

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0894217	(X3) Date Survey Completed 05/21/2019
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 review of Laboratory procedure manuals and interview with laboratory director (LD), the laboratory failed to establish a competency assessment procedure to assess the competency of 6 of 7 testing personnel (TP) who read histopathology slides and clinical consultant competency from 09/25/2017 to the date of survey. Findings include: 1. On the day of survey, 05/21/2019, the laboratory could not provide a written policy to assess the competency of TP who perform examination of histopathology slides and Clinical consultants. 2. The laboratoy could not provide documentation of competency assessed for 6 of 7 TP and 6 of 7 clinical consultants in 2017, 2018 and 2019. 3. In 2017, 35 patient slides were analyzed. 4. In 2018, 34 patient slides were analyzed. 5. The LD confirmed the findings above on 05/21/2019 around 09:30 am.</p>
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p>

This STANDARD is not met as evidenced by:
Based on review of records and interview with the laboratory director (LD), the laboratory failed to define reference ranges for reagents stored at room temperature and the internal cryostat temperature from 09/25/2017 to the date of survey. Findings Include: 1. On the day of survey, 05/21/2019, a review of temperature logs sheets revealed the laboratory documented daily room temperature and cryostat temperature, but failed to document the reference ranges followed by the laboratory. 2. In 2017, 35 patient slides were analyzed. 3. In 2018, 34 patient slides were analyzed. 4. The LD confirmed the finding above on 5/21/2019 around 10:45 am.

D5415

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(c)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:
Based on observation of reagents and interview with the laboratory director (LD), the laboratory failed to label The Davidson Marking Systems dyes (3 of 3 bottles), Royal marking dye (1 of 1 bottle), Azer Scientific Alcohol (2 of 2 bottles) and aliquots of ethyl alcohol (2 of 2 bottles) with open and expiration dates required proper to use from 2017 to the date of survey. Findings include: 1. While on tour of the laboratory (05/21/2019) it was observed that laboratory personnel did not document the open and expiration dates on the following reagent bottles prior to use: a) 1 of 1 Yellow The Davidson Marking Systems dye, Lot# 231-611330 b) 1 of 1 Blue The Davidson Marking Systems dye, Lot# (not legible) c) 1 of 1 Red The Davidson Marking Systems dye, Lot# 595621 d) 1 of 1 Black Royal Marking dye e) 2 of 2 bottles Azer Scientific Alcohol f) 2 of 2 aliquots of ethyl alcohol, made on 09/14/2015. 2. The LD could not provide a procedure describing steps taken when obtaining reagents from manufacturers that do not specify an expiration date. 3. In 2017, 35 patient slides were analyzed. 4. In 2018, 34 patient slides were analyzed. 5. The LD confirmed the findings above on 05/21/2019 around 10:00 am.

D5433

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

For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's procedure manual, review of maintenance records,

observation of the Olympus BH-2 microscope and interview with the Laboratory Director (LD), the laboratory failed to establish a maintenance procedure and document the maintenance activities for 1 of 1 Olympus BH-2 microscope used for microscopic examination of histopathology slides from 09/25/2017 to the date of survey. Findings Include: 1. On the date of survey, 05/21/2019, the LD could not provide a maintenance policy for 1 of 1 Olympus BH-2 microscope. 2. Review of microscope maintenance records revealed, in 2018 and 2019 daily maintenance was not recorded. 3. While on tour of the laboratory, observation of the microscope revealed, the microscope was last serviced on 2011, the LD could not provide records of recent calibrations performed. 4. In 2017, 35 patient slides were analyzed. 5. In 2018, 34 patient slides were analyzed. 6. On 05/21/2019 around 9:50 am, the LD confirmed the findings above.

D5805

TEST REPORT
CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:
Based on the review of Patient Test Report and interview with Laboratory Director (LD), the laboratory failed to include on test reports the location where Tissue Pathology slides were read from 09/25/2017 to the date of survey. Finding Include: 1. On the day of survey, 05/21/2019, a review of some test reports (3 of 3) revealed the test reports did not include the correct address where the slides were being read. 2. Slides were read at Abington Surgical Center (2701 Blair Mill road, Willow Grove PA 19090) but Abington Jefferson Hospital (1200 Old York Road, Abington PA 19001) was listed on the final reports. 3. In 2017, 35 patient slides were analyzed. 4. In 2018, 34 patient slides were analyzed. 5. The LD confirmed the findings above on 05/21/2019 around 11:00 am.

D6106

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(14)

The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process.

This STANDARD is not met as evidenced by:
Based on review of the procedure manual and interview with the laboratory director (LD), the laboratory failed to establish an approved procedure available to all personnel performing examination of histopathology slides for the specific location from 2017 to the date of survey. Findings Include: 1. On the day of survey, 05/21/2019, review of the procedure manual revealed the cover page stated "Abington Surgical Center Procedures", but the polices and procedures inside were labeled with the name and address for Abington Jefferson Hospital. 2. The surveyor could not

distinguish if the policies belonged to either the Abington Surgical Center or Abington Jefferson hospital since they were labeled with the hospitals information. The LD is the CLIA LD for both locations. 3. In 2017, 35 patient slides were analyzed. 4. In 2018, 34 patient slides were analyzed. 5. On 05/21/2019 around 09:45 am, the LD mentioned he was unaware each laboratory with a different CLIA number needs their own separate polices and procedures.