Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0618601	01/10/2018
Name of Provider or Supplier	**Street Address, City, State**	
Surprise Valley Health Care	741 Main St, Cedarville, 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 request and the lack of documentation in a proficiency testing (PT) program, random patient sampling test results and interview with the technical consultant, the laboratory failed to enroll for the Prothrombin Time (PT) test. The findings included: a. There was no documentation of PT enrollment for the Prothrombin Time test performed in an iStat instrument. b. For eighty five ((85) out of eighty five random patient sampling test results reviewed from 3/26/2017 to 1/7/2018, the laboratory analyzed and reported the above patients without the PT enrollment. c. The technical consultant affirmed (1/10/2018, 1330), that the laboratory failed to enroll in a PT program for Prothrombin Time test.
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 review and the lack of documentation in a proficiency testing (PT) program, random patient sampling test results and interview with the technical consultant, the laboratory failed to enroll for the Prothrombin Time (PT) test. The findings included: a. There was no documentation of PT enrollment for the Prothrombin Time test performed in an iStat instrument. b. For eighty five ((85) out of eighty five random patient sampling test results reviewed from 3/26/2017 to 1/7/2018, the laboratory analyzed and reported the above patients without the PT enrollment. c. The technical consultant affirmed (1/10/2018, 1330), that the laboratory failed to enroll in a PT program for Prothrombin Time test.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on review, request and the lack of documentation for refrigerator, freezer, instrument's, and other equipment temperature logs needed for reagent, QC materials storage and interview with the technical consultant (testing personnel), it was determined that the laboratory failed to document and retain temperature logs. The finding included: a. The laboratory failed to perform, document, and retain temperature logs for the following dates: 1/25/2016, 4/28/2016, 7/1/2016, 7/5/2016, 7 /6/2016, 10/12/2016, 10/21/2016, and 10/25/2016. b. The technical consultant (testing personnel) affirmed (1/10/2018, 1330), that the laboratory has no documentation of temperature logs to show for the above dates.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(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--

	At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review and the lack of documentation for Quality Control (QC) materials performed for Routine Chemistry, Complete Blood Count (CBC), PT/INR, random patient sampling test results and interview with the technical consultant (testing personnel), the laboratory failed to document all control procedure performed. The findings included: a. The laboratory has no documentation of QC materials have been performed for the following tests. Date: Patient: Test: 1/25/16 13781 CMP, Lipid, Cardiac, CBC, UA 4/28/16 11865 PT/INR 4/28/16 11844 PT/INR 7/1/16 40018 UA 7 /5/16 10989 PT/INR 7/5/`16 14763 UA 7/5/16 1167 A1C 7/6/16 10038 UA, A1C 10 /12/16 10592 BNP, CBC 10/21/16 19399 CBC, CMP, Lipid, Mg 10/25/16 10017 Hepatic Panels Lipid 1/15/17 10592 CBC, CMP, Troponin BNP, UA b. The technical consultant (testing personnel) affirmed (1/10/2018, 1330) that the laboratory has no documentation to show for the performance of QC materials for each of the above tests.
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 review and the lack of documentation for Wright's stain reactivity, random patient sampling test results and interview with the technical supervisor(testing personnel), it was determined that the laboratory failed to each day of use , test staining materials for intended reactivity to ensure predictable staining characteristics. The findings included: a. The laboratory stains with Wright Stain for the laboratory's manual differential count, but reactivity is not being documented. b. For seventeen out of seventeen random patient sampling test results reviewed from 1/25/2016 to 1 /52018, the laboratory analyzed and reported 1200 CBC that included WBC manual differential tests. c. The technical supervisor (testing personnel) affirmed (1/10/2018, 1330), that the laboratory has no documentation to show for the stain reactivity.
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 review and the lack of documentation for test using different methodologies or instruments (Horiba ABX Micros 60) vs manual differential to evaluate twice a year, random patient sampling test results reviewed and interview with the technical supervisor (testing personnel) it was determined that the laboratory failed to perform comparison between different methodologies or instruments. The findings included: a. The laboratory uses Horiba ABX Micros 60 for CBC tests and performing WBC manual differential, the laboratory has no documentation of twice a year comparison studies between the two methodologies. b. For seventeen out of seventeen random patient sampling test results reviewed from 1/25/2016 to 1/52018, the laboratory analyzed and reported 1200 CBC that included WBC manual differential tests. c. The technical supervisor (testing personnel) affirmed (1/10/2018, 1330), that the laboratory has no documentation to show for the twice a year comparison studies for Auto differential vs manual differential.
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 and the lack of establish and written policy and procedure for record retention, random patient sampling test results and interview with the technical consultant (testing personnel), it was determined that the laboratory failed to establish and follow written policy and procedure for the laboratory's record retention. The findings included: a. The laboratory has no policy and procedure in regards to record retention policy such as QC materials performance (See D 5447). b. The laboratory has no documentation to show for equipment temperatures needed for reagents and control storage as recommended by the manufacturer. (See D 5413). c. The technical consultant (testing personnel) affirmed (1/10/2018, 1330) that the laboratory failed to establish and follow written policy and procedure for the laboratory's record retention.
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 review, and the lack of documentation for the laboratory's PT enrollment for Prothrombin Time test, record retention policy and procedure, QC materials not performed, comparison studies between to methodologies and interview with the technical consultant (testing personnel), it was determined that the laboratory director failed to ensure meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. See D 6021.
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, and the lack of documentation for the laboratory's PT enrollment for Prothrombin Time test, record retention policy and procedure, QC materials performance, comparison studies between to methodologies and interview with the technical consultant (testing personnel), it was determined that the laboratory director failed to ensure responsibly 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 and to ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. See D 5413, D 5447, D 5473, D 5775, and D 5891.