Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D2017133	08/11/2021
Name of Provider or Supplier	**Street Address, City, State**	
Valley Pain Clinic	2208 Danville Rd St G, Decatur, 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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on a review of American Proficiency Institute (API) Proficiency Testing (PT) records and an interview with the Testing Personnel, the Laboratory Director and Testing Personnel failed to sign the attestation statements for four out of four 2019 - 2020 PT events reviewed. The findings include: 1. A review of API Urine Drug Screen PT records revealed the following: A) 2019-Events #1 and #2: Attestation statements not signed by the Laboratory Director or the Testing Personnel B) 2020-Event #1: The attestation statement was not retained or available C) 2020-Event #2: Attestation statement not signed by the Laboratory Director 2. A review of "Proficiency Testing" in the Policy and Procedure Manual revealed, "...14. The Medical Director designates that the Technical Director and the testing personnel must sign the attestation page prior to submitting the results to API ...". [Note: The Laboratory Director and the Technical Supervisor are the same individual on the Form CMS-209--Laboratory Personnel Report.] 3. During an interview with the Testing Personnel on 8/11/2021 at 10:50 AM, the surveyor reviewed the instructions on the attestation statement requiring the Laboratory Director (or designee) and testing personnel to sign the document. Testing Personnel #1 explained when the laboratory entered the results electronically, she had not known signing the statement was still a requirement. .
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)

	Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on a review of Quality Control (QC) records, Corrective Action logs, a lack of manufacturer's QC insert sheets, and an interview with the Testing Personnel, the laboratory failed to print and retain inserts to ensure QC ranges on the Indiko Plus Chemistry analyzer (used for qualitative Urine Drug Screen testing) were within the manufacturer's specifications. The surveyor further noted the laboratory had failed to implement a method to track and document the Lot number/Expiry of QC, reagents and calibrators utilized since the previous inspection on 3/13/2019. The findings include: 1. A review of 2021 QC records revealed one level of QC for the following analytes were outside acceptable ranges as follows: A) Ethanol (ETOH): Eleven days B) Methadone (MDT): Six days C) Cocaine (COC): Three days D) Oxycodone (OXY): Two days E) Amphetamines (AMP): Two days, and F) Heroin metabolite (6-AM): One day 2. A review of the Corrective Action for these days revealed, "In manufacturer's range", and the Testing Personnel had proceeded with patient testing with no further corrective action. 3. During an interview on 8/11/2021 at 1:45 PM, the surveyor requested the assay sheets for the QC used for each of the above tests to review the ranges specified by the manufacturer. The Testing Personnel explained the QC does not come with assay sheets. The surveyor reviewed the boxes for the QC currently in use with the notation, "For insert updates, go to www.thermofisher.com /diagnostics". The surveyor explained the laboratory was required to download the inserts with any new updates to ensure ranges in use and other instructions were the same, and implement changes when necessary. The surveyor further noted the laboratory had failed to implement a method to track and document the Lot number /Expiry of QC, reagents and calibrators utilized since the previous inspection on 3/13 /2019. .
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on a review of personnel files and an interview with the Testing Personnel and the Clinic Administrator, the Technical Supervisor (who also serves as the Laboratory Director) failed to perform and document a semi-annual competency evaluation (due in 2019) on one of one testing personnel. The findings include: 1. A review of personnel files revealed the Testing Personnel was trained on 2/6/2019 (reviewed during the previous survey). There was no documentation of a semi-annual competency evaluation due in 2019, and the employee's performance was not evaluated until 8/21/2020 (eighteen months after the original training) via an off-site record review. 2. During an interview on 8/11/2021 at 11:15 AM, the Testing Personnel and the Clinic Administrator stated they did not know about the requirement for semi-annual evaluations. SURVEYOR ID #32558 Licensure and Certification Surveyor