Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D2241348	(X3) Date Survey Completed 03/07/2023
Name of Provider or Supplier Gateway Foot And Ankle Center	**Street Address, City, State** 4230 Harding Pike Ste G12, Nashville, TN	

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
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of the laboratory's testing records, personnel files (2021 - 2022), and staff interview, the laboratory failed to have documentation of a semi-annual competency assessment by the laboratory's technical supervisor for 1 of 1 testing personnel for the first year the testing person was performing high complexity testing. Findings included: 1. A review of the laboratory's testing records revealed high complexity testing by the sole testing person was being performed on patient specimens in 2021 and 2022. 2. Review of the laboratory's personnel records for the sole testing person revealed the following: -The initial competency assessment for the testing person was completed by the technical supervisor on 10/4/2021. -No documentation of interim competency in either 2021 or 2022 for the testing person by the technical supervisor. 3. An interview with the General Supervisor on 3/7/2023 at 12:30 pm confirmed there was not a semiannual competency assessment for the sole testing person during the first year the testing person performed high complexity testing on patient specimens.
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated

	to include the use of the new test methodology or instrumentation. This STANDARD is not met as evidenced by: Based on review of the laboratory's testing records, personnel files, and staff interview, the laboratory failed to have documentation of an annual competency assessment by the laboratory's technical supervisor for 1 of 1 testing personnel in 2022. Findings included: 1. A review of the laboratory's 2022 testing records revealed high complexity testing was being performed by the sole testing person for 4 of 4 dates reviewed. 2. Review of the laboratory's personnel records for the sole testing person revealed the following: -The initial competency assessment for the testing person was completed by the technical supervisor on 10/4/2021. -No annual competency assessments were documented for the testing person by the technical supervisor in 2022. 3. An interview on 3/7/2023 at 12:30 pm with the General Supervisor confirmed there was not an annual competency assessment for the testing person in 2022.