Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D2073703	01/18/2018
Name of Provider or Supplier	**Street Address, City, State**	
Pennsylvania Dermatology Partners - Douglassville	258-260 E Ben Franklin Highway, Birdsboro, 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
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on observation, review of laboratory procedures manuals, interview with Histology Technologist (HT) and Mohs Technician (MT), the laboratory failed to have the current director's signature for the procedures currently in use. Findings include: 1. On the date of survey (01/18/2018), The first page of the Policies and Procedures manuals reviewed, stated, the Laboratory Director will review the manual yearly. 2. The laboratory director last reviewed the Dermatology procedure on 05/06 /2016 and the Mohs procedure manual on 05/16/2014. 3. The HT and MT confirmed the finding above on 01/18/2018 around 09:30 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 laboratory tour and interview with the Histology Technologist (HT) and Mohs Technician (MT), the laboratory failed to label Tissue Marking dyes with open and expiration dates. Findings Include: 1. On the date of survey 01/18/2018, the

	Dermatology and Mohs laboratory tours revealed the following Azed Scientific Tissue Marking Dyes did not have an open and expiration dates on the bottles: a. Dermatology Laboratory: 1 of 1 bottle of Orange Azed Scientific Tissue Marking Dye b. Mohs Laboratory: 1 of 1 bottle of Green Azed Scientific Tissue Marking Dye 1 of 1 bottle of Red Azed Scientific Tissue Marking Dye 1 of 1 bottle of Yellow Azed Scientific Tissue Marking Dye 1 of 1 bottle of Violet Azed Scientific Tissue Marking Dye 1 of 1 bottle of Orange Azed Scientific Tissue Marking Dye 1 of 1 bottle of Blick Black Water Proof India Ink 2. In 2016: 42,000 specimen were prepared. 3. The HT and MT confirmed the findings above on 01/18/2018 around 10:45 AM.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) 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. This STANDARD is not met as evidenced by: Based on laboratory tour and interview with the Histology Technologist (HT) and Mohs Technician (MT), the laboratory failed to ensure expired reagents were not used beyond the expiration dates. Findings Include: 1. On the date of survey 01/18/2018, the Dermatology and Mohs laboratory tours revealed that the following Azed Scientific Tissue Marking Dyes: were expired: 1 of 1 bottle of Red Dye: Lot# 33852 Expiration: 09/2016 1 of 1 bottle of Violet Dye: Lot# 01306 Expiration: 12/2016 1 of 1 bottle of Yellow Dye: Lot# 26486 Expiration: 12/2015 1 of 1 bottle of Green Dye: Lot# 013016 Expiration: 12/2016 2. In 2016: 42,000 specimen were prepared. 3. The HT and MT confirmed the findings above on 01/18/2018 around 10:45 AM.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on, the review of laboratory records and interview with Histology Technologist (HT), the Laboratory Director failed to ensure that the quality assessment programs are maintained and documented to assure the quality of Dermatology laboratory services provided from 2016 to 01/2018. Findings Include: 1) On the day of survey (01 /18/2018), review of quality assessment policy revealed that the laboratory's quality assessment of the pre-analytic, analytic and post analytic phases were not documented for the Dermatology laboratory from 2016 to January 2018. 2) The HT confirmed the findings above on 01/18/2018 around 11:30 AM.
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 review of competency assessment record and interview with the Histology Technologist (HT), the Technical Supervisor failed to evaluate and document the performance of the testing personnel #3 (TP#3) responsible for grossing and inking of dermatology specimen at least semi-annually during the first year. Findings include: 1. On the date of survey (01/18/2018), the laboratory was unable to produce documentation for testing personnel #3 semi-annual competency assessment during their first year (Started date of 01/07/2017). 2. The only competency assessment record for TP#3 available at the time of inspection, was performed on 12/12/2017. 2. The HT confirmed the findings above on 1/18/2018 around 9:45 AM.
D6168	TESTING PERSONNEL CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: Based on review of the CLIA ' s Laboratory Personnel Report (Form CMS-209), review of personnel qualification records, and interview with the Histology Technologist (HT) the laboratory failed to ensure that each individual performing High Complexity testing is qualified. Refer to D6171
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry 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; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training

	program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations. This STANDARD is not met as evidenced by: Based on review of the CLIA ' s Laboratory Personnel Report (Form CMS-209), review of personnel qualification records, and interview with the Histology Technologist (HT) the laboratory failed to ensure that each individual performing High Complexity testing is qualified. Findings include: 1. The CMS 209 form signed by the Laboratory Director (01/17/2018), lists Individual #2 and #3 as a Testing Personnel (TP). 2. On the date of the survey (01/18/2018) the HT failed to provide the educational credential for TP#2 and #3, which are 2 of 6 TP in the laboratory. 3. The HT confirmed the finding above on 01/18/2018 around 11:00 AM.