

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 13D2274131	(X3) Date Survey Completed 11/16/2023
Name of Provider or Supplier Incyte Diagnostics Inc	Street Address, City, State 750 North Syringa St Ste 101, Post Falls, ID	
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
D5445	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on a review of instrument quality control (QC) printouts and an interview with the laboratory compliance officer on 11/16/2023, the laboratory failed to perform QC each day of patient complete blood count (CBC) testing. The findings include: 1. A random review of Sysmex QC printouts for CBC testing identified that the laboratory failed to perform QC on August 13, 2023 and October 15, 2023. 2. A review of patient records identified five (5) patient CBC tests were reported on August 13, 2023 and one (1) patient CBC test was reported on October 15, 2023. 3. An interview with the laboratory compliance officer on 11/16/2023 at 10:16 am confirmed the above findings. 4. The laboratory reports performing 36,000 hematology tests annually.</p>
D5805	<p>TEST REPORT CFR(s): 493.1291(c)</p> <p>The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5)</p>

Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:

Based on a review of patient test reports and an interview with the laboratory compliance officer on 11/16/2023, the laboratory failed to clearly indicate the name of the performing laboratory for the reported tests. The findings include: 1. A review of laboratory patient test reports for chemistry and hematology testing identified that the laboratory failed to clearly indicate the name performing laboratory when testing is performed onsite since beginning patient testing in January of 2023. 2. An interview with the laboratory compliance officer on 11/16/2023 at 11:18 am confirmed the above finding. 3. The laboratory reports performing 126,050 tests annually.