

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  13D0980387	<b>(X3) Date Survey Completed</b>  02/20/2018
<b>Name of Provider or Supplier</b>  Ip Boise 1	<b>Street Address, City, State</b>  8660 W Emerald St #102, Boise, ID	
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>D2000</b>	<p><b>ENROLLMENT AND TESTING OF SAMPLES</b> 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 the review of proficiency testing records and an interview with the laboratory director, both from Interpath Laboratory in Twin Falls, Idaho, CLIA 13D1046008, the Interpath Laboratory in Boise, Idaho CLIA 13D0980387, failed to meet the requirements for proficiency testing. Refer to D2011 and D2013.</p>
<b>D2011</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> CFR(s): 493.801(b)(3)</p> <p>Laboratories that perform tests on proficiency testing samples must not engage in any inter-laboratory communications pertaining to the results of proficiency testing sample (s) until after the date by which the laboratory must report proficiency testing results to the program for the testing event in which the samples were sent. Laboratories with multiple testing sites or separate locations must not participate in any communications or discussions across sites/locations concerning proficiency testing sample results until after the date by which the laboratory must report proficiency testing results to the program.</p>

This STANDARD is not met as evidenced by:  
Based on proficiency testing (PT) records review and an interview with the laboratory director, both from Interpath Laboratory in Twin Falls, Idaho, the Interpath Laboratory in Boise, Idaho engaged in inter-laboratory communication on November 17, 2017 with Interpath Laboratory in Twin Falls, Idaho pertaining to the five American Proficiency Institute (API) Hematology complete blood count (CBC) samples from the third event in 2017. Findings: 1. A review of PT sample instrument printout results from two different Beckman Coulter DxH 600 hematology instruments, revealed separate results for 5 API 5C CBC samples retained from Interpath in Twin Falls (run on November 14, 2017) and Interpath in Boise (run on November 17, 2017). Interpath in Boise returned the results via laboratory information system back to Interpath Laboratory in Twin Falls prior to API's submission deadline of December 1, 2017. 2. An interview on February 8, 2018 at 8:45 AM, with the laboratory director from Interpath Laboratory in Twin Falls, confirmed the laboratory sent the 5 API CBC samples to Interpath laboratory in Boise to analyze prior to the submission deadline.

**D2013**

**TESTING OF PROFICIENCY TESTING SAMPLES**  
CFR(s): 493.801(b)(4)

The laboratory must not send proficiency testing samples or portions of proficiency testing samples to another laboratory for any analysis for which it is certified to perform in its own laboratory. Any laboratory that CMS determines intentionally referred a proficiency testing sample to another laboratory for analysis may have its certification revoked for at least one year. If CMS determines that a proficiency testing sample was referred to another laboratory for analysis, but the requested testing was limited to reflex, distributive, or confirmatory testing that, if the sample were a patient specimen, would have been in full conformance with written, legally accurate and adequate standard operating procedures for the laboratory's testing of patient specimens, and if the proficiency testing referral is not a repeat proficiency testing referral, CMS will consider the referral to be improper and subject to alternative sanctions in accordance with 493.1804(c), but not intentional. Any laboratory that receives a proficiency testing sample from another laboratory for testing must notify CMS of the receipt of that sample regardless of whether the referral was made for reflex or confirmatory testing, or any other reason.

This STANDARD is not met as evidenced by:  
Based on proficiency testing (PT) records review and an interview with the laboratory director, both from Interpath Laboratory in Twin Falls, Idaho, CLIA 13D1046008, the Interpath Laboratory in Boise, Idaho, CLIA 13D0980387 received five American Proficiency Institute (API) Hematology complete blood count (CBC) 5C samples from Interpath Laboratory in Twin Falls, Idaho for the third event in 2017 on November 17, 2017 and failed to notify CMS of the receipt of the samples. Findings: 1. A review of API PT records from Interpath Laboratory in Twin Falls, revealed Interpath Laboratory in Boise received 5 API 5C hematology CBC samples, from 2017 event 3, from Interpath Laboratory in Twin Falls. 2. A record review of the 5 CBC PT sample results received from Interpath Laboratory in Boise, revealed the laboratory tested the 5 hematology samples from Interpath Laboratory in Twin Falls, Idaho on November 17, 2017 and failed to notify CMS of the receipt of the samples.

	<p>3. An interview on February 8, 2018 at 8:45 AM, with the laboratory director from Interpath Laboratory in Twin Falls, confirmed Interpath Laboratory in Boise received, tested, and returned results for the 5 API CBC samples.</p>
<p><b>D6076</b></p>	<p><b>LABORATORY DIRECTOR</b> CFR(s): 493.1441</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on proficiency testing records review and an interview with the laboratory director from Interpath Laboratory in Twin Falls, Idaho, CLIA 13D1046008, the laboratory director of Interpath Laboratory in Boise, Idaho CLIA 13D0980387 failed to provide overall management and direction for proficiency testing. Refer to D6089.</p>
<p><b>D6089</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1445(e)(4)(i)</p> <p>The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on proficiency testing (PT) records review and an interview with the laboratory director, both from Interpath Laboratory in Twin Falls, Idaho, CLIA 13D1046008, the Interpath Laboratory in Boise, Idaho, CLIA 13D0980387 received, tested, and returned results to Interpath Laboratory in Twin Falls, for the 5 American Proficiency Institute (API) hematology complete blood count (CBC) proficiency test samples from the third event in 2017. Therefore, the laboratory director from the Interpath Laboratory in Boise, Idaho failed to ensure that the laboratory handled PT samples as directed under subpart H of the CLIA regulations. Findings: 1. A review of API PT records from Interpath Laboratory in Twin Falls, revealed Interpath Laboratory in Boise received 5 API 5C hematology CBC samples, from 2017 event 3, from Interpath Laboratory in Twin Falls. 2. A record review of the 5 CBC PT sample results received from Interpath Laboratory in Boise, revealed the laboratory tested the 5 hematology samples from Interpath Laboratory in Twin Falls, Idaho on November 17, 2017. 3. An interview on February 8, 2018 at 8:45 AM, with the laboratory director from Interpath Laboratory in Twin Falls, confirmed Interpath Laboratory in Boise received, tested, and returned results for the 5 API CBC samples.</p>