

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 02D0953045	(X3) Date Survey Completed 10/29/2025
Name of Provider or Supplier Hillside Family Medicine, Llc	Street Address, City, State 9220 Lake Otis Pkwy, Suite 5a, Anchorage, AK	
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
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 policies and procedures, lack of documentation, and an interview with testing personnel three (TP3) the laboratory failed to fully establish procedures and follow quality assessment activities described in the procedure since December 2023. The findings include: 1. A review of the procedure "Patient Result Review" listed quality assessment activities to review calculations, linearity, clerical error, unusual results, critical values and provider notification, and performance of reflex testing. 2. A request was made for quality assessment policies or procedures describing how quality assessment activities are performed but documentation could not be provided. 3. Documentation for performing review of quality assessment activities could not be provided. 4. An on-site interview with TP3 on 10/29/25 at 2:00 PM confirmed there was no documentation. 5. The laboratory reports performing 78096 tests annually.</p>
D5781	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)</p>

(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

Based on a review of maintenance logs, lack of documentation, and an interview with testing personnel three (TP3) the laboratory failed to document corrective actions for when temperatures and humidity were outside the acceptable range for 30 out of 140 days since January 2025. The findings include: 1. Review of the maintenance logs from January 2025 to September 2, 2025, revealed: a. Documented freezer and room temperatures were out of acceptable range on 30 out of 140 days where samples and reagents are stored and testing is performed without documentation of corrective actions. b. Temperatures were not documented on 25 out of 140 days without documentation of corrective actions. c. Humidity levels were documented without acceptable ranges on 140 out of 140 days. 2. A request was made for documentation of corrective actions taken but could not be provided. 3. An on-site interview with TP3 on 10/29/25 at 2:00 PM confirmed that documentation was not available. 4. The laboratory reports performing 78096 tests annually.

D6046

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(8)

(b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. The procedures for evaluation of the competency of the staff must include, but are not limited to--

This STANDARD is not met as evidenced by:

Based on review of competency assessment forms and an interview with testing personnel one (TP1), the Technical Consultant failed to evaluate the competency for three (3) of three (3) staff for the specialty of hematology and subspecialties of mycology, routine chemistry, urinalysis, and endocrinology since July 2024. Findings include: 1. Review of the competency assessment forms for 3 of 3 testing personnel revealed the competency assessments were evaluated by personnel who were not delegated as technical consultants. 2. An onsite interview with TP1 on 10/29/25 at 10:00 AM confirmed the findings. 3. The laboratory reports performing 78096 tests annually.