

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D2264786	(X3) Date Survey Completed 08/02/2023
Name of Provider or Supplier Warner Orthopedics & Wellness	Street Address, City, State 9373 Baringer-Forman Rd, Bldg 2, Baton Rouge, LA	
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 Initial survey was performed on August 2, 2023 at Warner Orthopedics Wellness, LLC, CLIA ID # 19D2264786. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D5417	<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 interview with laboratory personnel, the laboratory failed to ensure laboratory supplies were not used beyond their expiration date. Findings: 1. Observation by surveyors during the laboratory tour on August 2, 2023 at 9:50 a.m. revealed the following expired supplies: - Thirteen (13) Copan e-swabs, lot N2004800, expiration date April 30, 2023 2. In interview on August 2, 2023 at 10:01 a.m., the Technical Supervisor confirmed the supplies identified above were expired.</p>
D5423	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2)</p> <p>Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test</p>

results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance.

This STANDARD is not met as evidenced by:

I. Based on observation; review of the laboratory's test menu, policy and procedure menu, and performance verification studies; as well as interview with laboratory personnel, the laboratory failed to establish specimen stability for nail pathogen testing on the QuantStudio analyzer. Findings: 1. Observation by surveyors during the laboratory tour on August 2, 2023 at 9:50 a.m. revealed the laboratory utilized the QuantStudio analyzer for nail pathogen testing. 2. Review of the laboratory's test menu revealed the laboratory utilized the QuantStudio analyzer for the following nail pathogen testing: *Alternaria* species; *Aspergillus* species (*fumigatus*, *niger*, *terreus*, *versicolor*); *Candida albicans*; *Candida dubliniensis*; *Candida glabrata*; *Candida krusei*; *Candida lusitanae*; *Candida parapsilosis*; *Candida tropicalis*; *Curvularia lunata*; *Epidermophyton floccosum*; *Fusarium solani*; *Microsporum audouinii*; *Microsporum canis*; *Microsporum gypseum*; *Microsporum nanum*; *Pichia onychis*; *Trichophyton* species (*interdigitale*, *mentagrophytes*, *rubrum*, *soudanense*); *Trichophyton violaceum*, *tonsurans*; *Trichophyton beigelii*, *mucooides*; *Pseudomonas aeruginosa*; *Staphylococcus aureus*; and *Sarcoptes scabiei*. 3. Review of the laboratory's policy "Specimen Collection & Handling (Nail/Fungal)" revealed the following instructions for storage of nail samples: - The specimen is stored at room temperature until receipt at the lab and then refrigerated once received. The sample is stable for 72 hours at room temperature or 5 days at 2-8 degrees Celsius. - If testing will be delayed for >72 hours specimens should be transferred and stored at -20 degrees Celsius for up to 2 months (60 days). 3. Review of the laboratory's validation records revealed the laboratory did not perform a stability study for nail pathogen testing. 4. In interview on August 2, 2023 at 1:50 p.m., the Technical Supervisor confirmed the laboratory did not perform stability studies for nail pathogen testing when performing validation of the QuantStudio analyzer. II. Based on observation; review of the laboratory's test menu, policy and procedure menu, manufacturer's package insert, and performance verification studies; as well as interview with laboratory personnel, the laboratory failed to establish specimen stability for wound pathogen and antibiotic resistance testing on the QuantStudio analyzer. Findings: 1. Observation by surveyors during the laboratory tour on August 2, 2023 at 9:50 a.m. revealed the laboratory utilized the QuantStudio analyzer for wound pathogen testing. 2. Review of the laboratory's test menu revealed the laboratory utilized the QuantStudio analyzer for the following wound pathogen and antibiotic resistance testing: *Acinetobacter baumannii*; *Bacteroides fragilis*; *Citrobacter* species (*C. freundii*, *C. koseri*); *Enterobacter* species; *Escherichia coli*; *Klebsiella oxytoca*; *Klebsiella pneumoniae*; *Morganella morganii*; *Proteus* species (*P. vulgaris*, *P. mirabilis*); *Pseudomonas aeruginosa*; *Staphylococcus* species (*S. epidermidis*, *S. haemolyticus*, *S. saprophyticus*, *S. lugdunensis*); *Streptococcus pyogenes*; blaKPC; blaVIM, blaNDM; blaCTX-M; mecA, ermA, ermB, ermC; qnrA; tetM, vanA, vanB; and blaOXA. 3. Review of the laboratory's policy "Specimen Collection & Handling (Wound)" revealed the recommended collection device for wound specimens was the BD eSwab in liquid amies. 4. Further review of the laboratory's policy "Specimen Collection & Handling (Wound)" revealed the following instructions for storage of wound samples: - The specimen is stored at room temperature until receipt at the lab and then refrigerated once received. The sample is stable for 72 hours at room temperature or 5 days at 2-8 degrees Celsius. - If testing will be delayed for >72 hours specimens should be transferred and stored at -20 degrees Celsius for up to 2 weeks (14 days). 5. Review of the manufacturer's package insert for the eSwab revealed "To

