Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0618601	04/07/2021
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
D2153	ABO GROUP AND D(RHO) TYPING CFR(s): 493.859(a) Failure to attain a score of at least 100 percent of acceptable responses for each analyte or test in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's API proficiency testing (PT) records, and interview with the laboratory general supervisor on April 7, 2021 at 1:57 pm, the laboratory failed to attain a score of at least 100 percent of acceptable responses for ABO group and D type in 2020. The findings include: 1. The laboratory participated in the API PT events for the year of 2020. It received 80% of acceptable responses for ABO group at the 3rd event of 2020, and for D type at the 2nd event of 2020. 2. The laboratory general supervisor on April 7, 2021 at 1:57 pm, affirmed that the laboratory did not receive 100 percent of acceptable responses for ABO group and D type in 2020. 3. The laboratory's testing declaration form, signed by the laboratory director on 4/22/2021, stated that the laboratory performs 1 ABO group and D type tests, annually.
D2160	ABO GROUP AND D(RHO) TYPING CFR(s): 493.859(e) (1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or unsatisfactory testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

	This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's policy & procedure, API proficiency testing (PT) and corrective actions records, and interview with the laboratory general supervisor on April 7, 2021 at 1:57 pm, the laboratory failed to undertake appropriate training and employ the technical assistance necessary to correct problems associated with unsatisfactory PT events for ABO group and D type in 2020. The findings include: 1. The laboratory did not receive 100% but received a score of 80% of acceptable responses for ABO group at the 3rd event in 2020, and for D type at the 2nd event in 2020 of API PT events. Those were unsatisfactory testing events and the laboratory required to undertake appropriate training and employ the technical assistance necessary to correct problems associated with the PT failure. However, the laboratory's PT performance review and corrective action document signed by the laboratory director on 2/1/2021 stated that no corrective action necessary. 2. The laboratory general supervisor on April 7, 2021 at 1:57 pm, affirmed that the laboratory did not take any corrective action after having an unsatisfactory PT event. 3. The laboratory's testing declaration form, signed by the laboratory director on 4/22/2021, stated that the laboratory performs 1 ABO group and D type tests, annually.
D2173	COMPATIBILITY TESTING CFR(s): 493.863(a) Failure to attain an overall testing event score of at least 100 percent is unsatisfactory performance. This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's API proficiency testing (PT) records, and interview with the laboratory general supervisor on April 7, 2021 at 1:57 pm, the laboratory failed to attain a score of at least 100 percent of acceptable responses for compatibility testing at the 3rd event of 2020. The findings include: 1. The laboratory participated in the API PT events for the year of 2020. It received 80% of acceptable responses for compatibility testing at the 3rd event of 2020. 2. The laboratory general supervisor on April 7, 2021 at 1:57 pm, affirmed that the laboratory did not receive 100 percent of acceptable responses for compatibility testing at the 3rd event of 2020. 3. The laboratory's testing declaration form, signed by the laboratory director on 4/22 /2021, stated that the laboratory performs 1 compatibility test, annually.
D2179	COMPATIBILITY TESTING CFR(s): 493.863(d) (1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unsatisfactory testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's policy & procedure, API proficiency testing (PT) and corrective actions records, and interview with the laboratory general supervisor on April 7, 2021 at 1:57 pm, the laboratory failed to undertake appropriate

	training and employ the technical assistance necessary to correct problems associated with unsatisfactory PT events for compatibility testing at the 3rd event of 2020. The findings include: 1. The laboratory did not receive 100% but received a score of 80% of acceptable responses for compatibility testing at the 3rd event of 2020 from API PT events. This was an unsatisfactory testing event and the laboratory required to undertake appropriate training and employ the technical assistance necessary to correct problems associated with the PT failure. However, the laboratory's PT performance review and corrective action document signed by the laboratory director on 2/1/2021 stated that no corrective action necessary. 2. The laboratory general supervisor on April 7, 2021 at 1:57 pm, affirmed that the laboratory did not take any corrective action after having an unsatisfactory PT event. 3. The laboratory's testing declaration form, signed by the laboratory director on 4/22/2021, stated that the laboratory performs 1 compatibility test, annually.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's policy & procedure, random patient sample and quality control records, and interview with the laboratory technical supervisor on April 7, 2021 at 10:15 am, the laboratory failed to perform the testing following the manufacturer's instructions for 2 patients sample out of 20 patients sample reviewed. The findings include: 1. The laboratory tested samples #2104060002 and #2104060003 for COVID-19 on April 6, 2021 by using Biomeme reagents and instrument that uses PCR method. The test result came out as invalid. So, the laboratory re-tested the sample, and again the result came out as invalid. Therefore, according to the manufacturer's instruction, the patient sample must be reported as invalid. However, the laboratory reported the results as negative. The laboratory testing person informed that the invalid samples were re-tested before reporting, and the results were negative, but could not show the testing records. Therefore, it can not be assured that the sample was re-tested and the validity of the reported results. 2. The laboratory technical supervisor on April 7, 2021 at 10:15 am, affirmed that the laboratory reported the results as negative. 3. The laboratory's testing declaration form, signed by the laboratory director on 4/22/2021, stated that the laboratory performs 5,200 COVID-19 PCR tests, annually.
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) 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, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his

	or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's policy & procedure, random patient sample, quality control (QC) and proficiency test records, and interview with the laboratory general supervisor on April 7, 2021 at 1:57 pm, the laboratory director failed to assure laboratory's compliance with the applicable regulations. The findings include: See D2153, D2160, D2173, D2179, D5411, D6087 and D6092.
D6087	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(iii) The laboratory director must ensure that laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's policy & procedure, random patient sample and quality control (QC) records, and interview with the laboratory general supervisor on April 7, 2021 at 10:15 am, the laboratory director failed to ensure that the laboratory personnel are performing the test methods as required for accurate and reliable results. The findings include: See D5411.
D6092	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iv) The laboratory director must ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's policy and procedure, API proficiency testing and corrective actions records, and interview with the laboratory general supervisor on April 7, 2021 at 1:57 pm, the laboratory director failed to ensure that an approved corrective action plan is followed when any proficiency testing result is found to be unsatisfactory. The findings include: See D2153, D2160, D2173 and D2179.