Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0612335	(X3) Date Survey Completed 04/13/2018
Name of Provider or Supplier Sonoma Specialty Hospital	Street Address, City, State 501 Petaluma Ave, Sebastopol, 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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on observation of BioRad MRSA Selective agar media available for use, review of patients test reports, the lack of proficiency testing reports and laboratory proficiency testing records for "Culture MRSA Screen", and interview with the Technical Consultant, the laboratory failed to enroll in proficiency testing for bacterial culture to screen for Methicillin Resistant Staphylococcus aureus (MRSA). Findings include: a. The laboratory was unable to provide for review proficiency testing scores and proficiency testing records for bacterial culture to screen for MRSA. b. The Technical Consultant affirmed (4/04/18) the aforementioned failure to enroll in 2016 to 2018, date of this survey. c. The reliability and quality of results reported could not be assured. Based on the stated estimated annual test volume, the laboratory reported approximately 137 results annually using bacterial cultures to screen for MRSA. A few examples are as follows: Date Recv'd Accession / ID ---------- 1/26/16 ... ...414981 1/29/16 .....415404 2/09/16 .....416788 6/02/16 ... ...432238 10/04/16 ... ...446209 1/03/17 ..... 457688 1/20/17 ..... 459881 10/30/17 ... ...504538 1/01/18 .....523534 1/18/18 ... ...529861 .

D2021	BACTERIOLOGY CFR(s): 493.823(b) 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 2016 - 2017 Microbiology proficiency testing reports from API (American Proficiency Institute), laboratory proficiency testing records for bacterial Blood Culture, and patients test reports; and interview with the Technical Consultant, the laboratory failed to participate in 2 out of 6 events. Findings include: a. API reported no scores for Blood Culture proficiency testing in the 2nd events of 2016 and 2017. b. The Technical Consultant affirmed (4/04/18) the aforementioned lack of participation; and thus, unsatisfactory analyte performances in bacterial Blood Culture. c. The reliability and quality of results reported could not be assured. Based on the stated estimated annual test volume, the laboratory reported approximately 86 results for Blood Culture Screening each month during the timeframes April to August in 2016 and 2017. A few examples are as follows: Date Recv'd Accession / ID ---------- 5/04/16 ... ...428571 6/19/16 ... ...434497 7/26/16 ... ...438740 8/20/16 ... ...441181 4/27/17 .....470970 .
D2087	ROUTINE CHEMISTRY CFR(s): 493.841(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 review of 2016/event 1 proficiency testing reports from CMS (report 155D, Individual Laboratory Profile) and API (American Proficiency Institute), laboratory proficiency testing records for cardiac markers CK Iso (Creatine kinase Isoenzyme)/ CKMB (Creatine Kinase-Muscle/Brain) using the Vitros 5600 analyzer, and patients test reports; and interview with the Technical Consultant, the laboratory failed to attain a score of at least 80%, constituting unsatisfactory analyte performance for CKMB. Findings include: a. CMS and CAP reported the unsatisfactory score of 40% based on the laboratory's reporting of 3 unacceptable results out of 5 for proficiency testing. b. The Technical Consultant affirmed (4/04/18) the aforementioned unacceptable results and scores for CK-MB; and thus, unsatisfactory analyte performance. c. The reliability and quality of results reported could not be assured. Based on the stated estimated annual test volume, the laboratory reported approximately 4 to 5 CKMB results each month during the timeframe January to

