Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0185151	08/23/2018
Name of Provider or Supplier	**Street Address, City, State**	
Ph Dubois, Clearfield Campus	809 Turnpike Avenue, Clearfield, 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	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 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. This STANDARD is not met as evidenced by: Based of review of laboratory's Competency Assessment Plan Procedure, laboratory personnel competency assessment records and interview with the Technical Consultant (TC) #1, the laboratory failed to included the 6 points of CLIA competency assessment in their policy, that assess laboratory testing personnel responsible for Chemistry, Hematology, Immunohematology, Microbiology, Immunology and Histopathology in 2017. Findings include: 1. On the days of survey, 08/22/2018 and 08/23/2018, The laboratory could not provide a written policy for the competency assessment that including reviewing personnel for the 6 points of CLIA personnel competency assessment. 2. Review of personnel Competency assessment records revealed: a. 2 of 2 Histology technologist that perform grossing, competency assessments did not include the CLIA 6 points. b. 15 of 17 Laboratory Testing personnel who perform Chemistry, Hematology, Immunohematology, Microbiology and Immunology competency assessments did not include the CLIA 6 points. c. 8 of 9 Respiratory Therapist performing Blood Gases testing were not assessed for competency in 2017. 3. In 2017: 951,886 specimens were tested by the laboratory. 4. TC #1 confirmed the findings above on 08/22/2018 around 10:00 am.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) 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. This STANDARD is not met as evidenced by: Based on observation of microbiology media, review of temperature records and interview with the Microbiology Supervisor, the laboratory failed to define criteria conditions that are essential for proper storage of reagents, monitored and documented room temperature for various reagents stored in the microbiology laboratory form 2017 to the date of survey. Findings Include: 1. On the day of survey, 08/23/2018, review of temperature records revealed the microbiology laboratory was not recording and documenting daily room temperature. 2. Observation of a sample of reagents and media boxes found around the microbiology laboratory revealed: 3 of 3 boxes of tube media stated on the box to be stored between 2-25 degrees Celsius. 6 of 6 bottles of identification regent stated on the bottle to be stored between the temperatures of 15-30 degrees Celsius. 3. The MS confirmed the findings above on 08/23/2018 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 laboratory Tour, observation of Tissue Marking Dye bottles and interview with the Technical Consultant (TC) #1, the laboratory failed to label 8 of 8 stock and aliquot bottles of TBS Tissue Marking Dye and 1 of 1 bottle set of Davidson Tissue Marking Dye with an open and expiration dates from 2017 to the date of survey. Findings Include: 1. On the day of survey, 08/22/2018 to 08/23/2018, a tour of the Tissue pathology laboratory revealed that the laboratory did not write the open and expiration date on TBS Tissue Marking Dye stock and aliquot bottles (8 of 8 bottles) in use and on the Davidson Tissue Marking Dye set (5 of 5 bottles). 2. The TC#1 confirmed the findings above on 08/22/2018 around 11:30 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 tour of Laboratory and interview with the Technical Consultant (TC) #1, the laboratory failed to ensure that 1 of 1 bottle of Cancer Diagnostics Inc. (CDI) Tissue

	Marking Dye was not used beyond expiration date. Finding Include: 1. On the days of the survey, 08/22/2018 and 08/23/2018, during the tour of the laboratory, 1 of 1 bottle of Orange Cancer Diagnostics Inc. (CDI) Tissue Marking Dye was found that expired 12/2017. 2. The TC confirmed the above finding on 08/22/2018 around 11:45 am
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on review of chemistry calibration records, interview with the Technical Consultant (TC)#1, General Supervisor (GS) #2 and Testing personnel (TP) #9, the laboratory failed to have a system in place, that twice a year evaluates and defines the relationship between two Chemistry Siemens Dimension Vista 500's in 2017. Findings Include: 1. On the days of survey, 08/22/2018 and 08/23/2018, review in instrument calibration records reveals that the laboratory failed to perform relationship studies at least twice a year on 2 of 2 Siemens Dimension Vista 500's. 2. In 2017: 667,859 chemistry tests were performed. 3. The TC and GS confirmed thin findings above on 08/23/2018 around 9:45 am.