| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number<br>39D0184087 | (X3) Date Survey Completed<br>06/13/2023 |
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| **Name of Provider or Supplier**<br>Upmc Hillman Cancer Center At Erie | **Street Address, City, State**<br>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 |
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| **D5209** | PERSONNEL COMPETENCY ASSESSMENT POLICIES<br>CFR(s): 493.1235<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of competency assessment records and interview with the Techincal Supervisor (TS), the laboratory failed to establish a competency assessment procedure to assess 1 of 1 Techincal Supervisors for their supervisory responsibilities from 07/14/2021 to the day of survey. Findings Include: 1. On the day of survey, 06/15/2023 at 11:38 AM, the laboratory could not provide a competency assessment procedure to assess the competency for 1 of 1 TS from 07/14/2021 to the day of survey. 2. The laboratory could not provide competency assessment documentation for 1 of 1 TS from 07/14/2021 to the date of the survey. 3. The TS confirmed the findings above on 06/15/2023 around 2:30 PM. |
| **D5291** | GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT<br>CFR(s): 493.1239(a)<br><br>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of Quality Assessment (QA) records, QA Policy, and interview with the laboratory supervisor, the Laboratory failed to ensure QA programs were |

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| | maintained and documented to ensure the quality of laboratory's pre-analytical services provided from 01/01/2022 to 12/31/2022. Findings Include: 1. The QA policy on page 1, under pre-analytical analysis, states: "Chart review audits are performed to assure correct tests have been performed per physician order" 2. On the day of survey, 06/13/2023 at 1:00 PM, the supervisor could not provide QA documentation for the periodic evaluation of the laboratory's chart review processes from 01/01/2022 to 12 /31/2022. 3. The supervisor confirmed the findings above on 06/13/2023 around 2:30 PM. |