

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 46D0959710	<b>(X3) Date Survey Completed</b> 01/17/2019
<b>Name of Provider or Supplier</b> Intermountain Life Flight	<b>Street Address, City, State</b> 100 North Mario Capecchi Drive, Salt Lake City, UT	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5775</b>	<p>COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c)</p> <p>(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.</p> <p>This STANDARD is not met as evidenced by: Based on laboratory qualify assessment records review, quality control records review, and interview with the laboratory staff, the laboratory failed to ensure the twice a year evaluation of i-STAT test instruments compared the relationship between tests results for 14 of 16 different i-STAT instruments. Findings include: 1. The laboratory quality assessment records failed to include test values they compared more than two of the 16 instruments to each other at least twice annually in 2017 and 2018 for reporting test results for pH, partial pressure oxygen, partial pressure carbon dioxide, base excess, oxygen saturation, bicarbonate, sodium, potassium, chloride, total carbon dioxide, glucose, lactate, hemoglobin, and hematocrit using two test cartridges (CG4+ and CG8+). 2. The laboratory quality control records review failed to include instrument to instrument comparison using the same quality control materials at least twice annually. 3. In an interview conducted on 01/17/2019 at 11:40 A.M., the technical consultant stated the laboratory did not have a method to compare all 16 of the i-STAT instruments in use at the 5 base locations twice a year. The technical consultant stated the laboratory method was to compare two different units twice annually. The laboratory performed approximately 17,000 tests per year using the CG4+ and CG8+ cartridges on the 16 i-STAT unit use instruments.</p>
<b>D6018</b>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii)</p>

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 proficiency testing records review, lack of documentation and interview with the director, the director failed to ensure proficiency test results were reviewed and identify problems requiring corrective actions for 5 of 6 API proficiency testing events reviewed for tests performed on the i-STAT instruments for two years of test results reviewed between January 2017 and January 2019. Findings include: 1. American Proficiency Institute (API) testing records review included test report results of 80% score for oxygen partial pressure concentration (pO<sub>2</sub>) for the 2nd testing event of 2017, 80% for potassium (K) for the 3rd event of 2017, 60% for pO<sub>2</sub> for the 1st event of 2018, 80% for pH the 2nd event of 2018 and 80% for pO<sub>2</sub> and for hemoglobin (hgb) in the 3rd event of 2018. 2. The laboratory failed to document identification of problems that required corrective action. 3. In an interview conducted on 01/17/2019 at approximately 10:30 A.M. and again at approximately 1:30 P.M. the director stated the lack of corrective actions was an oversight for the failed proficiency test (60% from the 1st event of 2018).