

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0185046	(X3) Date Survey Completed 02/16/2024
Name of Provider or Supplier State College Urologic Mnpg	Street Address, City, State 164 Greenview Drive, State College, 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 College of American Pathologists (CAP) proficiency testing (PT) records and interview with the technical consultant (TC) (CMS 209 personnel #2), the laboratory failed to verify the accuracy of the PT results obtained for 2 of 6 API Clinical Microscopy testing events in 2022 and 2023. Findings Include: 1. On the day of survey, 02/16/2024 at 09:40 am., review of the laboratory's CAP PT records revealed that the laboratory did not verify the accuracy for the following analytes that were not scored by the PT agency due to non-consensus: - CM B 2022 Clinical Microscopy Transitional Epithelial CMP 14 - CM B 2023 Clinical Microscopy Erythrocyte Dysmorphic CMP 05 2. According to laboratory's proficiency testing policy "Ungraded results will be compared to all methods once results are returned to the laboratory." 3. The TC confirmed the findings above on 02/16/2024 at 12:30 pm.</p>
D5807	<p>TEST REPORT CFR(s): 493.1291(d)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of patient test reports and interview with the technical consultant</p>

(TC) (CMS 209 personnel #2), the laboratory failed to include pertinent reference intervals/normal values on patient test reports for 2 of 2 microscopic urinalysis and 1 of 1 semen analysis testing performed in 2022 and 2023. Findings Include: 1. On the day of the survey, 02/16/2024 at 11:50 am, review of patient reports revealed that the laboratory failed to include pertinent reference intervals/normal values on the final report for microscopic urinalysis (Red Blood Cells, White Blood Cells, Bacteria, Yeast, Trichomonas, Crystals) and semen analysis testing performed in following dates- - 11/22/2022 Microscopic Urinalysis - 07/11/2023 Microscopic Urinalysis - 07/14/2023 Semen Analysis 2. The TC confirmed the findings above on 02/16/2024 at 12:30 pm.