maintain optimum organism viability, transport specimens collected using ESwab directly to the laboratory, preferably within 2 hours of collection. If immediate delivery or process is delayed, then specimens should be refrigerated at 4-8 degrees Celsius or stored at room temperature (20-25 degrees Celsius) and processed within 48 hours except for Neisseria gonorrhoeae cultures, which should be processed within 24 hours." 6. Review of the laboratory's validation records revealed the laboratory did not perform a stability study for wound pathogen and antibiotic resistance testing. 7. In interview on August 2, 2023 at 1:50 p.m., the Technical Supervisor confirmed the laboratory did not perform stability studies for wound pathogen and antibiotic resistance testing when performing validation of the QuantStudio analyzer. III. Based on observation, review of the laboratory's performance verification studies, and interview with laboratory personnel, the laboratory failed to evaluate the accuracy studies performed for nail pathogen testing on the QuantStudio analyzer. Findings: 1. Observation by surveyors during the laboratory tour on August 2, 2023 at 9:50 a.m. revealed the laboratory utilized the QuantStudio analyzer for nail pathogen testing. 2. Review of the laboratory's validation records for nail pathogen testing revealed IV. Based on observation, review of the laboratory's performance verification studies, and interview with laboratory personnel, the laboratory failed to evaluate the accuracy studies performed for wound pathogen and antibiotic resistance testing on the QuantStudio analyzer. Findings: 1. Observation by surveyors during the laboratory tour on August 2, 2023 at 9:50 a.m. revealed the laboratory utilized the QuantStudio analyzer for wound pathogen testing. 2. Review of the laboratory's validation records for wound pathogen testing revealed

D5429

MAINTENANCE AND FUNCTION CHECKS
CFR(s): 493.1254(a)(1)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:
Based on observation, review of maintenance records and the laboratory's policy and procedure manual, as well as interview with laboratory personnel, the laboratory failed to ensure the monthly maintenance on the QuantStudio was performed as required by the laboratory for five (5) of nine (9) months reviewed. Findings: 1. Observation by surveyors during the laboratory tour on August 2, 2023 at 9:50 a.m. revealed the laboratory utilized the QuantStudio analyzer for microbiology testing. 2. Review of the laboratory's QuantStudio maintenance logs and policy "QuantStudio Systems Maintenance" revealed the laboratory was to perform the following monthly tasks: - Perform Background Calibration - Perform Instrument Self-Test - Run disc clean-up and defragmentation 3. Further review of the maintenance logs revealed the laboratory did not perform monthly maintenance for the following months: - November 2022 - December 2022 - January 2023 - March 2023 - May 2023 4. In interview on August 2, 2023 at 11:50 a.m., the Technical Supervisor stated the instrument was down from February 15, 2023 through March 20, 2023. She confirmed the maintenance was not performed for the months identified above.

