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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 33D0970412 | (X3) Date Survey Completed 06/06/2025 |
| Name of Provider or Supplier Cny Family Care Llp | Street Address, City, State 4939 Brittonfield Parkway, East Syracuse, NY | |
| 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 | <p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of personnel competency assessments records, Standard Operating Procedures (SOPs), as well as interview with the Laboratory Manager (LM), the laboratory failed to establish and draft procedures to assess Clinical Consultant (CC), Technical Consultant/Supervisor (TC/S), and General Supervisor (GS) competency. FINDINGS: 1. There was no documentation of CC, TC/S, and GS competency assessment performance. 2. The current, approved SOPs did not include instructions for performing such activity. 3. It was noted that Testing Personnel (TP) competency assessment was performed and documented. 4. The LM confirmed the findings on June 5, 2025, at approximately 11:00 A.M.</p> |
| D6075 | <p>TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(6)</p> <p>(b)(6) Document all corrective actions taken when test systems deviate from the laboratory's established performance specifications.</p> <p>This STANDARD is not met as evidenced by: Based on review of Quality Control (QC) records, SOPs, lack of corrective action records, as well as interviews with the LM and TP, the laboratory failed to document corrective action for analyzer QC results that deviated from the laboratory's established specifications. FINDINGS: 1. Abbott Alinity ci chemistry analyzer QC</p> |

Technopath electronic peer review report data confirmed analyte values were outside of acceptable limits. 2. There was no documentation of corrective action performance for analyzer QC analyte values which deviated from the acceptable range. 3. It was noted that the respective analyzer QC analyte results were reviewed, approved by TP. 4. This was also contrary to instructions indicated in the current, approved SOPs. 5. The LM and TP confirmed the findings on June 6, 2025, at approximately 12:45 P.M.

D6107

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(15)

(e)(15) Specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:
Based on review of job descriptions for all personnel involved in the preanalytic, analytic, and postanalytic phases of testing as well as interview with the LM, the Laboratory Director (LD) failed to draft, approve job responsibilities and duties for the LD, CC, TC/S, and GS. FINDINGS: 1. The LD job description did not include responsibilities and duties aligned to fulfill LD regulated requirements. 2. There was no documentation of CC, TC/S, and GS job descriptions. 3. The LM confirmed the findings on June 5, 2025, at approximately 11:00 A.M.