Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0612446	11/27/2018
Name of Provider or Supplier	**Street Address, City, State**	
Sonoma Valley Hospital District	347 Andrieux St, Sonoma, 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
D2020	BACTERIOLOGY CFR(s): 493.823(a) 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 the first quarter (Q1-2017), second quarter (Q2-2017) of the American Proficiency Institute (API) proficiency testing records, random patient sampling test results, and interview with the technical supervisor, it was determined that the laboratory failed to attain an overall testing event score of at least 80 percent is unsatisfactory performance. The findings included: a. API reported the following unsatisfactory proficiency testing scores: Analyte: Score: Event/Year: Wound Aerobic 50% Q1/2017 Eye/Ear Culture 0% Q2-2017 b. For eight (8) out of eight (8) random patient sampling test results reviewed covering period from 2/25/2017 to 7/24/2017, the laboratory analyzed and reported eye, ear, wound culture and sensitivity during the approximate period that the laboratory received an unsatisfactory proficiency testing scores. c. The technical supervisor confirmed (11/27/2018, 1600), that the laboratory received the above unsatisfactory proficiency test scores.
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 the second quarter (Q2-2018) of the American Proficiency Institute (API) proficiency testing records, random patient sampling test results, and

	interview with the technical consultant, it was determined that the laboratory failed to 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. The findings included: a. Q2-2018, API reported 60% for Iron, Total analyte. b. For four (4) out of four (4) random patient sampling test results reviewed covering period from 5/25 /2018 to 6/4/2018, the laboratory analyzed and reported Iron, Total analyte during the time the laboratory received an unsatisfactory proficiency testing score. c. The technical consultant confirmed (11/27/2018, 1600), that the laboratory received the above unsatisfactory proficiency test score.
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 the first quarter (Q1-2017) of the American Proficiency Institute (API) proficiency testing records, random patient sampling test results, and interview with the technical supervisor, it was determined that the laboratory failed to 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. The findings included: a. Q1-2017 API reported 50% for Direct Antiglobulin Antibody Test (DAT) IgG analyte. b. For two (2) out of two (2) random patient sampling test results reviewed covering period from 6/4/2018 to 11/29/2018, the laboratory analyzed and reported DAT test during the approximate time the laboratory received an unsatisfactory proficiency testing score. c. The technical supervisor confirmed (11/27/2018, 1600), that the laboratory received the above unsatisfactory proficiency test score.
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 request, direct observation for the 0.5 McFarland Solution Lot #: 12171, expiration date" 12/11/13, Cat #: ML05, interview with the testing personnel, and review of the laboratory's policy and procedure, it was determined that the laboratory failed to ensure that the laboratory must not use reagents when they have exceeded their expiration date, have deteriorated, or are of substandard quality. The findings included: a. On the day of the survey (11/27/2018), the surveyor directly observed that the 0.5 McFarland solution has expired since 2013. b. For eight (8) out of eight (8) random patient sampling test results reviewed covering period from 2/25/2017 to 7/24 /2017, the laboratory analyzed and reported eye, ear, wound culture and sensitivity. c. The testing personnel confirmed (11/27/2018, 1600), that the laboratory has been using an expired 0.5 McFarland standard for almost 5 years.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g)

	(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on request and the lack of documentation for Wright Stain, stain reactivity performance, random patient sampling test results reviewed, and interview with the technical supervisor, it was determined that the laboratory failed to each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. The laboratory must document all control procedures performed. The findings included: a. The laboratory has no documentation to show that Wright Stain, staining criteria has been met. b. For nine (9) out of nine (9) random patient sampling test results reviewed covering period from 11/12/2016 to 5/30/2018, the laboratory analyzed and reported approximately 124,000 Complete Blood Count (CBC) tests with manual differential count. c. The technical supervisor confirmed (11/27/2018, 1600) that there was no stain reactivity performance and documentation.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on request, review of the laboratory's Disk Diffusion, and the (Epsiloemeter Test (E-Test) Policies and Procedures and interview with the testing personnel, the laboratory failed to follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291. The findings included: a. On the day of the survey (11 /27/2018), based on direct observation of the 0.5 McFarland turbidity standards, lot #: 12171, Exp date: 12/11/13, Cat #: ML05, the laboratory has been using an expired 0.5 McFarland standard for almost 5 years. . The Laboratory's Disk Diffusion Policy and Procedure stated: "Select 4-5 isolated colonies of the same morphological type and inoculate into sterile water so that the turbidity is that of the 0.5 McFarland standards." The E-Test policy and procedure stated: "Inoculation Preparation, Compare turbidity to that in the 0.5 McFarland standards. Adjust turbidity of inoculum to match that standard." Note: 0.5 McFarland standards are essential in the turbidity preparation of an inoculum for the sensitivity test on both Mueller Hinton and E-Test procedures. b. For eight (8) out of eight (8) random patient sampling test results reviewed covering period from 2/25/2017 to 7/24/2017, the laboratory analyzed and reported eye, ear, wound culture and sensitivity. c. The technical supervisor, testing personnel confirmed (11/27/2018, 1600) that the laboratory did not follow the Disk Diffusion and the E-Test Policies and using an expired 0.5 McFarland standard for 5 years.

D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on request, review of the laboratory's Critical Value Reporting Policy and Procedure and interview with the technical supervisor, the laboratory failed to follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291. The findings included: a. The laboratory Critical Value Reporting Policy stated: "Read Back can be documented in the appropriate box or written in comments." b. For three (3) out of three (3) random patient sampling test results reviewed covering period from 11/26/2018 to 11/27/2018, three critical calls indicated "N" on the read back box. c. The technical supervisor, confirmed (11/27/2018, 1600) that the laboratory did not follow the Critical Value Reporting Policy and Procedure.
D6021	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 quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, procedures for Critical Value reporting, Disk Diffusion test, and the E-Test, and interview with the technical supervisor and testing personnel, it was determined that the laboratory director failed to ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. See D 5791 and D 5891.