

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0894217	(X3) Date Survey Completed 10/12/2023
Name of Provider or Supplier Abington Surgical Center	Street Address, City, State 2701 Blair Mill Road#17, Willow Grove, PA	
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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on lack of documentation and interview with Laboratory Director (LD), the laboratory failed to establish a written policy to evaluate the competency of 5 of 5 Testing Personnel (TP) that performed microscopic examinations of frozen tissue sections using Hematoxylin and Eosin (H&E) stains from 11/02/2021 to the date of survey. Findings include: 1. On the day of survey 10/12/2023 at 10:00am, the laboratory could not provide a written policy to evaluate the competency of 5 of 5 TP that performed microscopic examinations of frozen tissue sections using H&E stains from 11/02/2021 to the date of survey. 2. LD confirmed the above findings on 10/12/2023 at 11:10 am.</p>
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory procedure manual and interview with Laboratory Director (LD), the laboratory failed to establish a procedure for the verification of accuracy of microscopic examinations of frozen tissue sections using Hematoxylin and Eosin (H&E) stains performed from 11/02/2021 to the date of survey. Findings</p>

	<p>include: 1. On the day of survey, 10/12/2023, the LD could not provide a procedure manual for the verification of accuracy of the microscopic examinations of frozen tissue sections using H&E stains performed from 11/02/2021 to the day of survey. 2. The laboratory reported an annual volume of 6 in Histopathology (CMS 116). 3. The LD confirmed the above findings on 10/12/2023 at 11:10am.</p>
<p>D5429</p>	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on observation of the laboratory and interview with Laboratory Director (LD), the laboratory failed to perform and document maintenance on 1 of 1 Precision microscope from November of 2022 to date of survey. Findings include: 1. During the survey on 10/12/2023 at 10:37am the surveyor observed a sticker indicating a maintenance date of May 2022 and a due date of November 2022 for the Olympus BH-2 Precision microscope. 2. The laboratory could not provide records of maintenance performed on the Olympus BH-2 Precision microscope after May 2022. 3. Interview with LD on 10/12/2023 at 11:10am confirmed that no maintenance was performed since May 2022.</p>
<p>D6021</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Laboratory's Quality Assurance (QA) Program policy and interview with the Laboratory Director (LD), the LD failed to establish and maintain a QA program to ensure the quality of services provided by the laboratory from 11/02/2021 to date of survey. Findings include: 1. On the day of survey 10/12/2023 at 10:33 am, the laboratory could not provide documentation of the periodic QA activities to assess the laboratory's pre-analytical, analytical and post-analytical processes from 11/02/2021 to date of survey. 2. The LD confirmed the above findings on 10/12/2023 at 11:10 am.</p>
<p>D6107</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15)</p> <p>The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether</p>

supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:

Based on lack of documentation and interview with Laboratory Director (LD), the LD failed to specify in writing the responsibilities and duties of 5 individual laboratory positions involved in patient testing from 11/02/2021 to date of survey. Findings include: 1. At the time of survey on 10/12/2023 at 9:49 am, review of the laboratory procedure manual revealed the manual did not include the job responsibilities for the following: - Laboratory Director (LD) - Clinical Consultant (CC) - Technical Supervisor (TS) - General Supervisor (GS) - Testing Personnel (TP) 2. LD confirmed the above findings on 10/12/2023 at 11:10am.

D6127

TECHNICAL SUPERVISOR RESPONSIBILITIES

CFR(s): 493.1451(b)(9)

The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

Based on a review of Laboratory Personnel Report (CLIA) CMS-209, Competency Assessment records and interview with Laboratory Director (LD), the Technical Supervisor (TS) failed to evaluate and document the semiannual competency for 1 of 5 Testing Personnel (TP) who performed microscopic examinations of frozen tissue sections using Hematoxylin and Eosin (H&E) stains in 2023. Findings include: 1. On the day of survey 10/12/2023 at 10:07 am, a review of Competency Assessment records and interview with LD revealed TP #4(CMS-209 personnel number 5) began performing microscopic examinations of frozen tissue sections using H&E stains in September of 2022. 2. At the time of survey, the laboratory could not provide documentation of the 2023 semiannual competency assessment for TP #4 upon request by the surveyor. 3. On 10/12/2023 at 11:10am LD confirmed the semiannual competency was not performed for TP #4.