

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  45D2076634	<b>(X3) Date Survey Completed</b>  06/04/2024
<b>Name of Provider or Supplier</b>  Jemin N Gajipara Md Pa	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	The laboratory was found to be in substantial compliance with CLIA regulations 42 CFR Part 493. Standard level deficiencies were cited.
<b>D2009</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> CFR(s): 493.801(b)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor observation, review of American Association of Bioanalysts (AAB) proficiency testing (PT) results in 2023 and 2024, and confirmed in interview, the laboratory director and testing personnel failed to attest to the routine integration of PT samples into the patient workload for three of three in 2023 and two of two performed in 2024. Findings included: 1. During a tour of the laboratory on 06/04/2024 at 10:00 AM, the surveyor observed one LCMS analyzer (Serial Number: ARZ1610804) and one IR 500 chemistry analyzer (Serial Number: 140302) performing urine drug testing on patient samples. 2. Review of AAB PT results in 2023 and 2024 revealed no attestation signature pages included in the laboratory PT documentation. Further review of PT documentation revealed the following: "Reporting Results ...2. Be sure to keep attestation statements printed from your online reporting form ...The attestation statements must be signed for each analyte by the analyst performing the procedure and kept in your files for inspection purposes. In addition to analysts signatures, the director or director's designee must sign only once for each reporting form." The surveyor requested the above attestation documentation on 06/04/2024 at 11:40 AM, and none was provided. 3. In an interview on 06/04/2024 at 11:45 AM, testing person 1 (TP-1) stated they did not keep the PT attestation pages in 2023 and 2024. This confirmed the laboratory director and testing personnel failed to attest to the routine integration of PT samples into the patient workload for three of</p>

three in 2023 and two of two performed in 2024. Word Key LCMS- Liquid Chromatography Mass Spectrometry

**D5213**

**EVALUATION OF PROFICIENCY TESTING PERFORMANCE**

CFR(s): 493.1236(b)(1)

The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program.

This STANDARD is not met as evidenced by:

Based on surveyor observation, review of College of American Pathologists (CAP) proficiency testing (PT) results in 2023 and 2024, and confirmed in interview, the laboratory failed to document review of analytes not scored by the proficiency program for one of two in 2023 and one of one performed in 2024. Findings included: 1. During a tour of the laboratory on 06/04/2024 at 10:00 AM, the surveyor observed one AB Sciex LCMS analyzer (Serial Number: ARZ1610804) performing urine drug testing on patient samples. 2. Review of CAP PT records in 2023 and 2024 revealed the following: Drug Monitoring for Pain Management PT (DMPM) I. DMPM-A 2023 a. Method: Norfentanyl Specimen: DMPM-01 Your Grade: See Note 28 b. Method: Methadone Metabolite Specimen: DMPM-02 Your Grade: See Note 28 c. Method: Hydrocodone Specimen: DMPM-03 Your Grade: See Note 28 d. Method: Norhydrocodone Specimen: DMPM-03 Your Grade: See Note 28 II. DMPM-A 2024 a. Method: Oxycodone Specimen: DMPM-01 Your Grade: See Note 28 b. Method: Noroxycodone Specimen: DMPM-01 Your Grade: See Note 28 c. Method: Methamphetamine Specimen: DMPM-01 Your Grade: See Note 28 d. Method: Gabapentin Specimen: DMPM-02 Your Grade: See Note 28 e. Method: Norfentanyl Specimen: DMPM-02 Your Grade: See Note 28 f. Method: Morphine Specimen: DMPM-02 Your Grade: See Note 28 g. Method: Methadone Metabolite Specimen: DMPM-03 Your Grade: See Note 28 h. Method: Naloxone Specimen: DMPM-03 Your Grade: See Note 28 Review of CAP PT Results Booklet revealed the following: "Actions Laboratories Should Take when PT Result is Not Graded ...Code 28 Action Required: ...Document that the laboratory performed a self-evaluation and compared its results to the proper statistics supplied in the participant summary." The surveyor requested documentation of the above for all analytes not scored by the proficiency testing program in 2023 and 2024 on 06/04/2024 at 11:45 AM. No documentation was provided. 3. In an interview on 06/04/2024 at 11:45 AM, the laboratory director confirmed the laboratory failed to document review of analytes not scored by the proficiency program for one of two in 2023 and one of one performed in 2024. Word Key LCMS- Liquid Chromatography Mass Spectrometry

