Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 36D2112099	**(X3) Date Survey Completed** 08/10/2022
Name of Provider or Supplier Miami Valley Plastic Surgeons	**Street Address, City, State** 7865 Paragon Road, Suite 108, Dayton, OH	
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**
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on record review and an interview with the Testing Personnel (TP) #1, the Laboratory Director (LD), failed to ensure prior to testing patients' specimens, one out of one (TP) had received the appropriate training, and had demonstrated they could perform all testing operations reliably to provide and report accurate results for the high complexity test procedures performed. This deficient practice had the potential to affect 10,021 patients tested under the sub-specialty of histopathology from 12/21 /2020 to 08/03/2022. Findings Include: 1. Review of the form CMS 209 signed and dated by the LD on 08/03/2022, found one individual listed as TP. 2. An email received 08/16/2022 at 9:18 AM by TP#1 stated they had begun testing 12/21/2020. 3. Review of the laboratory's policy and procedure titled "2.2e Personnel Competency", provided on the date of inspection found the following statements: " After the initial evaluation, competency assessments will be done annually." 4. The Inspector requested initial competency assessment records for TP#1. 5. TP#1 confirmed the laboratory did not perform an initial competency assessment, and was unable to provide the requested documentation on the date of the inspection. The interview occurred 08/10/2022 at 10:00 AM.
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 record review and an interview with Testing Personnel (TP) #1, the Technical Supervisor failed to evaluate and document the performance of one out of one new Testing Personnel (TP), who was responsible for high complexity testing procedures at least semiannually during the first year the individual tested patient specimens. This deficient practice had the potential to affect 10,021 patients tested under the sub-specialty of histopathology from 12/21/2020 to 08/03/2022. Findings Include: 1. Review of the form CMS 209 signed and dated by the Laboratory Director on 08/03/2022, found one individual listed as TP. 2. An email received 08/16/2022 at 9:18 AM by TP#1 stated they had begun testing 12/21/2020. 3. Review of the laboratory's policy and procedure titled "2.2e Personnel Competency", provided on the date of inspection, did not find any mention of semiannual competency assessment. 4. The Inspector requested semiannual competency assessment records for TP#1. 5. TP#1 confirmed the laboratory did not perform a semiannual competency assessment, and was unable to provide the requested documentation on the date of the inspection. The interview occurred 08/10/2022 at 10:05 AM.
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 record review and an interview with Testing Personnel (TP) #1, the Technical Supervisor failed to annually evaluate and document the performance of one out of one new Testing Personnel (TP), who was responsible for high complexity testing procedures. This deficient practice had the potential to affect 10,021 patients tested under the sub-specialty of histopathology from 12/21/2020 to 08/03/2022. Findings Include: 1. Review of the form CMS 209 signed and dated by the Laboratory Director on 08/03/2022, found one individual listed as TP. 2. An email received 08/16/2022 at 9:18 AM by TP#1 stated they had begun testing 12/21/2020. 3. Review of the laboratory's policy and procedure titled "2.2e Personnel Competency", provided on the date of inspection found the following statements: " After the initial evaluation, competency assessments will be done annually." 4. The Inspector requested the 2021 annual competency assessment records for TP#1. 5. TP#1 confirmed the laboratory did not perform a 2021 annual competency assessment, and was unable to provide the requested documentation on the date of the inspection. The interview occurred 08/10/2022 at 10:05 AM.