

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0189685	(X3) Date Survey Completed 09/22/2023
Name of Provider or Supplier Integrated Medical Group Pc	Street Address, City, State 8 Oak Grove Road, Pine Grove, 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 Academy of Family Physicians (AAFP) and Wisconsin State Laboratory of Hygiene (WSLH) proficiency testing (PT) records and interview with Testing Personnel (TP), the laboratory failed to verify the accuracy of the PT results obtained for 7 of 7 events in Chemistry for 2021, 2022 and 2023. Findings include: 1) On the day of survey 09/22/2023 at 10:39 am, review of the laboratory's AAFP and WSLH PT records revealed that the laboratory did not verify the accuracy for the following analytes that were not graded by the PT agencies: - AAFP 2021-C Multichem 21+ Endocrinology HCG: CH-11N, CH-12N, CH-13N, CH-14N, CH-15N - AAFP 2022-C Multichem 21+ General Chemistry Cholesterol LDL: CH-11N, CH-12N, CH-13N, CH-14N, CH-15N - WSLH 2023A Special Chemistry Immunoassay Chemistry 6+ analytes Ferritin: CS-1, CS-2, CS-3 Folate: CS-2, CS-3 - WSLH 2023A Chemistry/Endocrinology/Therapeutic Drugs 31+ Chloride: CET-1, CET-2, CET-3, CET-4, CET-5 Cholesterol HDL: CET-1, CET-2 GGT: CET-2, CET-4, CET-5 2) TP confirmed the above findings during interview on 09/22/2023 at 12:05 pm</p>
D5421	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the</p>

manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

Based on review of Roche Diagnostics Cobas e411 validation study records and interview with Testing Personnel (TP), the laboratory failed to establish criteria for acceptable performance specifications and perform a reference range/normal value study for 1 of 1 analytes performed on the Roche Diagnostics Cobas e411 analyzer from 08/24/2023 to the date of the survey. Findings Include: 1. On the day of the survey, 09/22/2023 at 9:22 am, a review of the Cobas e411 analyzer EP evaluator validation records revealed the validation performed on 08/24/2023 did not include the laboratory's acceptable criteria for performance specifications for reportable ranges for Elecsys Insulin immunoassay. 2. The laboratory could not provide documentation of a validation summary or reference range/normal value study appropriate for the laboratory's patient population. 3. Interview with TP on 09/22/2023 at 12:05 pm confirmed the findings above.