

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  15D0360081	<b>(X3) Date Survey Completed</b>  11/23/2020
<b>Name of Provider or Supplier</b>  Internists Associated	<b>Street Address, City, State</b>  1910 W Royale Drive, Muncie, IN	
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>D5217</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to twice annually verify the accuracy of Vitamin-D testing for two of two years reviewed, 2018 and 2019. Findings include: 1) Review of the "ENCLOSURE I TEST METHODOLOGY AND ANNUAL TEST VOLUME LOG," indicated the laboratory had Vitamin-D listed as a testing analyte. 2) Medical record review indicated the following patients were tested for Vitamin-D in 2018 and 2019: PT=patient ng/mL=nanograms per milliliter PT Date Result (Vitamin-D) a) PT#1 7/17/19 41.6 ng/mL b) PT#2 8/30/19 60.0 ng/mL c) PT#11 12/3/18 22.23 ng/mL d) PT#12 12/18/18 16.64 ng/mL 3) In interview on 11/23 /20 at 10:35 am, SP-1 confirmed their laboratory has never twice annually verified the accuracy of Vitamin-D testing and no documentation for 2018 and 2019 was available for review. 4) Total annual test volume for Vitamin-D=3,936.</p>
<b>D5447</b>	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on record review and interview, the laboratory failed to document two different levels of quality control concentrations every day of patient testing and no IQCP (Individualized Quality Control Plan) has been implemented for one of seventeen analytes tested (Vitamin-D) and four of four Vitamin-D patient reports reviewed. Findings include: 1) Review of the "ENCLOSURE I TEST METHODOLOGY AND ANNUAL TEST VOLUME LOG," indicated the laboratory had Vitamin-D listed as a testing analyte. 2) Review of policy titled, "Roche cobas 6000 501 and 601 Analyzers - Calibration and QC Policy," read on page 1 of 1, "Quality Control Policy:...2. Two levels of controls for each analyte are used to establish control. (per shift)..." 3) Medical record review indicated the following patients were tested for Vitamin-D in 2018 and 2019: PT=patient ng/mL=nanograms per milliliter PT Date Result a) PT#1 7/17/19 41.6 ng/mL b) PT#2 8/30/19 60.0 ng/mL c) PT#11 12/3/18 22.23 ng/mL d) PT#12 12/18/18 16.64 ng/mL 4) In interview on 11/23/20 at 1:15 pm, SP-1 confirmed there was no quality control documentation available for review on the above patients tested for Vitamin-D and there was no IQCP implemented. 5) Total annual test volume for Vitamin-D=3,936.

**D6019**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(4)(iv)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory.

This STANDARD is not met as evidenced by:  
Based on record review and interview, the laboratory director failed to ensure an approved corrective action plan was followed for three of three analytes (Albumin=60%, Calcium=40%, and Thyroid Stimulating Hormone=0%) with unsatisfactory proficiency testing scores for events, 1/2020 and 3/2019. Findings include: 1) Review of the "ENCLOSURE I TEST METHODOLOGY AND ANNUAL TEST VOLUME LOG," indicated the laboratory had Albumin, Calcium, and TSH listed as testing analytes. 2) Review of "CASPER Report 0155D" indicated unsatisfactory proficiency testing scores for the following analytes: a) Albumin=60% for Event 1/2020 b) Calcium=40% for Event 3/2019 c) TSH=0% for Event 3/2019 3) Medical record review indicated the following patients had results reported for either Albumin, Calcium, or TSH testing: PT=patient a) PT#13 2/11/20 Albumin=4.0 g/dL (g/dL=grams per deciliter) b) PT#14 10/20/20 Calcium=9.0 mg/dL (mg/dL=milligrams per deciliter) c) PT#15 10/20/20 TSH=2.06 uIU/mL (uIU/mL=micro international units per milliliter) 4) In interview on 11/23/20 at 2:51 pm, SP-1 confirmed the laboratory had no approved corrective actions in place for the above failing proficiency testing scores. 5) Annual test volumes: Albumin=9,271, Calcium=10,555, and TSH=7,563.