Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0612446	10/16/2025
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
D2075	GENERAL IMMUNOLOGY CFR(s): 493.837(a) (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 surveyor's review of the American Proficiency Institute (API) proficiency testing (PT) records, nine randomly chosen patient reports, and interviews with the laboratory manager (LM) and technical consultant (TC); it was determined that the laboratory failed to attain a score of at least 80 percent of acceptable responses for the high sensitivity C-Reactive protein (hs-CRP) analyte. The findings include: 1. The laboratory participated in the API PT program and obtained an unsatisfactory score of 0% for the hs-CRP analyte during the first event of 2025 (Q1-2025). The results are as follows: Specimen Reported Expected HS-01 *0.560 0.000 - 0.159 HS-02 *3.827 0.273 - 0.509 HS-03 *6.400 0.456 - 0.848 HS-04 *1.773 0.087 - 0.288 HS-05 *6.603 0.456 - 0.849 Legend: * = unsatisfactory score 2. The LM and TC affirmed by interviews on October 16, 2025, at approximately 11:00 a.m. that the laboratory received the unsatisfactory PT scores for hs-CRP analyte as mentioned in statement#1. 3. The quality and reliability of patient results reported cannot be assured. 4. According to the testing declaration form submitted at the time of survey, the laboratory tested and reported approximately 1,336 hs-CRP test patient samples annually including the time when unsatisfactory scores were obtained. .
D2109	TOXICOLOGY CFR(s): 493.845(a) (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) results, and interviews with the laboratory manager (LM) and technical consultant (TC); it was determined that the laboratory failed to attain a score of at least 80 percent of acceptable responses for the salicylate analyte for the second event of 2025 (Q2-2025) obtaining an unsatisfactory performance. The findings include: 1. The laboratory performed salicylate, an analyte under Toxicology subspecialty. 2. The laboratory enrolled its proficiency testing program with API PT program and received a 40% unsatisfactory score for the Q2-2025 event for the salicylate analyte. The result as follows: Sample Reported Expected CH-06 8.0 5.8 - 8.0 CH-07 32.0 24.2 - 32.8 CH-08 *17.0 12.3 - 16.7 CH-09 *26.0 18.9 - 25.7 CH-10 *45.0 31.9 - 43.2 Legend: * = unsatisfactory score 3. The laboratory performed salicylate in approximately 191 patient samples annually. 4. The LM and TC affirmed by interviews on October 16, 2025, at approximately 11:00 a.m. that the laboratory attained a score of 40% for the salicylate analyte in the Q2-2025 Toxicology PT event, which was an unsatisfactory performance. .
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on the surveyor's review of nine randomly chosen patient records, lack of personnel competency documentation, and interviews with the laboratory manager (LM) and technical consultant (TC); as specified in the personnel requirements in subpart M, it was determined that the laboratory failed to perform competency assessment for the personnel involved in patient testing. The findings include: 1. The surveyor reviewed nine randomly chosen patient records wherein, three testing personnel were missing competency assessment records, affecting five out of nine. 2. The quality and reliability of patient samples processed and reported could not be assured. 3. The LM and TC stated in interviews on October 16, 2025, at approximately 3:45 p.m. that several of their testing personnel lacked records for competency assessments for the years 2023, 2024, and 2025. 4. According to the testing declaration form (Lab-144) submitted at the time of the survey, the laboratory reported and performed approximately 446, 928 patient samples annually, including the time when competency assessments for several testing personnel were missed.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) (d)(3)(i) Each quantitative procedure, include two control materials of different concentrations; This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedure manual, nine randomly

	chosen patient testing records, lack of quality control documentation, and interviews with the laboratory manager (LM) and technical consultant (TC); the laboratory failed to retain all levels of quantitative quality control (QC) for each day of patient testing. The findings include: 1. The surveyor reviewed nine patient records and one out of nine was missing the quality control documentation for review. 2. The LM and TC affirmed by interviews on October 16, 2025, at approximately 3:45 p.m. that the laboratory was unable to obtain past records for the complete blood count quality control, specifically for September 28, 2022. 3. According to the testing declaration form submitted at the time of survey, the laboratory performed and reported approximately 118,527 complete blood count tests including the time when records were not properly retained.
D5789	TEST RECORDS CFR(s): 493.1283(b) (b) Records of patient testing including, if applicable, instrument printouts, must be retained. This STANDARD is not met as evidenced by: Based on the surveyor's review of the laboratory's policy/procedure, nine patient records, preventive maintenance (PM) records, and interviews with the laboratory manager (LM) and technical consultant (TC); it was determined that the laboratory failed to retain test records. The findings include: 1. The laboratory's current practice involved the use of an electronic medical record (EMR) system that kept final reports but still retained the original reports printed from the instrument as well as the hadcopies of the PM performed. 2. The surveyor examined nine patient records, but one record could not be retrieved by the laboratory for the original test result and PM, specifically for Patient#082197 on March 10, 2022. 3. The LM and TC affirmed by interviews on October 16, 2025, at approximately 3:45 p.m., that the records for the patient and instrument PM mentioned in statement #2 were unavailable. 4. According to the testing declaration submitted at the time of survey, the laboratory processed and reported approximately 118,111 complete blood count patient samples annually including the time when the records of the patient and instrument PM were not retained properly. The quality and reliability of patient tests reported cannot be assured.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) (e)(4)(i) The proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on the surveyor's review of the unsatisfactory proficiency testing score for the year 2025 and interviews with the laboratory manager and technical consultant, the laboratory director is herein cited for failure to ensure that proficiency testing samples were tested as required under Subpart H of this part. The findings include: 1. Unsatisfactory proficiency testing score for General Immunology. See D2075. 2. Unsatisfactory proficiency testing score for Toxicology. See D2109.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES

	CFR(s): 493.1407(e)(5) (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur; This STANDARD is not met as evidenced by: Based on the surveyor's findings on October 16, 2025, lack of quality control documentation, preventive maintenance records, and instriument print-outs; the laboratory director is herein cited for the deficient practice of failure to ensure retention of documentation was followed. The findings include: 1. Missing quality control records. See D5447. 2. Missing test records. See D5789.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) (e)(12) Ensure that prior to testing patients specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results; This STANDARD is not met as evidenced by: Based on the lack of personnel competency assessment records, review of nine patient records, and interviews with the laboratory manager and technical consultant, it was determined that the laboratory director is herein cited for failure to ensure that prior to testing patient specimens, competency assessment were performed for all personnel involved in testing. See D5209.