

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D2107217	(X3) Date Survey Completed 02/14/2024
Name of Provider or Supplier Gates Physician Services, Llc	Street Address, City, State 2525 9th Avenue Suite 2b, Altoona, PA	
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
D5213	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the American Proficiency Institute (API) proficiency testing (PT) records and interview with the technical consultant (TC) (CMS 209 personnel #1), the laboratory failed to verify the accuracy of the PT results obtained for 1 of 2 API Hematology/Coagulation testing events in 2022. Findings Include: 1. On the day of survey, 02/14/2024 at 11:28 am., review of the laboratory's API PT records revealed that the laboratory did not verify the accuracy for the following analyte that was not scored by the PT agency due to non-consensus: - API 2022 Hematology / Coagulation 2nd event: Vaginal Wet Preparation - VA 02 2. The API Proficiency Testing performance Evaluation form states " Laboratories are responsible for documenting and performing corrective action for failures and must perform a self-evaluation using statistics presented in the Participant Data Summary for samples that have not been graded." 3. The TC confirmed the findings above on 02/14/2024 at 03:30 pm.</p>
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on observation of the laboratory and interview with the technical consultant (TC) (CMS 209 personnel #1), the laboratory failed to ensure that reagents and supplies used for examinations in chemistry were not used beyond the expiration dates from 01/31/2024 to the date of the survey. Findings Include: 1. On the date of the survey, 02/14/2024 at 03:00 pm, a laboratory tour revealed that the following reagents and supplies used for toxicology examinations were expired: - 1 of 1 STAT-SKREEN with MDMA, OXY & BUP control - Lot # SK01195, Expired 01/31/2024. 2. The TC confirmed the findings above on 02/14/2024 at 03:30 pm.

D5807

TEST REPORT
CFR(s): 493.1291(d)

Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.

This STANDARD is not met as evidenced by:
Based on review of patient test reports and interview with the technical consultant (TC) (CMS 209 personnel #1), the laboratory failed to include pertinent reference intervals/normal values on patient test reports for microscopic urinalysis testing performed in 2022 and 2023. Findings Include: 1. On the day of the survey, 02/14/2024 at 02:29 pm, review of patient reports revealed that the laboratory failed to include pertinent reference intervals/normal values on the final report for 1 of 4 microscopic urinalysis analytes performed in 2022 and 2023. - Urinalysis Epithelial Cells. 2. The TC confirmed the findings above on 02/14/2024 at 03:30 pm.