Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2313647	08/20/2025
Name of Provider or Supplier	**Street Address, City, State**	
Rocks And Roses Optimal Health Llc	5113 Sr 674 Ste 108, Wimauma, FL	

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
D0000	An announced CLIA initial survey was conducted at Rocks and Roses Optimal Health LLC on 8/19/2025-8/20/2025. The laboratory is not in compliance with 42 CFR Part 493, Requirement for Laboratories. The following Conditions were cited: D6000 493. 1403 Condition: Laboratory Director Moderate Complexity
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on record review and interview, the Laboratory Director failed to have documentation of qualification to manage and direct the laboratory personnel and the performance of moderate complexity Chemistry and Hematology testing performed at the laboratory from 02/13/25 to 08/19/25. (See D6003)
D6003	LABORATORY DIRECTOR QUALIFICATIONS CFR(s): 493.1405 AND 493.1406 The laboratory director must be qualified to manage and direct the laboratory personnel and the performance of moderate complexity tests and must be eligible to be an operator of a laboratory within the requirements of subpart R of this part. (a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if such licensing is required; and (b) The laboratory director 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 (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 had laboratory training or experience consisting of: (b)(2)(ii)(A) At least one year directing or supervising non-waived laboratory testing; and (b)(2)(ii)(B) Have at least 20 CE credit hours in laboratory practice that cover the laboratory director responsibilities defined in 493. 1407; or (b)(3)(i)(A) Hold an earned doctoral degree in a chemical, biological, clinical or medical laboratory science or medical technology from an accredited institution; or (b)(3)(i)(B) Hold an earned doctoral degree; and (b)(3)(i)(B)(1) Have at least 16 semester hours of doctoral level coursework in biology, chemistry, medical technology (MT), clinical laboratory science (CLS), or medical laboratory science (MLS); or (b)(3)(i)(B)(2) An approved thesis or research project in biology/chemistry /MT/CLS/MLS related to laboratory testing for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings; and (b)(3)(ii) Have at least 20 CE credit hours in laboratory practice that cover the laboratory director responsibilities defined in 493.1407; and (b)(3)(ii)(A) Be certified and continue to be certified by a board approved by HHS; and (b)(3)(ii)(B) Have had at least 1 year of experience directing or supervising nonwaived laboratory testing; or (b)(4)(i)(A) Have earned a master's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(4)(i)(B)(1) Meet bachelor's degree equivalency; and (b)(4)(i)(B)(2) Have at least 16 semester hours of additional graduate level coursework in biology, chemistry, medical technology, clinical or medical laboratory science; or (b)(4)(i)(C)(1) Meet bachelor's degree equivalency; and (b)(4)(i)(C)(2) Have at least 16 semester hours in a combination of graduate level coursework in biology, chemistry, medical technology, clinical or medical laboratory science coursework and an approved thesis or research project related to laboratory testing for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings; and (b)(4) (ii) Have at least 1 year of laboratory training or experience, or both, in nonwaived testing; and (b)(4)(iii) Have at least 1 year of supervisory laboratory experience in nonwaived testing; and (b)(4)(iv) Have at least 20 CE credit hours in laboratory practice that cover the director responsibilities defined in 493.1407; or (b)(5)(i)(A) Have earned a bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(5)(i) (B) At least 120 semester hours, or equivalent, from an accredited institution that, at a minimum, includes either- (b)(5)(i)(B)(1) 48 semester hours of medical laboratory science or medical laboratory technology courses; or (b)(5)(i)(B)(2) 48 semester hours of science courses that include- (b)(5)(i)(B)(2)(i) 12 semester hours of chemistry, which must include general chemistry and biochemistry or organic chemistry; and (b) (5)(i)(B)(2)(ii) 12 semester hours of biology, which must include general biology and molecular biology, cell biology or genetics; and (b)(5)(i)(B)(2)(iii) 24 semester hours of chemistry, biology, or medical laboratory science or medical laboratory technology in any combination; and (b)(5)(ii) Have at least 2 years of laboratory training or experience, or both, in nonwaived testing; and (b)(5)(iii) Have at least 2 years of supervisory laboratory experience in nonwaived testing; and (b)(5)(iv) Have at least 20 CE credit hours in laboratory practice that cover the director responsibilities defined in 493.1407. (b)(6) Notwithstanding any other provision of this section, an individual is considered qualified as a laboratory director of moderate complexity testing under this section if they were qualified and serving as a laboratory director of moderate complexity testing in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024.

	This STANDARD is not met as evidenced by: Based on record review and interview, the Laboratory Director failed to have documentation of qualification to manage and direct the laboratory personnel and the performance of moderate complexity Chemistry and hematology testing performed at the laboratory from 02/13/25 to 08/19/25. Findings include: 1. The personnel record for the Laboratory Director included a Medical Diploma from American University of the Caribbean University located in "Sint Maarten" [Saint Marten]. There failed to be documentation of Education Commission for Foreign Medical Graduates (ECFMG) evaluating qualifications to practice medicine in the United States of America as required. 2. The Laboratory Director on 08/19/25 at 2:15 PM via phone confirmed there was no documentation to review of his ECFMG. The Laboratory Director on 08 /20/25 verified via email he was not able to provide a copy of proof of his ECFMG during the survey.
D6005	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(c) (c) The laboratory director must: (c)(1) Be onsite at least once every 6 months, with at least 4 months between the minimum two on-site visits. Laboratory directors may elect to be on-site more frequently and must continue to be accessible to the laboratory to provide telephone or electronic consultation as needed; and (c)(2) Provide documentation of these visits, including evidence of performing activities that are part of the laboratory director responsibilities. This STANDARD is not met as evidenced by: Based on record review and interview, the Laboratory Director failed to establish a policy to be onsite once every six months and document the onsite visits. Findings included: 1. The Laboratory's policies and procedures were reviewed. There was no policy to reflect the Laboratory Director would be onsite at least once every six months or how an onsite visit would be documented. 2. The Laboratory Director confirmed the above via phone on 08/19/2025 at 2:15 p.m.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) (e)(11) 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 interview, the Laboratory Director failed to ensure that prior to testing Patient specimens, all Personnel had demonstrated that they could perform all testing operations reliably to provide and report accurate results for one of one Testing Personnel (TP#A) and one of one Technical Consultant (TC). Findings include: 1. The CMS-209 Laboratory Personnel Report signed by the Laboratory Director on 08/15/25 listed one Testing Personnel TP#A and one Technical Consultant (TC). 2. The Personnel Orientation, Training & Competency policy approved by the Laboratory Director on 01/11/25, which stated initial competency to be documented at the completion of orientation and training. 3. TP#A's and the TC personnel records failed to include initial competency prior to performing patient

	testing on 02/13/2025 as required. There was no evidence the Laboratory Director had ensured the procedure for personnel had been followed. 4. The Laboratory Director confirmed via phone on 8/19/25 at 2:15 PM there was no record of initial competency prior to performing Patient testing.