

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 29D2236751	(X3) Date Survey Completed 01/04/2023
Name of Provider or Supplier Professional Wound Specialists	Street Address, City, State 5597 Spring Mountain Rd, Las Vegas, NV	
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	<p>This Statement of Deficiencies was created as a result of an on-site initial CLIA certification survey conducted at your facility on January 4, 2023. The findings and conclusions of any investigation by the Division of Public and Behavioral Health shall not be construed as prohibiting any criminal or civil investigations, actions or other claims for relief that may be available to any party under applicable federal, state, or local laws.</p>
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on the lack of records of proficiency testing enrollment for 2022, a review of the director approved proficiency testing policy and procedure, and an interview with the office manager, the laboratory failed to enroll in an approved proficiency testing program during 2022 for the PCR testing in the subspecialty of bacteriology as required. Findings include: 1. There were no records of enrollment in an approved proficiency testing program during 2022 for the PCR testing in the subspecialty of bacteriology. 2. The director approved policy and procedure entitled, "Proficiency Testing and Split Sample Policy" in section II entitled "Procedures," stated, "The laboratory participates in proficiency testing programs obtained from a commercial provider." 3. The findings were confirmed during an interview with the office</p>

manager on January 4, 2023 at approximately 11:00 AM. The laboratory performs approximately 30,000 Microbiology tests annually.

D5217

EVALUATION OF PROFICIENCY TESTING PERFORMANCE

CFR(s): 493.1236(c)(1)

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.

This STANDARD is not met as evidenced by:

Based on a review of laboratory records, a review of the director approved proficiency testing policy and procedure, a review of the document entitled "Split Sample Agreement," and an interview with the office manager, the laboratory failed to perform the twice per year verification of accuracy during 2022 for the fungus PCR panel. Findings include: 1. There were no records of the twice per year verification of accuracy during 2022 for the fungus panel available for review at the time of the survey. 2. The director approved policy and procedure entitled, "Proficiency testing and Split Sample Policy," in the section entitled "Split Sample Procedure" stated, "The laboratory must perform and compare the results of the external samples (sic) on at least five specimens twice a year. There must be a minimum of one (1) positive and one (1) negative results for every analyte on the lab's test menu." 3. The document entitled, "Split Sample Agreement" stated, "1) Testing will be performed at least twice annually. 2) Each shipment will include at least five (5) samples. 3) Each sample set will include at least one (1) positive result for each analyte/target." 4. The findings were confirmed during an interview with the office manager on January 4, 2023 at approximately 11:45 AM. The laboratory performs approximately 30,000 Microbiology tests annually.

D5401

PROCEDURE MANUAL

CFR(s): 493.1251(a)

A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

This STANDARD is not met as evidenced by:

Based on a review of a random patient audit, a review of the director approved procedures entitled, "Wound by PCR" and "Fungus by PCR", and an interview with the office manager, the director failed to ensure that the testing personnel followed the procedures when performing the wound and fungus PCR panels. Findings include: 1. The director approved policies and procedures entitled, "Wound by PCR" and "Fungus by PCR" each stated on page 2, in section IV. "Sample Storage and Stability" that the specimens must be tested within 72 hours of collection. 2. A random patient audit of six patients tested between the dates of February 25, 2022 and September 30, 2022 revealed that the wound panel specimens for two patients, identified as AA and MB, were held more than 72 hours before testing. The specimens were collected on August 31, 2022 and tested on September 7, 2022. 3. A random patient audit of six patients tested between the dates of February 25, 2022 and September 30, 2022 revealed that the wound panel specimen for one patient, identified as JJ, was held more than 72 hours before testing. The specimen was collected on September 14,

	<p>2022 and tested on September 30, 2022. 4. The findings were confirmed during an interview with the office manager conducted on January 4, 2023 at approximately 12:00 PM. The laboratory performs approximately 30,000 Microbiology tests annually.</p>
<p>D5417</p>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on observation, and an interview with the office manager, the laboratory failed to ensure that there were no expired reagents available for use. Findings include: 1. During a tour of the laboratory, two bottles of frozen master mix, lot number 01140671, with an expiration date of September 30, 2022 were available for use. 2. The finding was confirmed during an interview with the office manager on January 4, 2023 at approximately 1:45 PM. The laboratory performs approximately 30,000 microbiology tests annually.</p>
<p>D6102</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of testing personnel records, a review of the CMS-209 form, and an interview with the office manager, the director failed to ensure that the testing personnel had the appropriate education and experience, received the appropriate training for the type and complexity of the services offered, and demonstrated that they can perform all testing operations to provide and report accurate results. Findings include: 1. There were no records for the highest level of education for the testing personnel #1 listed the CMS-209 form available for review at the time of the survey. 2. The initial training and competency assessment documents were not complete for testing personnel #1 listed on the CMS-209 form. The orientation document was not signed or dated by the employee or by the director, and did not specify the instruments that the testing personnel was trained to operate, or the testing the employee was trained to perform. The initial document entitled "Testing Personnel Competency" was not completed except for the personnel name, hire date and indication that the document was for the initial competency assessment, and the document was not signed and dated by a trainer and the lab director. The personnel was hired in approximately August, 2022. 3. The findings were confirmed during an interview with the office manager conducted on January 4, 2023 at approximately 10:30 AM. The laboratory performs approximately 30,000 microbiology tests annually.</p>
<p>D6116</p>	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(3)</p>

The technical supervisor is responsible for enrollment and participation in an HHS approved proficiency testing program commensurate with the services offered.

This STANDARD is not met as evidenced by:

Based on the lack of proficiency testing enrollment records, a review of the director approved policy and procedure, and an interview with the office manager, the technical supervisor failed to ensure that the laboratory enrolled in an approved proficiency testing program during 2022 for the PCR testing in the subspecialty of bacteriology. Findings include: 1. There were no records of enrollment in an approved proficiency testing program during 2022 for the PCR testing in the subspecialty of bacteriology. 2. The director approved policy and procedure entitled, "Proficiency Testing and Split Sample Policy" in section II entitled "Procedures," stated, "The laboratory participates in proficiency testing programs obtained from a commercial provider." 3. The findings were confirmed during an interview with the office manager on January 4, 2023 at approximately 11:00 AM. The laboratory performs approximately 30,000 Microbiology tests annually.

D6170

TESTING PERSONNEL QUALIFICATIONS

CFR(s): 493.1489(a)

Each individual performing high complexity testing must possess a current license issued by the State in which the laboratory is located, if such licensing is required.

This STANDARD is not met as evidenced by:

Based on review of Form CMS-209, Division personnel certification documents, a random patient audit of three patients tested in September, 2022, and an interview with the office manager, the laboratory failed to ensure that personnel possessed an appropriate State of Nevada personnel certificate for all specialties of high complexity testing performed in the laboratory. Findings include: 1. A review of Division of Public and Behavioral Health personnel certificates and the personnel records of the two testing personnel employed by the laboratory revealed that testing personnel, designated as #1 on Form CMS-209, who began employment with the laboratory in approximately August, 2022 had a State of Nevada General Supervisor of Licensed Laboratory certificate with a specialty in Chemistry and Toxicology only. 2. A review of the records for three patients tested during the month of September, 2022 revealed that testing personnel #1 performed high complexity PCR testing in the subspecialties of bacteriology and mycology on the dates of September 7, 2022 and September 30, 2022. These tests are classified as microbiology and are outside of the chemistry specialty. 3. In an interview on January 4, 2022 at approximately 10:30 AM, the office manager confirmed these findings. The laboratory performs approximately 30,000 microbiology tests annually.