Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D1074950	08/23/2023
Name of Provider or Supplier	**Street Address, City, State**	
Pennsylvania Specialty Pathology Llc	2301 Harrisburg Pike, Suite 201, Lancaster, 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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) 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. This STANDARD is not met as evidenced by: Based on review of the College of American Pathologists (CAP) proficiency testing (PT) records and interview with the Medical Director (MD), the laboratory director failed to sign 4 of 7 CAP PT attestation statements for Immunohistochemistry and Virology testing in 2021, 2022, 2023. Findings Include: 1. On the day of the survey, 08/23/2023 at 9:19 am, review of CAP PT records revelaed the following attestations for Immunohistochemistry and Virology testing were not signed by the medical director in 2021, 2022, and 2023: - 2021 (Event #3) CHPV-C Human Papillomavirus - 2021 (Event #2) MK-B 2021 Immunohistochemsitry - 2022 (Event #1) CHPV-A Human Papillomavirus - 2023 (Event #1) P16-A Immunohistochemical Tissue Microarray 2. The LD confirmed the findings above on 08/23/2023 at 12:30 pm.
D3013	FACILITIES CFR(s): 493.1101(e) Records and, as applicable, slides, blocks, and tissues must be maintained and stored under conditions that ensure proper preservation. This STANDARD is not met as evidenced by: Based on observation of the laboratory and interview with the Laboratory Director (LD) the laboratory failed to record the room temperature for paraffin block storage for 2 of 3 areas to ensure proper preservation from 10/28/2021 to the day of the

	survey. Findings include: 1. On the day of the survey, 08/23/2023 at 11:45 AM, during the laboratory tour it was observed that the paraffin blocks were not stored in temperature monitored areas. 2. The laboratory could not provide room temperature records for paraffin blocks stored in foyer of laboratory and in the administrative office next to the laboratory from 10/28/2021 to the day of the survey. 3. The LD confirmed the finding above on 08/23/2023 at 12:30 PM.
D5213	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1) The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program. This STANDARD is not met as evidenced by: Based on review of the College of American Pathologist (CAP) proficiency testing (PT) records and interview with the Laboratory Director (LD), the laboratory failed to evaluate the accuracy of the non graded results obtained for 2 of 6 CAP events for Immunohistochemistry and Virology in 2022. Findings Include: 1. On the day of survey, 08/23/2023 at 09:19 am, review of the laboratory's CAP PT records revealed that the laboratory did not verify the accuracy for the following analytes in Immunohistochemistry and Virology that were not graded by the PT agency: -CAP MK-B 2022 Event #2 Immunohistochemsitry -CAP CHPV-A 2022 Event #1 Human Papillomavirus 2. The LD confirmed the findings above on 08/23/2023 at 12:30 PM.
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 the review of the laboratory's quality control (QC) staining records and an interview with the Laboratory Director (LD), the laboratory failed to document negative staining reactivity each time of use for 65 of 65 immunohistochemical (IHC) stains used for histopathology examinations from 10/28/2021 to the date of the survey. Findings include: 1. On the day of the survey, 08/23/2023 at 11:00 am, review of the laboratory's IHC quality control log revealed that a control for negative reactivity was not documented each use of the following 65 of 65 IHC stains used for histopathology examinations from 10/28/2021 to the date of the survey -Adiopohlilin -BCL-2 -BCL-6 -BER-EP4 -Calderom -CD1-A -CD3 -CD4 -CD8 -CD10 -CD15 -CD20 -CD21 -CD23 -CD30 -CD31 -CD34 -CD56 -CD63 -CD68 -CD117 -CD138 -CD163 -CDX2 -CEA -Chromogranin A -CMB -Cytokeratin 5&6 -Cytokeratin 7 -Vimentin -Cyclin D1 -Cytokeratin 20 -Cytokeratin 8&18 -Desmin -EMA -Estrogen Receptor -GCDFP-15 -H. Pylori -HMB-45 -Ki-67 -HSV-1 -HSV-2 -Melan-A -MLH-1 -MSH2 -MSH6 -Neurofilament -Actin (Muscle specific) -P16 -P63 -Cytokeratin AE1/AE3 -PMS2 -P504S -Podoplanin -PgR -S100 -Actin (smooth muscle) -SOX-10 -

	Snyaptophysin -Tenascin C -TTF-1 -Tyrosine -Ubiquitin -Cytokeratin HMW 34E12 -PHH3 2. The LD confirmed the findings above on 08/23/2023 at 12:30 pm.
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 Laboratory Personnel Report (Form CMS-209), review of personnel qualification records and interview with the Testing Personnel (TP#7), the laboratory failed to ensure that each individual performing High Complexity testing (1 of 7) have the minimum qualifications required for grossing and inking from 10/28/2021 to the date of the survey. Findings Include: 1. On the day of survey, 08/23/2023 at 09:00 a.m, review of the personnel qualification records revealed 1 of 7 TP (CMS 209 form personnel #7) did not meet the minimmum qualifications to perform High Complexity testing in Histopathology from 10/28/2021 to the date of survey. 2. On 8/28/2023 at 3:32 pm, the laboratory provided the following documents for TP#7 - Undergraduate Advising Transcript for a Bachelors in Anthropological Science 3. On 08/29/2023, a review of personnel qualification documents revealed that TP#7 did not have the minimum qualifications to fulfull the required 6 semester hours of chemsitry. 4. The LD confirmed the findings above on 08/29/2022 at 08:44 am.