Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D1009099	01/05/2022
Name of Provider or Supplier	**Street Address, City, State**	
Apex Diagnostic Laboratories	2702 Triana Blvd, Huntsville, AL	

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
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on a review of the CAP (College of American Pathologists) proficiency testing (PT) records, and interviews with the Technical Consultant and the Technical Supervisor, the laboratory failed to produce acceptable quantitative results for 42% of the positive drugs on the 2019-2021 Drug Monitoring for Pain Management (DMPM) CAP surveys. The findings include: 1. A review of the PT records revealed the laboratory failed to produce acceptable quantitative results on the Sciex Triple Quad LC/MS (Liquid Chromatography/Mass Spectrometry) platform for 42 out of 101 (42%) positive drugs on the 2019-2021 DMPM CAP surveys, as follows: A) 2019 DMPM-A: 3 samples with a total of 17 positive drugs, however on a) Sample 01: 2 of 6 drugs were lower than the acceptable ranges b) Sample 02: 2 of 5 drugs were lower than the acceptable ranges B) 2019 DMPM-: 3 samples with a total of 14 positive drugs, however on Sample 06, 2 of 6 drugs were lower than the acceptable range C) 2020 DMPM-A: 3 samples with a total of 18 positive drugs, however on a) Sample 01: 3 of 5 drugs were higher than the acceptable ranges b) Sample 02: 1 of 6 drugs was lower than the acceptable ranges c) Sample 03: 2 of 7 drugs were lower than the acceptable ranges D) 2020 DMPM-B: 3 samples with a total of 19 positive drugs, however on a) Sample 05: 6 of 6 drugs were higher than the acceptable ranges b) Sample 06: 4 of 6 drugs was higher than the acceptable ranges c) Sample 07: 5 of 7 drugs were higher than the acceptable ranges, with 1 of 7 was lower than the acceptable ranges E) 2021 DMPM-A: 3 samples with a total of 16 positive drugs, however on a) Sample 01: 3 of 5 drugs were lower than the acceptable ranges b) Sample 02: 2 of 5 drugs were lower than the acceptable ranges c) Sample 03: 5 of 6 drugs were lower than the acceptable ranges F) 2021 DMPM-B: 3 samples with a total

	of 17 positive drugs, however on Sample 06, 4 of 6 drugs was lower than the acceptable ranges 2. During interviews on 1/5/2022 between 11:40 AM and 12:20 PM, the Technical Supervisor confirmed the quality control results were always within acceptable ranges, however she was unable to give a definitive reason for the discrepancies in the CAP PT quantitative results for this laboratory when compared with a majority of other labs using LC/MS platforms; the Technical Supervisor theorized lower cutoff ranges for their platform, diluting samples that tested above the linear limit, and PM (Preventative Maintenance) issues during the COVID pandemic as possible reasons. The surveyor explained the laboratory was required to have a mechanism verifying the accuracy of their quantitative results at least twice annually. If CAP did not have participants using comparable LC/MS procedure platforms, the laboratory must find another method to verify the accuracy of their quantitative results. .
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on reviews of the Horiba ABx Micros 60 Hematology analyzer records, and an interview with the Technical Consultant and the Technical Supervisor, the surveyor determined the laboratory failed to follow the laboratory's procedure on calibration frequency. This affected two of four Hematology calibrations in 2020-2021. The findings include: 1. A review of the Horiba ABx Micros 60 Hematology analyzer records revealed the following: A) No calibration in March 2020; a note documented the Horiba technician would not come because of COVID B) Acceptable calibration on 9/21/2020 C) Acceptable calibration on 4/27/2021 D) No calibration in October 2021; a note dated 1/4/2022 from the Technical Consultant documented Horiba had stopped "drop shipments" (standing orders) so the laboratory had missed performing the calibration. 2. During an interview on 1/5/2022 at 3:04 PM, the surveyor asked how often Horiba calibrations should be performed. The Technical Consultant and Technical Supervisor confirmed the policy has been to perform calibrations every six months. The Technical Supervisor explained she had not realized the laboratory should have ordered the calibrator and performed the calibration when the Horiba technician was unable to make site visits. In addition, the Technical Consultant and Technical Supervisor confirmed no one noticed drop shipments were discontinued in late 2021, so a calibration was not performed until the day of the survey on 1/5/2022. .
D6090	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(ii) The laboratory director must ensure the results are returned within the timeframes

	established by the proficiency testing program. This STANDARD is not met as evidenced by: Based on a review of the API (American Proficiency Institute) proficiency testing (PT) records, and an interview with the Technical Consultant, the Laboratory Director failed to ensure results were submitted within the timeframes established by API for one of two 2020 Urine Drug Screen (UDS) surveys. The findings include: 1. A review of the API 2020 PT records revealed no scores for the 2020 Event #2 UDS survey. Only instrument printouts dated 10/27/2020 were available for this survey. 2. During an interview on 1/5/2021 at 9:20 AM, the surveyor requested the 2020 Event #2 UDS records. The Technical Consultant explained the laboratory did not submit the results by the deadline, and received a 0 % score for "Failure to Participate" SURVEYOR ID#32558 Licensure and Certification Surveyor