D6086

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(3)(ii)

The laboratory director must ensure that verification procedures used are adequate to

determine the accuracy, precision, and other pertinent performance characteristics of the method.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's Plan of Correction, performance specification studies, and interview with personnel, Laboratory Director failed to establish complete performance specifications for testing. Findings: 1. The laboratory failed to establish specimen stability for nail pathogen testing on the QuantStudio analyzer. Refer to D5423 I. 2. The laboratory failed to establish specimen stability for wound pathogen and antibiotic resistance testing on the QuantStudio analyzer. Refer to D5423 II. 3. The laboratory failed to evaluate the accuracy studies performed for nail pathogen testing on the QuantStudio analyzer. Refer to D5423 III. 4. The laboratory failed to evaluate the accuracy studies performed for wound pathogen and antibiotic resistance testing on the QuantStudio analyzer. Refer to D5423 IV.

D6087

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(3)(iii)

The laboratory director must ensure that laboratory personnel are performing the test methods as required for accurate and reliable results.

This STANDARD is not met as evidenced by:
Based on observation, record review and interview with personnel, the Laboratory Director failed to ensure laboratory personnel performed test methods as required. Refer to D5417.

D6095

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(6)

The laboratory director must ensure the establishment and maintenance of acceptable levels of analytical performance for each test system.

This STANDARD is not met as evidenced by:
Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure that the laboratory performed the required maintenance to ensure acceptable levels of analytical performance. Refer to D5429.

D6112

TECHNICAL SUPERVISOR RESPONSIBILITIES
CFR(s): 493.1451

The technical supervisor is responsible for the technical and scientific oversight of the laboratory. The technical supervisor is not required to be on site at all times testing is performed; however, he or she must be available to the laboratory on an as needed basis to provide supervision as specified in (a) of this section.

This STANDARD is not met as evidenced by:
Based on observation and interview with personnel, the Technical Supervisor failed to provide technical and scientific oversight for the laboratory. Findings: 1. The laboratory failed to ensure laboratory supplies were not used beyond their expiration

date. Refer to D5417. 2. The laboratory failed to ensure the monthly maintenance on the QuantStudio was performed as required by the laboratory for five (5) of nine (9) months reviewed. Refer to D5429.

D6115

TECHNICAL SUPERVISOR RESPONSIBILITIES
CFR(s): 493.1451(b)(2)

The technical supervisor is responsible for verification of the test procedures performed and establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system.

This STANDARD is not met as evidenced by:
Based on observation by surveyor, record review, and interview with personnel, the Technical Supervisor failed to ensure the laboratory established complete performance studies. Findings: 1. The laboratory failed to establish specimen stability for nail pathogen testing on the QuantStudio analyzer. Refer to D5423 I. 2. The laboratory failed to establish specimen stability for wound pathogen and antibiotic resistance testing on the QuantStudio analyzer. Refer to D5423 II. 3. The laboratory failed to evaluate the accuracy studies performed for nail pathogen testing on the QuantStudio analyzer. Refer to D5423 III. 4. The laboratory failed to evaluate the accuracy studies performed for wound pathogen and antibiotic resistance testing on the QuantStudio analyzer. Refer to D5423 IV.

D6144

GENERAL SUPERVISOR RESPONSIBILITIES
CFR(s): 493.1463

The general supervisor is responsible for day-to-day supervision or oversight of the laboratory operation and personnel performing testing and reporting test results.

This STANDARD is not met as evidenced by:
Based on observation, record review and interview with personnel the General Supervisors failed to provide day-to-day supervision to testing personnel to ensure accurate and reliable test performance of laboratory testing. Findings: 1. The laboratory failed to ensure laboratory supplies were not used beyond their expiration date. Refer to D5417. 2. The laboratory failed to ensure the monthly maintenance on the QuantStudio was performed as required by the laboratory for five (5) of nine (9) months reviewed. Refer to D5429.