

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 46D0933827	(X3) Date Survey Completed 08/25/2023
Name of Provider or Supplier Intermountain West Jordan Clinic	Street Address, City, State 2655 W 9000 S, W Jordan, UT	
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
D2016	<p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.</p> <p>This CONDITION is not met as evidenced by: Based on a routine desk review of the CMS-155 report for Proficiency Testing (PT) performance and email communications with the laboratory director, the laboratory failed to achieve successful PT scores for the American Proficiency Institute (API) PT for Cell I.D. or WBC Diff testing for three out of four PT events in 2022 and 2023 (events 1 and 2 in 2022 and events 1 in 2023). See D2130.</p>
D2130	<p>HEMATOLOGY CFR(s): 493.851(f)</p>

Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:

Based on review of proficiency testing scores from the American Proficiency Institute (API) and email communications with the laboratory director, the laboratory failed to meet successful PT participation for Cell I.D. or WBC Diff for events 1 and 2 in 2022 and for event 1 in 2023. Findings include: 1. A review of the CMS-155 Individual Laboratory Profile on 8/25/2023, at 11:00 AM, revealed the Cell I.D. or WBC Diff testing scores for 2022 event 1 was 32%, for 2022 event 2 was 0% and for 2023 event 1 was 0%. 2. Email received from the laboratory director on 8/17/2023, at 9:18 AM, confirmed the subsequent unsuccessful proficiency testing scores for Cell I.D. or WBC Diff.

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 a routine desk review of the CMS-155 report for Proficiency Testing (PT) performance and email communications with the laboratory director, the laboratory director failed to provide overall management of the laboratory by failing to ensure accurate PT testing and reporting for the Cell I.D. or WBC Diff. 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 a routine desk review of the CMS-155 report for Proficiency Testing (PT) performance and email communications with the laboratory director, the laboratory failed to meet successful PT participation for the Cell I.D. or WBC Diff. Findings include: 1. A review of the CMS-155 Individual Laboratory Profile on 8/25/2023, at 11:00 AM, revealed the American Proficiency Institute (API) PT for Cell I.D. or WBC Diff testing scores for 2022 event 1 was 32%, for 2022 event 2 was 0%, for 2023 event 1 was 0%. 2. Email received from the laboratory director on 8/17/2023, at 9:18 AM, confirmed the subsequent unsuccessful proficiency testing scores for Cell I. D. or WBC Diff.