Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2076634	08/31/2022
Name of Provider or Supplier	**Street Address, City, State**	
Jemin N Gajipara Md Pa	8210 Walnut Hill Ln, #905, Dallas, TX	

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
D0000	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended.
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: I. Based on a review of the laboratory's submitted Centers for Medicare and Medicaid Services (CMS)-116 form, the laboratory's policies, the laboratory's proficiency testing records from 2021, and staff interview, it was revealed that the laboratory failed to have documentation of verifying the accuracy of the non-regulated urine toxicology analyte, Norhydromorphone, at least twice annually in 2021. Findings include: 1. A review of the laboratory's CMS-116 form submitted at survey revealed the following non-regulated urine toxicology analyte was tested by the laboratory: Norhydromorphone 2. A review of the laboratory policy titled, "Proficiency Testing" revealed the following: "Drugs of abuse are not analytes within the specialties /subspecialties that are regulated by CLIA. For analytes that do not require proficiency testing or analytes that are not regulated, the laboratory will verify the accuracy of the test procedure twice annually through external assessment programs or split sample comparisons with another laboratory's instrument/method." 3. A review of the laboratory's proficiency testing records revealed the laboratory failed to have documentation of performing twice annual accuracy assessments for the non-regulated urine toxicology analyte Norhydromorphone in 2021. 4. An interview with the laboratory director on 8/31/22 at 10:00 a.m. in the hallway outside of the laboratory, after review of the records, confirmed the above findings. II. Based on a

	review of the laboratory's policies, a review of the laboratory's proficiency testing records from 2021, and staff interview, it was revealed that the laboratory failed to define the acceptability criteria for the twice annual accuracy assessments of non-regulated toxicology analytes. Findings include: 1. A review of the laboratory's policy titled "Proficiency Testing" revealed the following: "Assessment for Non-Regulated Analytes- Alternate Proficiency When testing is performed on analytes that are not regulated, an alternate proficiency may be performed twice a year to validate the accuracy of the testing procedure. - The comparison of the results must be within the acceptable limits for reporting, i.e., A positive result would be positive, negative result neg, or the same bacteria. If the result is numerical, both results should compare according to the CMS guidelines or as Approved by the Laboratory Director." 2. A review of the laboratory's proficiency testing records from 2021 revealed the laboratory sent samples to a reference laboratory for comparison of results. A CV% (coefficient of variation) was calculated for each analyte. 3. Further review of the laboratory's policies and the proficiency testing records revealed the laboratory failed to define the acceptable CV% value for the toxicology analytes. 4. An interview with the laboratory director on 8/31/22 at 9:30 a.m. in the hallway outside of the laboratory, after review of the records, confirmed the above findings.