tested as required under Subpart H of this part. (See D6016)
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii) 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)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on the deficiency cited, the Laboratory Director is herein cited for failing in responsibility to ensure that testing persons perform hematology testing as required for accurate and reliable results. See D6459.
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 a desk review of CMS PT records, it was determined the laboratory director, moderate complexity testing, failed to ensure that PT samples were tested as required under subpart H. of this part. The findings included: For the analytes Automated Erythrocyte (RBC), Hemoglobin (HGB), Hematocrit (HCT), Leukocyte (WBC) count, Platelet count, and White Blood (WBC) Differential analysis, the laboratory repeatedly failed to achieve satisfactory performance for the same analyte or test. (See D2016 and D2130)
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 and the lack of documentation for competency assessments, and interview with a testing person, it was determined that the laboratory technical consultant (laboratory director) failed to perform and document the performance of individuals responsible for moderate complexity testing at least semiannually during the first year and yearly thereafter the individual tests patient specimens. The evaluations must include but are not limited to the following: a. No documentation could be retrieved to show that six (6) testing personnel from 2018 and 2019 were evaluated during the first six months and annually thereafter for their responsibilities as testing personnel. The evaluation must include following: Direct observations of the testing performed (including sample handling, processing and testing) Monitoring the recording and reporting of results Direct observation of instrument maintenance Review of intermediate worksheets, quality control records. Assessment of testing previously analyzed specimens (external QC and proficiently testing) Assessment of

	problem-solving skills b. The laboratory testing personnel confirmed 03/19/2020 (survey date) that no competency assessments were performed and documented by the laboratory director/technical consultant. c. The laboratory's testing declaration form, signed by the laboratory Director on 03/16/2020, stated that the laboratory performs 2,500 automated CBCD tests annually.