Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D2319952	06/03/2026
Name of Provider or Supplier	**Street Address, City, State**	
Diamed Laboratory Services Inc	8162 Van Nuys Blvd, Panorama City, 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
D2121	HEMATOLOGY CFR(s): 493.851(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 the surveyors' review of the American Proficiency Institute (API) proficiency testing (PT) records, the CASPER 0155D report, and an interview with the technical consultant (TC) on June 3, 2026, it was determined that the laboratory failed to achieve at least 80 percent acceptable responses for the White Blood Cell (WBC) Differential analyte during the third PT event in 2025 (Q3-2025) under the Hematology specialty. The findings include: 1. Review of the laboratory's API PT records showed that the laboratory received an unsatisfactory score of 20% for the WBC Differential analyte in the Q3-2025 event. This result was further verified through the CASPER 0155D report. 2. The TC confirmed by an interview on June 3, 2026, at approximately 10:20 a.m. that the laboratory obtained the PT unsatisfactory score as mentioned in statement #1. 3. According to the testing declaration form (Lab-144) submitted on the day of the survey, the laboratory tested and reported approximately 4,214 patient sample results annually for Hematology specialty that included the WBC Differential analyte. .
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratorys and, as applicable, the manufacturers test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.

	This STANDARD is not met as evidenced by: Based on the surveyors' review of the laboratory's quality control (QC) documentation, policy and procedure, eight patient records dated from 07/16/2025 to 01/28/2026, and interviews with the technical consultant (TC) and testing personnel (TP) on June 3, 2026, it was determined that the laboratory failed to perform QC prior to patient testing on October 30, 2025. The findings include: 1. Review of the laboratory's QC documentation and policies and procedures showed that QC must be performed and acceptable prior to patient testing. This was not followed specifically on October 30, 2025 for the Vitamin D test. 2. The surveyors reviewed eight patient records dated from 07/16/2025 to 01/28/2026 and found one record (Accession #25302012) in which Vitamin D test was performed outside the QC validity on October 30, 2025. 3. Further review of patient record for Vitamin D tested on October 30, 2025, showed that a total of 10 patient samples-including the accession identified during the record review-were tested beyond QC validity. a. The QC for Vitamin D was performed on October 29, 2025 at 11:14 a.m. for level 1 and at 11:18 a.m. for level 3. b. The next QC performed for Vitamin D was on October 30, 2025 at 6:12 p. m. for level 1 and at 6:17 p.m. for level 3. c. The records performed on October 30, 2025 are as followed: Accession | Time Tested - | - 25302013 | 1:44 p.m. 25302014 | 1: 48 p.m. 25302015 | 1:51 p.m. 25302016 | 1:52 p.m. 25302001 | 2:03 p.m. 25302008 | 2:06 p.m. 25302009 | 2:10 p.m. 25302010 | 2:13 p.m. 25302011 | 2:15 p.m. 25302012 | 2:17 p.m. 4. The TC and TP confirmed in an interview on June 3, 2026, at approximately 11:30 a.m., that the 10 patient samples tested on October 30, 2025, were performed beyond QC validity and that no repeat testing or corrective action was documented. 5. According to the testing declaration form (Lab-144) submitted at the time of the survey, the laboratory tested and reported approximately 13,904 Chemistry tests annually, including the Vitamin D test.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on the lack of corrective action documentation and quality control records, review of the laboratory's quality assessment policy and procedure, eight patient reports dated from 07/16/2025 to 01/28/2026, and interviews with the technical consultant (TC) and testing personnel (TP) on June 3, 2026, it was determined that the laboratory failed to perform and document corrective actions for any testing performed outside of quality control (QC) validity. The findings include: 1. The laboratory failed to follow its quality assessment protocol requiring corrective actions when testing is performed beyond QC validity prior to patient testing. 2. Eight patient test records were randomly selected for review, and one of the eight was performed outside QC validity. In addition, nine other records were found to be tested on the same day as shown below: Accession Date Tested 25302013 10/30/2025 25302014 10 /30/2025 25302015 10/30/2025 25302016 10/30/2025 25302001 10/30/2025 25302008 10/30/2025 25302009 10/30/2025 25302010 10/30/202525302011 10/30

	/2025 25302012* 10/30/2025 Legend: * = accession included in the eight patient test record review 3. Review of QC records showed that QC on October 29, 2025, was performed at approximately 11:00 a.m., and the next QC was not performed until October 30, 2025, at approximately 6:00 p.m. All ten patient tests dated October 30, 2025, were performed during the period in which QC was expired or beyond its validity. 4. The TC and TP confirmed in an interview on June 3, 2026, at approximately 11:30 a.m. that the laboratory performed and reported ten patient test results on October 30, 2025 when QC had expired and that no corrective action report was documented. 5. According to the testing declaration form (Lab-144) submitted at the time of the survey, the laboratory performed and reported approximately 13,904 Chemistry tests annually, including the period in which corrective actions were not documented for testing performed beyond QC validity. .
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 surveyors' review of the laboratory's proficiency testing documentation for White Blood Cell Differential Count analyte during the third event of 2025, and interviews with the technical consultant and testing personnel on June 3, 2026, the laboratory director is herein cited due to failure to ensure that proficiency testing samples were tested as required under Subpart H of this part. See D2121
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 review of the laboratory's policy and procedure, lack of corrective action documentation and interviews with the technical consultant and testing personnel on June 3, 2026, the laboratory director is herein cited for failure to ensure that the quality control and quality assessment policy was followed to ensure compliance. The findings include: 1. The laboratory failed to perform quality control prior to patient testing. See D5481. 2. The laboratory failed to follow their established and approved quality assessment policy, specific to corrective action. See D5783