Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D2163451	06/08/2022
Name of Provider or Supplier	**Street Address, City, State**	
Upmc Urgent Care Pleasant Hills	617 Clairton Blvd, Pleasant Hills, 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
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 laboratory and interview with the Technical Consultant (TC), the laboratory failed to perform and document maintenance for the 2 of 2 thermometer for the storage of chemistry and hematology reagents from 10/03/2019 to 06/08/2022. Findings Include: 1. Based on observation of the lab on 06/08/2022 at 2:16 pm, revealed that the following thermometers were expired: a. Traceable Fisher Thermofisher refrigerator S/N 192326416 expired July 11,2021. b. Traceable Fisher room temperature S/N 192075115 expired April 1, 2021. 2. The following sampling reagents were stored in the refrigerator:. - 1 of 1 boxes Siemens Innovance Ddimer Control Control 1 and Control 2 - 1 of 1 boxes Istat PT Level 1 lot 281138 exp date 6 /30/22 - 1 of 1 boxes Istat PT Level 2 lot 291139 exp date 07/31/2022 - 2 of 2 boxes Istat Tri controls Level 1 lot 301145 exp date 01/31/23 - 2 of 2 boxes Istat Tri controls Level 3 lot 321146 exp date 02/28/23 - 2 of 2 boxes Istat Ctnl Level 1 lot 011155 exp date 11/30/23 - 2 of 2 boxes Istat Ctnl Level 2 lot 021151 exp date 07/31/23 3. Interview with TC on 06/08/2022 at 2:16 pm confirmed the findings above.
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 lack of documentation and interview with the Technical Consultant (TC), the laboratory failed to establish a maintenance protocol, to ensure the accuracy for 2 of 2 pipettes from 10/03/2019 to 06/08/2022. Findings include: 1. At the time of the survey 06/08/2022 at 01:54 pm, the laboratory failed to provide the following documentation of calibration from 10/03/2019 to 06/008/2022: - Model - MLA D-tipper pipette Serial # 956094 - Model - MLA D-tipper pipette Serial # 955680. 2. The laboratory failed to provide a calibration protocol for accuracy of pipettes. 3. On the day of survey, 06/08/2022 at 3:00pm the Technical Consultant confirmed the above findings.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of quality control (QC) records and interview with Technical Consultant (TC), the laboratory failed to include two control materials of different concentrations for White Blood Cell (WBC) count on the Hemocue analyzer in hematology at least once each day of patient testing from 10/03/2019 through 06/08 /2022. Findings include: 1. On the day of survey 06/08/2022 at 01:14 pm, review of the Hemocue control log revealed, the laboratory did not perform 2 levels of QC every day of patient testing from 10/03/2019 to 06/08/2022. 2. The Technical Consultant on 06/08/2022 at 1:30 pm confirmed that Hemocue QC was not performed each day of patient testing.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests 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 Technical Consultant (TC), the laboratory failed to ensure that each individual performing moderate complexity testing is qualified. Refer to D6065
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i)

	(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy 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; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and 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 Technical Consultant (TC), the laboratory failed to ensure that each individual performing moderate complexity testing is qualified. Findings include: 1. At the time of the survey 06/08/2022 at 11:40 am, the TC failed to provide the educational credentials for 1 of 7 TP (CMS 209 TP #5) 2. Form CMS 209 signed by the Laboratory Director on 6/07/2022. 3. The TC #1 confirmed the finding above on 06/08/2022 at 03:00 pm.
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 the Technical Consultant (TC), the TC failed to evaluate the competency assessment of 2 of 7 testing personnel (TP) for hematology in 2020 and 2021. Findings Include: 1. On the day of survey, 06/08/2022 at 12:05pm, the TC failed to provide documentation of competency assessments performed for 2 of 7 TP (CMS 209 personnel #2 and #3) who performed testing on Istat PT/INR, Siemens stratus CS Ddimer and Hemocue white blood cell (WBC) count in 2020 and 2021. 2. The TC failed to provide documentation of a competency assessment procedure that included the 6 points of CLIA. 3. The Technical consultant confirmed the findings above on 06/08/2022 around 2:00 pm.