**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:

I. Based on surveyor observation, review of laboratory policy, American Association

of Bioanalysts (AAB) proficiency testing (PT) results, and confirmed in interview, the laboratory failed to follow their own policy for analytes not scored by the proficiency program for three of three in 2023 and two of two performed in 2024. Findings included: 1. During a tour of the laboratory on 06/04/2024 at 10:00 AM, the surveyor observed one LCMS analyzer (Serial Number: ARZ1610804) and one IR 500 chemistry analyzer (Serial Number: 140302) performing urine drug testing on patient samples. 2. Review of laboratory policy, "Proficiency Testing" (Reviewed by the laboratory director on 06/03/2024) revealed the following: "...Procedure: ...All attestation forms must be signed and dated by the testing personnel and medical director/designated individual." 3. Review of AAB PT results in 2023 and 2024 revealed no attestation signature pages included in the laboratory PT documentation. Further review of PT documentation revealed the following: "Reporting Results ...2. Be sure to keep attestation statements printed from your online reporting form ...The attestation statements must be signed for each analyte by the analyst performing the procedure and kept in your files for inspection purposes. In addition to analysts signatures, the director or director's designee must sign only once for each reporting form." The surveyor requested the above attestation documentation, and none was provided. 4. In an interview on 06/04/2024 at 11:45 AM, testing person 1 (TP-1) stated they did not keep the PT attestation pages in 2023 and 2024. This confirmed the laboratory failed to follow their own policy for analytes not scored by the proficiency program for three of three in 2023 and two of two performed in 2024. II. Based on surveyor observation, review of laboratory policy, College of American Pathologists (CAP) proficiency testing (PT) results, and confirmed in interview, the laboratory failed to follow their own policy for analytes not scored by the proficiency program for one of two in 2023 and one of one performed in 2024. Findings included: 1. During a tour of the laboratory on 06/04/2024 at 10:00 AM, the surveyor observed one LCMS analyzer (Serial Number: ARZ1610804) and one IR 500 chemistry analyzer (Serial Number: 140302) performing urine drug testing on patient samples. 2. Review of laboratory policy, "Proficiency Testing" (Reviewed by the laboratory director on 06/03/2024) revealed the following: "...Assessing Ungraded Proficiency Performance To ensure accuracy with all proficiency testing, un-graded proficiency testing result will be reviewed and self-graded." 3. Review of CAP PT records in 2023 and 2024 revealed the following: 2. Review of CAP PT records in 2023 and 2024 revealed the following: Drug Monitoring for Pain Management PT (DMPM) I. DMPM-A 2023 a. Method: Norfentanyl Specimen: DMPM-01 Your Grade: See Note 28 b. Method: Methadone Metabolite Specimen: DMPM-02 Your Grade: See Note 28 c. Method: Hydrocodone Specimen: DMPM-03 Your Grade: See Note 28 d. Method: Norhydrocodone Specimen: DMPM-03 Your Grade: See Note 28 II. DMPM-A 2024 a. Method: Oxycodone Specimen: DMPM-01 Your Grade: See Note 28 b. Method: Noroxycodone Specimen: DMPM-01 Your Grade: See Note 28 c. Method: Methamphetamine Specimen: DMPM-01 Your Grade: See Note 28 d. Method: Gabapentin Specimen: DMPM-02 Your Grade: See Note 28 e. Method: Norfentanyl Specimen: DMPM-02 Your Grade: See Note 28 f. Method: Morphine Specimen: DMPM-02 Your Grade: See Note 28 g. Method: Methadone Metabolite Specimen: DMPM-03 Your Grade: See Note 28 h. Method: Naloxone Specimen: DMPM-03 Your Grade: See Note 28 Review of CAP PT Results Booklet revealed the following: "Actions Laboratories Should Take when PT Result is Not Graded ...Code 28 Action Required: ...Document that the laboratory performed a self-evaluation and compared its results to the proper statistics supplied in the participant summary." The surveyor requested documentation of the above for all analytes not scored by the proficiency testing program in 2023 and 2024 on 06/04/2024 at 11:45 AM. No documentation was provided. 4. In an interview on 06/04/2024 at 11:45 AM, the laboratory director confirmed the laboratory failed to follow their own policy for analytes not scored by

the proficiency program for one of two in 2023 and one of one performed in 2024.  
Word Key LCMS- Liquid Chromatography Mass Spectrometry

**D6126**

**TECHNICAL SUPERVISOR RESPONSIBILITIES**

CFR(s): 493.1451(b)(8)(vi)

The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of problem solving skills.

This STANDARD is not met as evidenced by:

Based on Centers for Medicare and Medicaid Services (CMS) 209 personnel form, personnel competencies from 2022-2024, and confirmed in interview, revealed the technical supervisor failed to evaluate problem solving skills for one of one testing personnel from 2022-2024. Findings Included: 1. Review of CMS-209 form submitted at time of survey, revealed one testing person (TP-1) performing moderate and high complexity testing. 2. Review of TP-1 competencies in 2022, 2023 and 2024, revealed the following section titled: "Assessment of Problem Solving Skills" All questions listed under this section were left blank on each of the competencies, and the competencies were signed by the technical supervisor (TS-1). The surveyor requested documentation on 06/04/2024 at 11:50 AM of the assessment of problem solving skills for TP-1 in 2022, 2023 and 2024. No documentation was provided. 3. In an interview on 06/04/2024 at 11:45 AM, the laboratory director confirmed the technical supervisor failed to evaluate problem solving skills for one of one testing personnel from 2022-2024.