Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0886217	08/17/2021
Name of Provider or Supplier	**Street Address, City, State**	
Central Valley Diagnostic Laboratory	31 W Alexander Ave, Merced, 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
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 of proficiency testing reports from CMS (report 155 - Individual Laboratory Profile), API (American Proficiency Institute), and laboratory proficiency testing records, it was determined that the laboratory failed to successfully participate in a proficiency testing program for each test/analyte in which the laboratory is certified under CLIA. Findings included: 1. The laboratory failed to achieve satisfactory performance in testing for Total Bilirubin and Triglycerides for two out of three consecutive testing events. See D2096. .
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 reviews of 2019 - 2021 Chemistry proficiency testing reports from CMS (report 155, Individual Laboratory Profile) and API (American Proficiency Institute) and laboratory proficiency testing records, and interview with laboratory personnel, it was determined the laboratory failed to attain at least 80% scores for Magnesium (Mg), Sodium (Na), Total Bilirubin, and Total Iron. Findings included: 1. Magnesium a. For 2019: Event 2, CMS and API reported a score of 0% based on the laboratory's 5 unacceptable results out of 5, demonstrating unsatisfactory testing as follows: Sample Lab result API Expected result CH-06 2.8 1.1 - 2.0 CH-07 6.4 2.5 - 4.3 CH-08 4.9 2.0 - 3.5 CH-09 5.8 2.4 - 4.2 CH-10 4.2 1.8 - 3.1 b. For 4 out of 4 test results selected at random from the timeframe May - August 2021 for this survey, the laboratory analyzed and reported results for Magnesium when test performance was unsatisfactory: Date Accession # 7/03/19 582 - 979 7/17/19 583 - 667 7/19/19 583 - 761 7/24/19 584 - 024 2. Sodium (Na) a. For 2021: Event 1, CMS and API reported a score of 60% based on the laboratory's 2 unacceptable results out of 5, demonstrating unsatisfactory testing as follows: Sample Lab result API, Mean result CH-02 122 128.7 CH-04 164 169.1 b. For 3 out of 3 test results selected at random from the timeframe January - April 2021 for this survey, the laboratory analyzed and reported results for Na when test performance was unsatisfactory: Date Accession # 3/26/21 343134 4/07/21 343509 4/20/21 343882 3. Total Bilirubin a. For 2021: Event 2, CMS and API reported a score of 0% based on the laboratory's 5 unacceptable results out of 5, demonstrating unsatisfactory testing as follows: Sample Lab result API, Mean result CH-06 2.0 0.59 CH-07 3.2 1.59 CH-08 4.9 3.35 CH-09 4.1 2.58 CH-10 5.7 4.04 b. For 3 out of 3 test results selected at random from the timeframe May - August 2021 for this survey, the laboratory analyzed and reported results for Total Bilirubin when test performance was unsatisfactory: Date Accession # 5/10/21 344439 5/13/21 344589 5/28/21 345036 4. Total Iron a. For 2021: Event 2, CMS and API reported a score of 60% based on the laboratory's 2 unacceptable results out of 5, demonstrating unsatisfactory testing as follows: Sample Lab result API, Mean result CH-07 63 86.8 CH-08 102 141.4 b. For 3 out of 3 test results selected at random from the timeframe May - August 2021 for this survey, the laboratory analyzed and reported results for Total Iron when test performance was unsatisfactory: Date Accession # 6/10/21 345385 7/01/21 345914 7/22/21 346507 5. The reliability and quality of results for Magnesium, Sodium, Total Bilirubin, and Total Iron reported during the aforementioned timeframes could not be assured. .
