

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  13D1046008	<b>(X3) Date Survey Completed</b>  02/08/2018
<b>Name of Provider or Supplier</b>  Ip Twin Falls 1	<b>Street Address, City, State</b>  358 Cheney Dr W Ste 102, Twin Falls, 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 proficiency testing records and an interview with the laboratory director, the laboratory failed to meet the requirements for proficiency testing in hematology for complete blood counts. 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, the laboratory engaged in inter-laboratory communication pertaining to the American Proficiency Institute (API) Hematology complete blood count (CBC) samples from the third event in 2017 to another CLIA-certified laboratory on November 17, 2017. Findings: 1. A review of PT records from API, revealed the laboratory tested five (5) API 5C CBC samples for the Beckman Coulter DxH 600, from the 2017 event 3, on November 14, 2017. 2. A review of the 5 CBC PT sample results from the DxH, revealed the laboratory sent the 5 CBC samples to Interpath Laboratory in Boise, Idaho, CLIA number 13D0980387, on November 17, 2017 prior to API's submission deadline of December 1, 2017. 3. An interview on February 8, 2018 at 8:45 AM, with the laboratory director, confirmed the laboratory sent the 5 API CBC samples to Interpath laboratory in Boise, Idaho for analysis prior to the submission deadline for hematology.

**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, the laboratory referred the American Proficiency Institute (API) Hematology complete blood count (CBC) samples from the third event in 2017 to another CLIA-certified laboratory on November 17, 2017. Findings: 1. A review of PT records from API, revealed the laboratory tested five (5) API 5C hematology CBC samples for the Beckman Coulter DxH 600, event 3, on November 14, 2017. 2. A record review of the 5 CBC PT sample results from the DxH revealed the laboratory sent the 5 hematology samples to Interpath Laboratory in Boise, Idaho CLIA number 13D0980387 on November 17, 2017 prior to API's submission deadline of December 1, 2017. 3. A record review of the API PT results report revealed the laboratory submitted their CBC results obtained on November 14, 2017. 4. An interview on February 8, 2018 at 8:45 AM, with the laboratory director, confirmed the laboratory sent the 5 API CBC samples to Interpath laboratory in Boise, Idaho for analysis.

**D6000**

**MODERATE COMPLEXITY LABORATORY DIRECTOR**  
 CFR(s): 493.1403

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.

This CONDITION is not met as evidenced by:

Based on proficiency testing records review and an interview with the laboratory director, the laboratory director failed to ensure the successful participation of proficiency testing for the analyte complete blood count as required under Subpart H. See D6016.

**D6016**

**LABORATORY DIRECTOR RESPONSIBILITIES**

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

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)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;

This STANDARD is not met as evidenced by:

Based on proficiency testing (PT) records review and an interview with the laboratory director, the laboratory referred the American Proficiency Institute (API) Hematology complete blood count (CBC) samples from the third event in 2017 to another CLIA-certified laboratory on November 17, 2017. Findings: 1. A record review of PT records from API, revealed the laboratory tested five (5) API 5C CBC samples for the Beckman Coulter DxH 600, from 2017 event 3, on November 14, 2017. 2. A record review of the 5 CBC PT sample results from the DxH, revealed the laboratory sent the 5 hematology samples to Interpath Laboratory in Boise, Idaho CLIA number 13D0980387 on November 17, 2017 prior to API's submission deadline of December 1, 2017. 3. An interview on February 8, 2018 at 8:45 AM, with the laboratory director, confirmed the laboratory sent the 5 API CBC samples to Interpath in Boise, Idaho for analysis.