Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 39D0184087	**(X3) Date Survey Completed** 07/14/2021
Name of Provider or Supplier Upmc Hillman Cancer Center At Erie	**Street Address, City, State** 2500 West 12th Street, Erie, 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 on review of the Competency assessment policy, lack of documentation and interview with the technical supervisor (TS) #2, the laboratory failed to follow their competency assessment policy and document proficiency testing (PT) performed by 4 of 4 testing personnel (TP) on each test system and establish a supervisor competency assessment policy from 07/14/2019 to the day of survey. Findings include: 1. The competency assessment policy states: - " Competence assessment is performed by the laboratory director, laboratory supervisor or designee, on new employees at 6 months for the 1st year, and yearly thereafter". - "Competence is determines is determined for each test that the individual is approved to perform by: 2. Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples". 2. On the day of survey, 07/14/2021, review of 4 of 4 TP competency assessment records revealed, the assessment of previously analyzed specimens, internal blind testing samples or external PT samples were not documented for each tests system on TP competency records in 2019, 2020 and 2021. 3. TP#1 was not assessed for competency in 2019, 2020 and 2021. 4. The competency assessment policy did not include the assessment of the technical consultant, technical supervisor or general supervisor for competency. 5. The TP #6 confirmed the findings above on 03/26/2019 around 09:30 am.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)

	For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on observation of the laboratory, and interview with the Technical Supervisor (TS) #2, the laboratory failed to perform maintenance/calibration on 3 of 3 thermometers and 3 of 3 pipettes from 7/14/2019 to the day of survey. Findings include: 1. On the day of survey, 07/14/2021, observation of the laboratory revealed, the follow thermometers and pipettes were due for maintenance: - Laboratory: Fisher Scientific Traceable Thermometer. S/N: 150470504. Due for maintenance 06/2017. - Refrigerator: Fisher Scientific Traceable Thermometer. S/N: 150539029. Due for maintenance 06/2017. - 100 to 1000 micro liter pipette (1 of 1): S/N: 150877. Due for calibration 01/31/2020. - 10 to 100 micro liter pipettes (2 of 2): S/N: 189716. S/N: 346987. Due for calibration 01/31/2020. 2. The laboratory could not provide a policy for thermometer maintenance. 3. TS#2 confirmed the finding above on 07/14/2021 around 3:30 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 laboratory records and interview with the technical supervisor (TS) #2, the laboratory failed to perform calibration verification studies at least once every 6 months for sodium (Na), potassium (K) and chloride (Cl) analyzed on the Siemens Dimension EXL 200 in 2019 and 2020. Findings Include: On the day of survey, 07/14/2021, the laboratory could not provide calibration verification studies performed at least once every 6 months in 2019 and 2020 on the Siemens Dimension EXL 200 for Na, K and Cl. 2. The current validation for Na, K and Cl was performed

	on 05/17/2021. 3. On 07/14/2021, the TS confirmed they could not find documentation of CV performed for the Siemens Dimension EXL 200 for Na, K and Cl prior to 05/17/2021 around 3:15 pm.
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. This STANDARD is not met as evidenced by: Based on the review of the College of American Pathologist (CAP) proficiency testing (PT) records and interview with technical supervisor (TS) #2, the laboratory director failed ensure all proficiency testing reports received, were reviewed to identify any problems that require corrective action in 2020 and 2021. Findings Include: 1. On the day of survey, 07/14/2021, the laboratory could not provide complete correction action plans documented for the following CAP PT events: - 2020 CAP PT Event #1 - Total Protein score of 0%. - 2020 CAP PT Event #3 - Cell Identification score of 80%. - 2021 CAP PT Event #1 - Sodium score of 80%. 2. The TS#2 confirmed the findings above at 07/14/2021 around 1:30 pm.