D2096	ROUTINE CHEMISTRY CFR(s): 493.841(f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: . Based on review of Chemistry proficiency testing reports (CMS report 155), API reports, and laboratory's records, it was determined that the laboratory failed to

	achieve satisfactory performance and scores of at least 80% for two out of three consecutive testing events, constituting unsuccessful testing for Total Bilirubin and Triglycerides. Findings included: 1. Total Bilirubin (a) Records showed this was a Non-initial/ Subsequent unsuccessful performance: 2016 Q2 2016 Q3 2019 Q3 2020 Q1 60% 0% 40% 60% (b) The reliability and quality of Total Bilirubin results reported during the timeframe September 2019 - April 2020 could not be assured. For 12 out of 12 test results selected at random for this survey the laboratory tested for Total Bilirubin when test performance was unsuccessful: Date ID Barcode 12/09/2019 27 --- 12/09/2019 26 --- 12/09/2019 31 --- 01/15/2020 40 1000923 01/15/2020 48 1000922 01/27/2020 23 1001269 01/27/2020 17 1001265 02/03/2020 12 1001449 02 /03/2020 3 1001444 02/05/2020 61 1001514 02/06/2020 5 1001549 02/06/2020 6 1001547 Noted: API and laboratory reports documented testing was performed when it was at a different location: Central Valley Diagnostic Laboratory 5805 Capistrano Ave, Ste C Atascadero, CA 93422 2. Triglycerides (a) Records showed this was an initial unsuccessful performance: 2021 Q1 2021 Q2 60% 0% (b) The reliability and quality of results reported during the timeframe January - August 2021 could not be assured. For 6 out of 6 test results selected at random for this survey the laboratory tested for Triglycerides when test performance was unsuccessful: Date Accession# 03 /16/2021 342826 04/09/2021 343564 04/27/2021 344084 06/03/2021 345144 07/01 /2021 345926 07/08/2021 346221 .
D2109	TOXICOLOGY CFR(s): 493.845(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 reviews of 2019 Toxicology proficiency testing reports from CMS (report 155, Individual Laboratory Profile) and API (American Proficiency Institute), laboratory proficiency testing records, and patients test records, it was determined the laboratory failed to attain at least 80% score for Lithium. Findings included: 1. For 2019: Event 2, CMS and API reported a score of 40% based on the laboratory's 3 unacceptable results out of 5 for Lithium, demonstrating unsatisfactory testing as follows: Sample Lab result API, Mean result CH-07 2.4 1.71 CH-08 1.7 1.30 CH-10 1.5 1.10 2. The reliability and quality of results reported during the timeframe May - July 2019 could not be assured. For 3 out of 3 test results selected at random for this survey, the laboratory analyzed for Lithium when test performance was unsatisfactory: Date Accession # 7/05/19 583 - 102 7/10/19 583 - 342 8/01/19 584 - 416
D2121	HEMATOLOGY CFR(s): 493.851(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 reviews of 2019 Hematology proficiency testing reports from CMS (report 155, Individual Laboratory Profile) and API (American Proficiency Institute), laboratory proficiency testing records, and patients test records, it was determined the

	laboratory failed to attain at least 80% score for Hematocrit and Prothrombin Time (ProTime). Findings included: 1. Hematocrit a. For 2019: Event 1, CMS and API reported a score of 40% based on the laboratory's 3 unacceptable results out of 5, demonstrating unsatisfactory testing as follows: Sample Lab reported API result XE-03 16 45 - 52 XE-04 16 43 - 49 XE-05 6 18 - 21 b. The laboratory document titled, "Performance Review and Corrective Action Documentation", attributed the root cause to clerical transcription errors when manually reporting results to API. c. The effect of this error on patients test reports was not addressed, and thus, the reliability and quality of Hematocrit results reported for the timeframe January - April 2019 could not be assured. 2. Prothrombin Time a. For 2021: Event 1, CMS and API reported a score of 60% based on the laboratory's 2 unacceptable results out of 5, demonstrating unsatisfactory testing. b. The reliability and quality of results could not be assured. For 3 out of 3 test results selected at random from 3/22/21 to 4/12/21, the laboratory analyzed coagulation and reported Prothrombin Time when test performance was unsatisfactory: Date Accession 3/22/21 343001 4/07/21 343494 4/12 /21 343596 .
