

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D0954433	(X3) Date Survey Completed 08/24/2021
Name of Provider or Supplier Silver Pine Medical Group	Street Address, City, State 43455 Schoenherr Rd, Suite 19, Sterling Heights, MI	
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
D3000	<p>FACILITY ADMINISTRATION CFR(s): 493.1100</p> <p>Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe.</p> <p>This CONDITION is not met as evidenced by: . Based on record review, lack of documentation, and interview with Testing Personnel #1 (TP1) and the Office Administrator, the laboratory failed to report SARS-CoV-2 test results every day of patient testing for 14 (June 2020 to August 2021) of 14 months of patient testing. Findings include: 1. A review of the laboratory's test menu revealed the laboratory is performing SARS-CoV-2 testing using the Quidel Sofia Flu+SARS Antigen FIA and the SARS-CoV-2 IGG (COV2G) assay using the Advia Centaur analyzer. 2. An interview with the Office Administrator on 8/24/21 at 10:17 am revealed the laboratory does not send results of its antigen testing to the health department. 3. An interview with TP1 on 8/24/21 at 1:15 pm confirmed the laboratory does not send results of its antibody testing to the health department. 4. A review of the laboratory's testing volumes revealed the total tests performed for each test system since June 2020: a. Quidel Sofia kits had 1,799 patient tests performed from November 2020 to August 2021. b. Advia Centaur assay had 1,851 patient tests performed from June 2020 to August 2021. 5. The surveyor</p>

requested documentation from the laboratory's local health department asking the laboratory not to send all SARS-CoV-2 results on 8/24/21 at 11:44 am and it was not made available.

D6033

TECHNICAL CONSULTANT-MODERATE COMPLEXITY
CFR(s): 493.1409

The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.

This CONDITION is not met as evidenced by:

. Based on record review and interview with Testing Personnel #1, the laboratory failed to ensure Testing Personnel #1 and Testing Personnel #2, performing the duties of a Technical Consultant, met the qualification requirements at 493.1411. Findings include: 1. The laboratory failed to ensure the personnel performing the Technical Consultant duty of performing testing personnel competency assessments was qualified. Refer to D6035.

D6035

TECHNICAL CONSULTANT QUALIFICATIONS
CFR(s): 493.1411

(a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity

testing in all specialties and subspecialties of service.

This STANDARD is not met as evidenced by:

. Based on record review and interview with Testing Personnel #1, the laboratory failed to ensure personnel performing the Technical Consultant duty of performing testing personnel competency assessments was qualified for 2 (Testing Personnel #1 and Testing Personnel #2) of 2 personnel listed on the CMS-209 form. Findings include: 1. A review of the laboratory's personnel competency records revealed Testing Personnel #1 and Testing Personnel #2 had performed competency assessments for each other on the following dates: a. 2/6/20 b. 2/11/21 2. A review of the qualifications for Testing Personnel #1 and Testing Personnel #2 revealed they did not meet the qualification requirements to perform Technical Consultant responsibilities. 3. An interview with Testing Personnel #1 on 8/24/21 at 1:15 pm confirmed Testing Personnel #1 and Testing Personnel #2 had been performing the competency assessments for each other and did not meet the qualification requirements to be Technical Consultants.