

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 08D1028005	(X3) Date Survey Completed 08/31/2023
Name of Provider or Supplier Delaware Outpatient Center For Surgery	Street Address, City, State 774 Christiana Road, Suite 2, Newark, DE	
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	A Recertification Survey was conducted at approximately 9:00 am on August 31, 2023 at Delaware Outpatient Center for Surgery. The laboratory was surveyed according to 42 CFR part 493 CLIA requirements. Specific deficiencies are as follows:
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: During document review and interview, the laboratory director (LD) failed to sign the attestation page for Proficiency Testing (PT) for 5 of 5 events. Findings include: 1. During document review at approximately 0920 on August 31, 2023 the surveyor determined that the PT attestation page was not signed by the LD for Events 1, 2, and 3 for 2022 and Events 1 and 2 for 2023. 2. During the interview, the PM confirmed that the LD did not sign 5 of 5 PT attestation pages as required for all PTs.</p>
D5291	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.</p> <p>This STANDARD is not met as evidenced by:</p>

During document review and during interview, the laboratory did not have a quality improvement process in place for the time period of 11/5/2021 to 8/31/2023. Findings include: 1. At approximately 10:00 am on August 31, 2023 during document review the laboratory failed to provide policies and procedures to monitor, assess and problems identified in the laboratory, to include patient test management, quality control, proficiency testing, maintenance, inventory, communications, and complaints. 2. During the interview the surveyor determined there were no internal audit when the CD stated that they did them but not "specifically regarding the laboratory". 3. By the end of the survey at approximately 10:00 am no process improvement or quality indicators were provided for the surveyed time period.

D5303

TEST REQUEST
CFR(s): 493.1241(b)

The laboratory may accept oral requests for laboratory tests if it solicits a written or electronic authorization within 30 days of the oral request and maintains the authorization or documentation of its efforts to obtain the authorization.

This STANDARD is not met as evidenced by:

During document review and interview the laboratory failed to establish a policy for the use of verbal orders for the period of 11/5/2021 to 8/31/2023. Findings include: 1. During document review at approximately 9:50 am on August 31, 2023, it was determined that the laboratory had no test requests forms for the surveyed time period. 2. During interview at that same approximate time, the PM confirmed there were no test requests because the laboratory performed its testing based on verbal orders. 3. The surveyor requested a written policy regarding verbal orders, but the laboratory could not provide one as confirmed by the CD. 4. By the end of the survey at approximately 10:30 am the laboratory did provide a copy of a test request, or a written verbal order policy.

D5403

PROCEDURE MANUAL
CFR(s): 493.1251(b)

The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

	<p>This STANDARD is not met as evidenced by: During interview and document review the laboratory failed to have an approved procedure manual for current procedures for the time period 11/5/21 to 8/31/2023. Findings include: 1. During document review at approximately 9:45 am on August 21, 2023 it was determined that the laboratory did not have written policies and procedures for all aspects of testing of the testing process to include current test procedures, how to handle unacceptable specimens, and test requests. 2. The PM did provide loose product inserts in no organized binder. The PM also provided a document entitled "CLIA Waived Testing" which did not cover the scope of this survey. 3. During the interview, the CD confirmed that there was no approved procedure manual available for the TP to use as a reference. 4. The laboratory did not provide a procedure manual by the end of the interview at approximately 10:30 am.</p>
<p>D6051</p>	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(v)</p> <p>The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples.</p> <p>This STANDARD is not met as evidenced by: The laboratory failed to include all Testing Personnel (TP) for participation in Proficiency Testing (PT) for 9 of 10 personnel. Findings include: 1. During document review of PT surveys at approximately 9:10 am on August 31, 2023 it was noted that the same TP identifier was on 5 of 5 PT surveys. 2. During the interview, the PM (also a TP 1) confirmed that she was the only TP who performs PTs, and not 10 of 10 TP as required. 3. By the end of the interview at approximately 10:30 am, no PT documentation was provided for any of the other TP.</p>
<p>D6063</p>	<p>LABORATORY TESTING PERSONNEL CFR(s): 493.1421</p> <p>The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.</p> <p>This CONDITION is not met as evidenced by: During review of documents and interview, the laboratory director (LD) failed to ensure testing personnel (TP) were qualified for the period 11/5/2021 to 8/31/2023. Findings include: Refer to D6065</p>
<p>D6065</p>	<p>TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i)</p> <p>(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have</p>

successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:

During review of documents and interview, the laboratory director (LD) failed to ensure testing personnel (TP) were qualified for the period 11/5/2021 to 8/31/2023. Findings include: 1. At approximately 10:10 am on August 31, 2023 during document review of appropriate education and training the laboratory failed to provide required educational documentation in the form of transcripts or diplomas for 10 of 10 Testing Personnel (TP). 2. During the interview at approximately 10:12 am the Clinical Director (CD) stated that the nurses "all have licenses, and a degree is required to have a license" She confirmed that the laboratory did not have transcripts or diplomas for any of the TP. 2. At the end of the survey at approximately 10:30 am when requested, no educational documentation was provided for any of the ten testing personnel.