Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0612446	05/05/2022
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
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 American Proficiency Institute (API) proficiency testing (PT) records, randomly chosen patient results' review, and interview with the general supervisor (GS); it was determined that the laboratory failed to attain a score of at least 80 percent of acceptable responses for the following Routine Chemistry analytes: Calcium ionized (Blood Gas), CO2, pH, and pCO2 for the third event of 2021 (Q3-2021). The finding included: 1. Based on review of PT records for the Q3-2021 API reported the following unsatisfactory scores: Analyte Score Calcium 0% CO2 20% pH 20% pO2 0% 2. Based on the laboratory testing declaration submitted at the time of the survey on May 5, 2022, the laboratory analyzed and reported approximately 364,049 Routine Chemistry tests during the time the laboratory had unsatisfactory proficiency testing results. 3. The GS affirmed on 05/05/202 2at approximately 11:15 a.m. that the laboratory received the above unsatisfactory proficiency testing scores.
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 the American Proficiency Institute (API) proficiency testing (PT) records, random patient sampling test results, and interview with the general

	supervisor (GS) and laboratory testing personnel (TP); it was determined that the laboratory failed to attain a score of at least 80 percent of acceptable responses for Parathyroid Hormone analyte PT for the Second Event of 2021 (Q2-2021). The findings included: 1. Analyte Event Performance PTH Q2-2021 50% 2. For one (1) out of seven (7) random patient sampling test results reviewed covering period from 10 /11/2021 to 2/17/2022, the laboratory analyzed and reported approximately 2,160 PTH test results during the period the laboratory received the unsatisfactory proficiency testing score. 3. The GS and TP confirmed on May 5, 2022, at approximately 11:15 a.m. that the laboratory received the above unsatisfactory proficiency testing scores for PTH.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on the surveyor's observation during the laboratory tour, lack of calibration records, and interview with the laboratory's testing personnel (TP); it was determined that the laboratory failed to perform annually the calibration of the microscope's ocular lenses according to the criteria verified or established by the laboratory as specified in 493.1253(b)(3)- when identifying ova and parasites. The findings included: 1. The laboratory performs identification of ova and parasites test procedures by light microscopy (Olympus Microscope). 2. The laboratory did not have available the calibration record of the microscope's oculars, procedure, or documentation of performing calibration of the oculars when identifying ova and parasites. 3. The TP affirmed on May 5, 2022, at approximately 12:00 p.m., that calibration of the microscope's ocular have not taken place annually. 5. According to the testing volume declaration at the time of the survey, the laboratory performed 30 parasitology samples annually.
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 review of patient test records, laboratory's policy and procedure manual, and interview with the general supervisor (GS) and testing personnel (TP); it was determined that the laboratory failed to establish written policies and procedures for

	an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the post analytic systems. The findings included: 1. The laboratory did not have a written policy or procedure of turnaround time (TAT) established for all the tests performed in the laboratory. 2. Based on the laboratory's annual test declaration submitted at the time of the survey on May 5, 2022; the laboratory analyzed and reported 407,422 test results for which there was no TAT established policy to monitor timely test results reporting during the postanalytic phase of testing. 3. The GS and TP affirmed on May 5, 2022, at approximately 11:30 a.m. that the laboratory did not have a written policy or procedure for monitoring TAT for each test performed in the laboratory.
D6082	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1) The laboratory director must ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing. This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing, lack of calibration and documentation for the microscope oculars, lack of establishment of tests' turnaround time, and interview with the laboratory's general supervisor and testing personnel on May 5, 2022; it was determined that the laboratory director failed to ensure that several aspects of the preanalytic, analytic, and postanalytic phases of laboratory testing were monitored. See D2087, D2098, D5437, and D5891.