

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 43D2089912	<b>(X3) Date Survey Completed</b> 09/26/2018
<b>Name of Provider or Supplier</b> Genetroit Laboratories	<b>Street Address, City, State</b> 5009 W 12th Street Suite 8, Sioux Falls, SD	
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>	A recertification survey for compliance with 42 CFR Part 493, Requirements for Laboratories, was conducted on 9/26/18. The Genetroit laboratory was found not in compliance with the following requirements: D5217 and D6103.
<b>D5217</b>	<p><b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b> 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 review of proficiency testing (PT), policy review, and interview with the technical and general supervisors, the laboratory failed to verify and document the accuracy of the pharmacogenetic test method used for patient testing twice a year for the time frame of January 2017 through September 2018 (22 of 22 months). Findings include: 1. Review of the laboratory's documentation of PT records revealed there was no enrollment for the pharmacogenetic test method for that site. There was no other documentation available noting that test method's accuracy had been verified twice a year for the time frame above. Interview on 9/26/18 at 4:00 p.m. with the technical and general supervisors revealed this laboratory had not been enrolled in PT that might have included the pharmacogenetic test method. The twice a year accuracy had been included in competency evaluations. However those competencies had not been done the last two years.</p>
<b>D6103</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1445(e)(13)</p> <p>The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to</p>

process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills.

This STANDARD is not met as evidenced by:

Based on review of personnel competency records and Quality Control policy manual, and interview with the general supervisor, the laboratory director failed to implement policies to ensure the technical and general supervisors maintained their competency to process specimens, perform test procedures, and report test results accurately on an annual basis for 25 of 25 months (August 2016 through September 2018). In addition lack of competency evaluations could potentially have caused remedial training or continuing education needs to not be identified. Findings include: 1. Review of competency records for the technical supervisor revealed the last competency was dated 1/25/15. There was no competency record available for review for the general supervisor. Review of the Quality Control policy manual revealed the policy for annual competency evaluations was on page thirty-one. Interview on 9/26/18 at 4:00 p. m. with the technical and general supervisors revealed: \*The technical supervisor's annual competency had not been done since 1/25/15. \*It had been planned to provide re-orientation to the technical supervisor since no on-site testing had been performed in 2017 and up to September 2018.