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of patients test records and a laboratory document by Testing Person-2 summarizing accuracy and precision for "Biomeme PCR SARS-COVID-19" (EUA) that was approved by the Laboratory Director on 8/19/20, the lack of a written procedure, and interview with Testing Person-1, it was determined the laboratory failed to have a written procedure for testing personnel to follow. Findings included: 1. Laboratory documents reviewed were as follows: a. A summary by the Technical Supervisor (Personnel Report: Testing Person-2) for the accuracy and precision of the "Biomeme PCR SARS-COVID-19" (EUA) assay, approved by the Laboratory Director on 8/19/20. b. Test Requisition Forms dated 8/26/20 to 9/03/20 requested "SARS-CoV-2 by RT- PCR (COVID-19)". c. Laboratory PCR assay run records documented tests were performed from 8/28/20 to 9/03/20 by Testing Person-2 at CVDL, location: Atascadero. d. Fifteen (15) patients test results were selected at random from 8/28/20 to 9/03/20 to review for this survey. 2. The laboratory was unable to provide a written procedure for review. The laboratory was unable to provide records that SARS CoV-2 results had been reported to Public Health. 3. Testing Person-1 affirmed (8/17/21 @ 5pm) the laboratory in Atascadero failed to provide a written procedure for the Biomeme PCR assay for SARS-COVID-19. 4. And thus the reliability and quality of SARS-CoV-2 PCR test results reported by the laboratory/Testing Person-2 while at Atascadero could not be assured. .
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the

	manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on observation of the IL- ACL1000 coagulation analyzer (no serial number), review of laboratory records and patients test reports, the lack of laboratory documents, and interview with laboratory personnel, it was determined the laboratory failed to demonstrate and verify that the test system for Partial Thromboplastin Time (PTT) and Prothrombin Time (ProTime) obtained accuracy, precision, and reportable range of results comparable to manufacturer's established specifications. Findings included: 1. Laboratory records documented that 10 Normal patients specimen had been tested to verify the reference range for use with the new lot number of thromboplastin. However, the laboratory failed to provide for review documents for verifying the test system's accuracy, precision, and reportable range prior to testing patients specimen. 2. Laboratory personnel affirmed (8/17/21 @ 4pm) that the ACL-1000 was put into use in November 2020; and the failure to verify that the test system obtained results that were accurate, reproducible, and within the reportable range established by the manufacturer. 3. For 6 out of 6 patients test results randomly selected from 3/22/21 to 4/12/21, the laboratory analyzed and reported coagulation testing without first verifying the test system for accuracy, precision, and reportable range. The reliability and quality of PTT and ProTime results reported since November 2020 could not be assured. .
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 the findings and cumulative effect of deficiencies cited, the Condition: Laboratories Performing Moderate Complexity Testing: Laboratory Director was not met. The Laboratory Director, moderate complexity testing, is herein cited for failing to ensure that proficiency test samples were tested as required under Subpart H of this part. (See D6016)
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) 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)(4)(i) Ensure that 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 findings and deficiencies cited, the Laboratory Director is herein cited for deficient practice in responsibility for overall operation and administration of the laboratory to ensure proficiency testing samples are tested as required under Subpart H of this part: for Total Bilirubin and Triglycerides, the laboratory repeatedly failed to achieve satisfactory performance for the same analyte or test in two out of three consecutive testing events, constituting unsuccessful proficiency test performance. (See D2016 and D2096)
D6040	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(2) The technical consultant is responsible for-- (b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system. This STANDARD is not met as evidenced by: Based on the findings and deficiency cited, the Technical Consultants (Laboratory Director and Testing Person-1) are herein cited for deficient practice in responsibility for verifying test sytem performance (analyzer, reagents, QC, operators) for accuracy, precision, and reportable range prior to testing patients specimen. Findings included: 1. The laboratory installed a Coagulation analyzer, ACL 1000, and began testing patients specimen prior to verifying the test system could provide accurate and reproducible results within the reportable range as established by the manufacturer.