

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 46D1047127	(X3) Date Survey Completed 02/26/2026
Name of Provider or Supplier Intermountain Health Southridge Instacare	Street Address, City, State 3723 West 12600 South Ste 150, Riverton, 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
D5421	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>(b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: _ Based on record review and interview with Technical Consultant 1 (TC1), the laboratory failed to ensure verification of performance specifications of within run and operator variance precision and reportable range of all of test results of all parameters measured of the PixCell HemoScreen complete blood count (CBC) analyzer. _ Findings include: 1. Record review of the "PixCell Precision Worksheet" revealed that precision samples for the CBC analyzer were performed one time each on 06/26/2024 and 07/05/2024. 2. Record review of verification of performance specifications raw data showed that Technical Consultant 2 (TC2) performed all precision samples on 06/26/2024 and 07/05/2024. 3. Interview with TC1 on 02/26/2026 at approximately 4:47 PM confirmed that precision studies did not verify the precision of within-run variation and operator variance. 4. Record review of "PixCell HemoScreen Linearity" failed to verify the reportable range of test results for Mean Corpuscular (erythrocyte) Volume (MCV), Mean Cell (erythrocyte) Hemoglobin (MCH), Mean cell (erythrocyte) Hemoglobin Concentration (MCHC), Red blood cell Distribution width (RDW)-CV Mean Platelets Volume (MPV), Neutrophils (NEUT; #/%), Monocytes (MONO; #/%), Lymphocytes (LYMP; #/%), Eosinophils (EO; #/%) and Basophils (BASO; #/%). 5. Interview with TC1 on 02/26/2026 at approximately 5:30 PM confirmed that the reportable range of the test results for Mean Corpuscular</p>

(erythrocyte) Volume (MCV), Mean Cell (erythrocyte) Hemoglobin (MCH), Mean cell (erythrocyte) Hemoglobin Concentration (MCHC), Red blood cell Distribution width (RDW)-CV Mean Platelets Volume (MPV), Neutrophils (NEUT; #/%), Monocytes (MONO; #/%), Lymphocytes (LYMP; #/%), Eosinophils (EO; #/%) and Basophiles (BASO; #/%) was not verified. 6. The laboratory performs approximately 13,434 annually. _

D5449

CONTROL PROCEDURES
CFR(s): 493.1256(d)(3)(ii)(g)

(d)(3)(ii) Each qualitative procedure, include a negative and positive control material;

This STANDARD is not met as evidenced by:

_ Based on record review and interview with the technical supervisor 1 (TS1), the laboratory failed to perform control procedures each day patient specimens are examined for urine sediment examinations. The laboratory performed approximately 17 mycology tests annually. _ Findings include: 1. A review of laboratory records revealed the laboratory failed to include records of positive and negative control procedures being performed for urine sediment examinations each day of patient testing. 2. An interview on 02/26/2026, at 4:08 PM, with the TS1 confirmed the laboratory failed to perform control procedures each day patient specimens were examined for urine sediment examinations.