

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D2156309	(X3) Date Survey Completed 04/08/2025
Name of Provider or Supplier Paradigm Family Health Np Pllc	Street Address, City, State 4721 Transit Road, Ste B, Depew, 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
D5221	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d)</p> <p>All proficiency testing evaluation and verification activities must be documented.</p> <p>This STANDARD is not met as evidenced by: Based on review of American Proficiency Institute (API) Proficiency Testing (PT) summary reports, lack of corrective action documentation, as well as interview with the LD (Laboratory Director), the laboratory failed to document corrective action for PT failures. FINDINGS: a. A review of the non-regulated Chemistry Toxicology report from API (2024) revealed the following unsatisfactory scores: 1. Creatinine, UAD Interpretation: 2024 First Event = 0% 2024 Second Event = 0% 2. Urine Drug Screen (UDS) 6-Acetylmorphine (qual): 2024 First Event = 0% 2024 Second Event = 0% 3. UDS Amphetamines (qual): 2024 First Event = 0% 2024 Second Event = 0% 4. UDS Benzodiazepines (qual): 2024 First Event = 0% 2024 Second Event = 0% 5. UDS Cannabinoids (qual): 2024 First Event = 0% 2024 Second Event = 0% 6. UDS Cocaine Metabolites (qual): 2024 First Event = 0% 2024 Second Event = 0% 7. UDS Methamphetamines (qual): 2024 First Event = 0% 2024 Second Event = 0% 8. UDS Opiates (qual): 2024 First Event = 0% 2024 Second Event = 0% 9. UDS Oxycodone (qual): 2024 First Event = 0% 2024 Second Event = 0% b. There was no documentation of corrective action performance for unsuccessful PT participation. c. The LD confirmed the findings on April 8, 2025, at approximately 1:00 P.M.</p>
D5291	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>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.</p>

	<p>This STANDARD is not met as evidenced by: Based on review of laboratory systems Quality Assurance (QA) Standard Operating Procedures (SOPs), lack of QA records, as well as interview with the LD, the laboratory failed to perform and document QA. FINDINGS: 1. There was no documentation of annual QA performance. It was noted there was a January 2024 QA review checklist form. 2. This was contrary to instructions indicated in the current, approved QA SOPs. 3. The LD confirmed the findings on April 8, 2025, at approximately 2:00 P.M.</p>
<p>D5417</p>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on direct observation, review of thermometer calibration records and SOPs, as well as interview with the LD, the laboratory failed to perform and document thermometer calibration. FINDINGS: 1. There was no documentation of calibration performance for Traceable thermometer, Serial Number (SN): 221755356, utilized for monitoring laboratory temperature and humidity; calibration expiration: September 12, 2024. 2. There was no documentation of calibration performance for Traceable thermometer, SN: 230075981, utilized for monitoring laboratory refrigerator temperature; calibration expired February 1, 2025. 3. The current, approved SOPs did not include instructions for performing such activity. 4. The LD confirmed the findings on April 8, 2025, at approximately 12:30 P.M.</p>
<p>D5421</p>	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>(b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on lack of analyzer verification records as well as interview with the LD, the laboratory failed to perform and document ImmTox Automated Clinical Analyzer verification. FINDINGS: 1. There was no documentation of ImmTox Automated Clinical Analyzer verification performance after the analyzer was moved to a new location in March 2024. 2. The LD assured no patient specimens were tested utilizing the ImmTox Automated Clinical Analyzer after the respective move date. 3. The LD confirmed the findings on April 8, 2025, at approximately 2:00 P.M.</p>
<p>D6004</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES</p>

CFR(s): 493.1407(a)(b)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reappropriates performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:

Based on review of SOPs, job descriptions, personnel education, experience, and qualification records, the LD failed to employ a qualified Clinical Consultant (CC) to perform moderate complexity test procedures, and record and report test results promptly, accurately, and proficiently to assure compliance with applicable regulations. Refer to D6057.

D6013

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(3)(ii)

(e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and

This STANDARD is not met as evidenced by:

Based on lack of ImmTox Automated Clinical Analyzer verification records as well as interview with the LD, the LD failed to perform and document analyzer verification to determine the accuracy, precision, and other pertinent performance characteristics of the testing method. Refer D5421.

D6018

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(4)(iii)

(e)(4)(iii) 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; and

This STANDARD is not met as evidenced by:

Based on review of API PT summary reports, lack of corrective action documentation, as well as interview with the LD, the LD failed to evaluate the laboratory's performance and to identify any problems that require corrective action. Refer to D5221.

D6020

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(5)

(e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;

	<p>This STANDARD is not met as evidenced by: Based on review of laboratory systems QA SOPs, lack of QA records, as well as interview with the LD, the LD failed to comply with instructions indicated in the current, approved QA SOPs to assure the quality of laboratory services provided and to identify failures in quality as they occur. Refer to D5291.</p>
<p>D6027</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(9)</p> <p>(e)(9) Ensure that consultation is available to the laboratorys clients on matters relating to the quality of the test results reported and their interpretation concerning specific patient conditions;</p> <p>This STANDARD is not met as evidenced by: Based on review of SOPs, job descriptions, personnel education, experience, and qualification records, the LD failed to employ a qualified CC for moderate complexity testing to ensure that consultation is available to the laboratory's clients on matters relating to the quality of the test results reported and their interpretation concerning specific patient conditions. Refer D6057.</p>
<p>D6056</p>	<p>CLINICAL CONSULTANT CFR(s): 493.1415</p> <p>The laboratory must have a clinical consultant who meets the qualification requirements of 493.1417 of this part and provides clinical consultation in accordance with 493.1419 of this part.</p> <p>This CONDITION is not met as evidenced by: Based on review of SOPs, job descriptions, personnel education, experience, and qualification records, the LD failed to employ a qualified CC for moderate complexity testing who meets the qualification requirements of 493.1417 of this part and provides clinical consultation in accordance with 493.1419 of this part. Refer to 6057.</p>
<p>D6057</p>	<p>CLINICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1417</p> <p>The clinical consultant must be qualified to consult with and render opinions to the laboratory's clients concerning the diagnosis, treatment and management of patient care. The clinical consultant must-- (a) Be qualified as a laboratory director under 493.1405(b)(1), (2), or (3); or (b) Be a doctor of medicine, doctor of osteopathy or doctor of podiatric medicine and possess a license to practice medicine, osteopathy or podiatry in the State in which the laboratory is located.</p> <p>This STANDARD is not met as evidenced by: Based on review of SOPs, job descriptions, personnel education, experience, and qualification records, the LD failed to employ a qualified CC for moderate complexity testing to consult with and render opinions to the laboratory's clients concerning the diagnosis, treatment and management of patient care. FINDINGS: 1. The facility did</p>

not employ a qualified CC for moderate complexity testing. 2. There was no documentation of CC job description or responsibilities. 3. It was noted that current, approved Pre-Analytical Policies included instructions that all specimen requisitions must be approved by a CC. 4. The LD confirmed the findings on April 8, 2025, at approximately 12:15 P.M.