	April 2016. A few examples are as follows: Date reported Accession ---------- 1/03/16 ... ...411927 2/06/16 ... ... 416582 3/01/16 ... ...419807 4/14/16 ... ...425917 .
D2098	ENDOCRINOLOGY CFR(s): 493.843(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 review of 2017/event 3 proficiency testing reports from CMS (report 155D, Individual Laboratory Profile) and API (American Proficiency Institute), laboratory proficiency testing records for Free T4 (Free Thyroxine) and TSH (Thyroid Stimulating Hormone) using the Vitros 5600 analyzer, and patients test reports; and interview with the Technical Consultant, the laboratory failed to attain scores of at least 80%, constituting unsatisfactory analyte performances. Findings include: a. CMS and CAP reported the unsatisfactory scores based on the laboratory's reporting of unacceptable results for proficiency testing as follows: Analyte Score Unacceptable Results ---------- Free T4 ....60%.....3 out of 5 TSH ... .60%.....3 out of 5 b. The Technical Consultant affirmed (4/04/18) the aforementioned results and scores for Free T4 and TSH; and thus, unsatisfactory analyte performances. c. The reliability and quality of results reported could not be assured. Based on the stated estimated annual test volume, the laboratory reported approximately 32 Free T4 results and 73 TSH results each month during the timeframe September to December 2017. A few examples are as follows: Date Accession Test ---------- 9/13/17 ... ...489754 ... . TSH 9/14/17 ... ...489753 ... . Free T4 10/13/17 ... ...497495 ... .Free T4 10/18 /17 ... ...497496 ... .TSH 11/08/17 ... ...507116 ... . TSH 11/08/17 ... ...507139 ... . Free T4 12/13/17 ... ...516587 ... . Free T4 12/13/17 ... ...516588 ... . TSH .
D2099	ENDOCRINOLOGY CFR(s): 493.843(b) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance. This STANDARD is not met as evidenced by: Based on review of 2017/event 3 proficiency testing reports from CMS (report 155D, Individual Laboratory Profile) and API (American Proficiency Institute) and interview with the Technical Consultant, the laboratory failed to attain an overall testing event score of at least 80%, constituting unsatisfactory performance in Endocrinology. Findings include: a. CMS and CAP reported the unsatisfactory score of 66% overall in Endocrinology based on individual analytes scores as follows: Free T4 . ...60% HcG ... . 80% TSH ... .60% b. See D2098
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 review of 2016/event 1 proficiency testing reports from CMS (report 155D, Individual Laboratory Profile) and API (American Proficiency Institute), laboratory proficiency testing records for coagulation test Prothrombin Time (PT/ ProTime) using the Siemens CA 600 analyzer, and patients test reports; and interview with the Technical Consultant, the laboratory failed to attain a score of at least 80%, constituting unsatisfactory analyte performance for ProTime. Findings include: a. CMS and CAP reported the unsatisfactory score of 60% based on the laboratory's reporting of 2 unacceptable results out of 5 for proficiency testing. b. The Technical Consultant affirmed (4/04/18) the aforementioned unacceptable results and scores for ProTime; and thus, unsatisfactory analyte performance. c. The reliability and quality of results reported could not be assured. Based on the stated estimated annual test volume, the laboratory reported approximately 96 Prothrombin Time results each month during the timeframe January to April 2016. A few examples are as follows: Date Accession ---------- 1/11/16 ... ...412951 2/17/16 ... ... 417995 3/31/16 ... ...424294 4/02/16 ... ...424511 .
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 review of 2016 - 2017 proficiency testing reports from API (American Proficiency Institute), laboratory proficiency testing records for Troponin using the Alere Biosite Triage test system, and patients test reports; and interview with the Technical Consultant, the laboratory failed to verify the accuracy of Troponin. Findings include: a. The laboratory chose to participate in API's proficiency testing program, "Cardiac Markers", as the means to satisfy the requirement to verify the accuracy of testing for Troponin at least twice annually. b. For the 1st event of 2016, the laboratory reported 4 unacceptable result out of 4 as follows: Sample Reported Expected ---------- CM - 02 1.720 0.371 - 0.587 CM - 03 0.760 0.210 - 0.411 CM - 04 10.900 1.115 - 1.725 CM - 05 5.260 0.609 - 0.977 c. The Technical Consultant affirmed (4/04/18) the aforementioned results; and thus, accuracy was not verified. d. The reliability and quality of results reported could not be assured. Based on the stated estimated annual test volume, the laboratory reported approximately 33 results for Troponin each month during the timeframe January to May 2016. A few examples are as follows: Date recv'd Accession ---------- 1/03/16 ... ...411927 2/06/16 ... ... 416582 3/01/16 ... .419807 4/14/16 ... .425917 .
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.

	This STANDARD is not met as evidenced by: Based on reviews of the list of tests performed (LAB 144A, 4/04/18), laboratory documents, and patients' test records; the lack of laboratory documents, observation of the Beckman Coulter DxH 600 automated hematology analyzer and the microscope in the laboratory, and interview with the Technical Consultant/Technical Supervisor, the laboratory failed to have a system that twice a year evaluated and defined the relationship between automated and manual methodologies for Differentials in 2016. Findings include: a. The Laboratory Testing Declaration and patients test records revealed the laboratory reported hematology Differential results using the automated Beckman Coulter DxH 600 analyzer and manual microscopic examinations by testing personnel. b. The laboratory provided for review (4/13/18) documents comparing the relationship between automated and manual differential results for 2017. c. The laboratory was unable to provide for review documents for 2016, and written policy, procedure, and process for a system that compared the two methods for reporting Differential results. d. The Technical Consultant/Technical Supervisor affirmed (4/04 /18) the aforementioned lack of written policy and procedure; and thus, the failure to have a process and practice to compare automated and manual results for Differentials twice each year. e. The relationship between automated and manual results reported were not defined for 2016. Based on the stated estimated annual test volume the laboratory reported approximately 5,208 automated and 157 manual Differentials. A few examples are as follows: Date recv'd Accession ---------- 6 /02/16 .....432082 10/24/16 .....448693 11/29/16 .....453316 12/21/16 456016