

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 46D1100997	(X3) Date Survey Completed 08/22/2019
Name of Provider or Supplier Legacy Point Family Medicine	Street Address, City, State 81 North 2000 West, Ste F2, West Point, UT	
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
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on lack of documentation and confirmation by the laboratory director, the laboratory failed to enroll in proficiency testing for the specialty of Hematology for 2019 testing. The laboratory did not enroll for the 1st and 2nd Hematology proficiency testing events.</p>
D3037	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4)</p> <p>Proficiency testing records. Retain all proficiency testing records for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on proficiency testing records review, lack of documentation, and interview with staff, the laboratory failed to retain proficiency testing attestation statements for 2 of 4 proficiency testing events reviewed from the 3rd American Proficiency Institute (API) event of 2017 through the 3rd event of 2018 (the last event participated in by the laboratory). Findings include: 1. The laboratory failed to retain the attesting</p>

	<p>statement signed by the director and testing personnel from the 2nd and 3rd API Hematology events of 2018. 2. In an interview with staff on 08/22/2019 at approximately 11:30 A.M. staff confirmed the attestation statements signed by the director and testing personnel were not maintained for at least 2 years.</p>
<p>D5291</p>	<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 lack of documentation and confirmation by the laboratory director, the laboratory failed to ensure they had a quality assurance plan to monitor proficiency testing records to ensure enrollment in an approved proficiency testing program and that corrective actions were taken when the laboratory failed to receive proficiency testing reports for regular quality assessment review of the the laboratory's scored results. Findings include: 1. The laboratory failed to establish and follow a general laboratory qualify assurance plan to monitor proficiency testing results. 2. The laboratory failed to enroll in Hematology proficiency testing for 2019 testing. 3. Failure to establish and follow a general laboratory quality assurance plan contributed to the failure of the laboratory to identify they had not enrolled in Hematology complete blood cell testing proficiency testing in 2019. 4. In an interview conducted with the director on 08/22/2019 at approximately 9:15 A.M. the director stated the lab did not recognize the enrollment failure until just prior to the on-site survey.</p>
<p>D5407</p>	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on procedure manual review, lack of documentation, and interview with the director, the current director failed to sign and date the procedure manual as approved. Findings include: 1. The procedure manual review failed to include the signature and date of approval by the current director. 2. In an interview with the director on 08/22 /2019 at approximately 10:00 A.M. the director stated the hematology procedure manual for complete blood cell testing did not include a signature and date of approval.</p>
<p>D6000</p>	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.</p>

This CONDITION is not met as evidenced by:
Based on lack of documentation and interview with the director, the laboratory director failed to provide overall laboratory direction by failure to ensure the laboratory enrolled in an HHS approved proficiency testing program for Hematology testing in 2019 (See D6015); failure to ensure corrective actions were taken when the laboratory failed the 3 Hematology testing event of 2018 (See D6018); and failure to ensure the laboratory established and maintained a quality assurance program (See D6021).

D6015

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(4)

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. (e) The laboratory director must-- (e)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed.

This STANDARD is not met as evidenced by:
Based on lack of documentation and interview with the director, the laboratory director failed to ensure the laboratory enrolled in Hematology proficiency testing for complete blood cell counts in 2019. (See D2000)

D6018

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(4)(iii)

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. (e) The laboratory director must-- (e)(4)(iii) Ensure that 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 lack of documentation and interview with staff, the laboratory director failed to ensure the laboratory reviewed 1 of 4 proficiency testing events reviewed, the 3rd American Proficiency Institute (API) Hematology proficiency testing event of 2018 for corrective actions required for a zero per cent score for complete blood cell count (CBC) testing. Findings include: 1. The laboratory lacked documentation they participated in the 3rd API Hematology proficiency testing event of 2018 receiving a score of 0%. 2. The laboratory director failed to ensure the laboratory documented corrective actions taken for a 0% score to prevent recurrence. 3. The laboratory failed to participate in the 1st and 2nd testing events of 2019. 4. The laboratory failed to document an alternative to proficiency testing as a method to verify complete blood count testing accuracy and reliability. 5. In an interview on 08/22/2019 at approximately 12:00 Noon, the director confirmed proficiency testing review, enrollment, and corrective actions taken were not addressed from October 2018 (for the 3rd event of 2018) through August 2019 at the time of survey.

D6021

LABORATORY DIRECTOR RESPONSIBILITIES

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

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. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

Based on lack of documentation, proficiency testing records review, and interview with the laboratory staff, the director failed to ensure the laboratory maintained a hematology quality assessment program to maintain the quality of the complete blood cell count test process. Findings include: 1. The laboratory failed to participate in hematology proficiency testing for the 3rd event of 2018 resulting in a score of 0 percent for the 3rd event of 2018. The laboratory failed to document corrective actions or document an alternate quality assessment activity. 2. The laboratory failed to enroll in proficiency testing for the specialty of Hematology in 2019. The laboratory failed to document alternate quality assessment activities as corrective actions or to demonstrate the laboratory results were accurate and reliable. 3. In an interview with staff on 08/22/2019 at approximately 11:30 P.M., the director confirmed the quality assessment plan failed to include the frequency the laboratory monitored proficiency testing enrollment or corrective actions to take when the laboratory failed to participate or failed complete blood cell count proficiency testing. .