Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D2073703	08/07/2020
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
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) 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. This STANDARD is not met as evidenced by: Based on review of peer review records, and interview with testing personnel (TP) #2, the Laboratory failed to perform twice annual verification of accuracy for mohs and dermatopathology examinations analyzed in 2019. Findings Include: 1. On the day of survey, 08/07/2020, TP #2 could not provide twice annual verification performed for mohs and dermatopathology examination analyzed in 2019. 2. TP#2 confirmed the findings above on 08/07/2020 around 09:10 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 the laboratories and interview with Testing personnel (TP) #2, the laboratory failed to label tissue Marking dyes with open and expiration dates. Findings include: 1. On the date of survey 08/07/2020, observation of the Dermatology and Mohs laboratories 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. - 1 of 1 bottle of Violet Azed Scientific Tissue Marking Dye. b. Mohs Laboratory: -1 of 1 bottle of Orange Azed Scientific Tissue Marking Dye. - 1 of 1 bottle of Violet Azed Scientific Tissue Marking Dye. 2. Testing personnel #2 confirmed the findings above on 08/07/2020 around 10:20 AM. *** Repeat Deficiency***
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 observation of the laboratories and interview with testing personnel (TP) #2, the laboratory failed to ensure expired reagents were not used beyond the expiration dates. Findings include: 1. On the date of survey 08/07/2020, observation of the Mohs laboratory revealed, the following Azed Scientific Tissue Marking Dyes had expired: - 1 of 1 bottle of Green Azed Scientific Tissue Marking Dye, expired 10/2019. - 1 of 1 bottle of Blue Azed Scientific Tissue Marking Dye, expired 10/2019. - 1 of 1 bottle of Black Azed Scientific Tissue Marking Dye, expired 10/2019. - 1 of 1 bottle of Yellow Azed Scientific Tissue Marking Dye, expired 04/2019. - 1 of 1 bottle of Red Azed Scientific Tissue Marking Dye, expired 10/2019. 2. Testing personnel #2 confirmed the findings above on 08/07/2020 around 10:20 AM. *** Repeat Deficiency***
D5601	HISTOPATHOLOGY CFR(s): 493.1273(a)(f) (a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (f) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review of slide staining records and interview with testing personnel (TP) #2, the laboratory failed to document Immunohistochemical (IHC) slide stain QC performed on dermatopathology and mohs examinations in house from 01/18/2020 to 08/07/2020. Findings include: 1. On the day of survey, 08/07/2020, review of the dermatopathology and mohs examinations staining records revealed, the IHC stain QC were not performed and documented by the reading physician onsite (TP#1). 2. TP#2 confirmed the findings above on 08/07/2020 around 9:00 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 review of laboratory quality assessment records and interview with testing personnel (TP) #2, the Laboratory Director failed to ensure quality assessment programs were maintained and documented to assure the quality of the dermatopathology and mohs laboratory services provided from January, 2018 to June, 2020. Findings include: 1. The CMS 2567 plan of correction form signed by the laboratory director on 02/12/2018, states, "The lab director will complete assessments monthly and will document them on the form." 2. On the day of survey, 08/07/2020, review of the dermatopathology and mohs laboratories QA logs from January 2018 to July 2020 revealed: A). Dermatopathology Laboratory: - QA Logs were not documented from October 2018 to June 2020. - QA logs were signed by the laboratory director but not filled out from January 2018 to September 2018. B). Mohs Laboratory: - QA Logs were not documented on May 2018 and August 2018. 3. TP#2 confirmed the finding above on 08/07/2020 around 8:50 am. ****This is a Repeat Deficiency****
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on review of the laboratory procedure manual, personnel competency assessment records, and interview with testing personnel (TP) #2, the technical supervisor (laboratory director) failed to ensure 5 of 7 TP received training and were evaluated for the competency of inking and grossing of dermatopathology specimen from January 2018 to the day of survey. Findings Include: 1. On the day of survey, 08 /07/2020, TP #2 could not provide training documentation and evaluated competency assessment documentation for the following personnel performing inking and grossing of dermatopathology specimen: - TP #2- Hired July 2020: No training documentation. - TP #3- Hired May 2018: No training documentation, 6 month or annual competency assessment documentation. - TP #4- Hired February 2019: No training documentation 6 month or annual competency assessment documentation. - TP #5- Hired March 2020: No training documentation. - TP #6- Hired January 2020: No training documentation and no 6 month competency assessment documentation. 2. TP#2 confirmed the findings above on 08/07/2020 around 8:45 am. **** THIS IS A REPEAT DEFICIENCY****
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 testing personnel (TP) #2, the laboratory failed to ensure that each individual performing High Complexity testing is qualified. Refer to: D6171 *** Repeat Deficiency***
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 testing personnel (TP) #2, the laboratory failed to ensure that each individual performing High Complexity testing is qualified. Findings include: 1. The CMS 2567 form signed by the laboratory director on 02/12/2018 states, "For future employment, only employees with the correct qualifications that can provide proof of qualifications will be employed and will be allowed to do high complexity testing". 2. The CMS 209 form signed by the Laboratory Director on 08/05/2020, lists individuals #3, #5, #6 and #7 as a Testing Personnel (TP) performing inking and grossing of dermatopathology and mohs laboratory specimen. 3. On the date of the survey, 08/07/2020, TP #2 could not provide the minimum educational requirements for TP #3, #5, #6 and #7 who performed inking and grossing of dermatopathology and mohs examinations specimens from 2019 to 2020. 4. TP #2 confirmed the finding above on 08/07/2020 around 12:00 pm. *** Repeat Deficiency***