Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D2080642	09/21/2023
Name of Provider or Supplier	**Street Address, City, State**	
Upmc Hillman Cancer Center	2020 Technology Parkway, Mechanicsburg, 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 College of American Pathologists (CAP) proficiency testing (PT) records and interview with the laboratory manager (LM), the laboratory director (LD) /designee and testing personnel (TP) failed to sign 6 of 12 CAP PT attestation statement documents for chemistry and hematology testing performed in 2021 and 2022. Findings include: 1. The CAP PT Attestation/Use of Other Form states, " The laboratory director and the testing personnel must sign on the result form. Retain a signed copy of this page in your laboratory for your records and inspection purposes." 2. On the day of survey, 09/21/2023 at 10:00 am., review of CAP PT attestation records revealed the following 4 of 14 CAP PT attestation statement documents were not signed by the LD/designee or TP in 2021 and 2022: -2021 Chemistry: Event C - (C1) C Chemistry-General, Limited -2022 Hematology: Events A and B - (FH13) Hematology Automated Differential Series -2022 Chemistry: Event B - (C1) C Chemistry-General, Limited 3. The LM confirmed the findings above on 09/21/2023 at 02:00 p.m.
D3009	FACILITIES CFR(s): 493.1101(c) The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements.

	This STANDARD is not met as evidenced by: Based on record review and interview with the laboratory manager (LM), the laboratory failed to ensure that the State of Pennsylvania (PA) regulations were met regarding having a supervisor on site during all normal scheduled working hours in which tests were performed in 2022, and 2023. Findings include: 1. The PA regulations (5.23(b)(1) states: "A general supervisor who meets all the requirements of subsection (a)(1), (2) or (3) and is on the laboratory premises during all normal scheduled working hours in which tests are being performed." 2. Review of the application for Exception to Section 5.22 (f) form signed by the laboratory director (LD) on 10/16/2020 states: " the laboratory director will appoint a qualified general supervisor for each laboratory who will be on-site to oversee laboratory operations during all hours in which testing is being performed and who will review quality control records on a weekly basis". 3. On the day of the survey, 09/21/2023 at 10:30 am, review of the laboratory personnel report (PA State) and personnel credentials revealed that the laboratory failed to ensure that the PA regulations were met regarding having a qualified supervisor on site during all hours of patient testing for 24 of 24 months in 2022 and 2023. 4. The LM confirmed the findings above on 09/21 /2023 at 02:00 pm.
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 on review of the laboratory's competency assessment's and interview with the laboratory manager (LM), the laboratory failed to establish and follow a competency assessment procedure to assess the competency of 6 of 6 technical consultants (TC) for their supervisory responsibilities in 2021 and 2022. Findings Include: 1. On the day of the survey, 09/21/2023 at 9:35 am, the laboratory could not provide a competency assessment procedure to assess the competency of the following personnel for their supervisory responsibilities in 2021 and 2022: - 6 of 6 TC (CMS 209 personnel #4, #5, #8, #9, #10, and #11). 2. The laboratory could not provide site specific competency assessment documents for 6 of 6 TC. 3. The LM confirmed the findings above on 09/21/2023 at 2:00 pm.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on review of College of American Pathologists (CAP) Proficiency testing (PT) records, and interview with the laboratory manager (LM), the laboratory failed to document the evaluation and verification activities performed when the laboratory receives a score of less than 100% for 1 of 3 CAP PT chemistry events in 2022. Findings include: 1. On the day of the survey, 09/21/2023 at 10:16 am, review of CAP PT records revealed the laboratory failed to document the corrective action taken when the laboratory received a score of less than 100% for the following 1 of 3 CAP

	PT chemistry events in 2022: - CAP B 2022: General Chemistry and Therapeutic drugs 2. The LM confirmed the findings above on 09/21/2023 at 2:00 pm.
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 review of the laboratory's temperature records, and interview with the laboratory manager (LM), the laboratory failed to monitor and document the relative humidity and room temperatures to ensure operating conditions were met for the proper storage of reagents and to ensure reliable test system operation of the Abaxis Express Piccolo from 01/01/2023 to 09/11/2023. Findings Include: 1. On the day of the survey, 09/21/2023 at 1:45 pm, review of the laboratory's humidity and temperature control logs revealed the laboratory failed to monitor and document room temperature (Acceptable range- 18-24 degrees Celsius) and humidity (Acceptable range- 20-69%) to ensure operating conditions were met for the following days from 01/01/2023 to 09/11/2023: - 11 of 31 days in January 2023 - 8 of 28 days in February 2023 -10 of 31 days in March 2023 -10 of 30 days in April 2023 -12 of 21 days in May 2023 - 11 of 30 days in June 2023 -13 of 31 days in July 2023 - 12 of 31 days in August 2023 - 6 of 11 days in September 2023 2. The hours of laboratory testing per the CMS 116 are Monday-Friday 07:00 am to 03:30 pm. The laboratory could not provide documentation of temperatures for weekends and holidays. 3. The LM confirmed the findings above on 09/21/2023 at 2:00 pm.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for

	verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review of calibration verification records and interview with the laboratory manager (LM), the laboratory failed to perform and document calibration verifications at least once every 6 months as required for 2 of 2 Abaxis Piccolo Express chemistry analyzers from January 2022 to date of the survey. Findings include: 1. On the day of survey, 09/21/2023 at 01:02 pm, review of Abaxis Piccolo Xpress calibration verification records revealed the laboratory failed to perform calibration verification at least once every 6 months for the required analytes tested on 2 of 2 Abaxis Piccolo Xpress analyzers from January 2022 to the date of the survey. 2. The laboratory performed calibration verification procedures for the required chemistry analytes performed on the Abaxis Piccolo Xpress for the following dates: - 01/28/2022 - 04/14 /2022 - 01/18/2023 - 04/23/2023 3. The LM confirmed the above findings on 09/21 /2023 at 2:00pm.
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 lack of documentation and interview with the laboratory manager (LM), the laboratory failed to evaluate twice a year the relationship between test results using different instrumentation for routine chemistry examinations in 2021 and 2022. Findings include: 1. On the day of survey, 09/21/2023 at 12:56 pm, the laboratory failed to provide documentation of the biannual comparison studies for 1 of 1 routine chemistry test performed on the Abaxis Piccolo Xpress analyzer for 2021 and 2022: - Magnesium (moderate complexity) 2. The LM confirmed the finding above on 09/21 /2023 at 02:00 pm.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on review of the laboratory's quality control records (QC), and interview with testing personnel #1 (TP), the laboratory failed to provide documentation of the

	corrective actions taken for QC results that failed to meet the laboratory's established acceptable criteria for hematology testing performed for 5 of 15 days in September 2023. Findings include: 1) On the day of the survey, 09/21/2023 at 01:00 pm, review of the laboratory's QC records revealed that the following QC results for hematology testing performed from 09/01/2023 to 09/21/2023 failed to meet the laboratory's established acceptable criteria: - 5 of 15 days in September 2023: Beckman DxH 600: Complete Blood Count with differential (Level 1) - 09/05/2023 - 09/13/2023 - 09/14 /2023 - 09/19/2023 - 09/20/2023 2. The laboratory's Laboratory Quality Plan procedure, states "corrective actions are to be documented on control sheets, documentation of corrective action will be noted in software for DxH." 3. The laboratory could not provide documentation of the corrective actions taken for Level 1 of QC performed on the Beckman DxH 600 that did not meet the laboratory's established acceptable criteria. 4. The LM confirmed the findings above on 09/21 /2023 at 02:00 pm.