

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 29D0538339	(X3) Date Survey Completed 02/15/2023
Name of Provider or Supplier Intermountain Healthcare - Wynn	Street Address, City, State 4880 Wynn Rd, Las Vegas, NV	
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
D0000	This Statement of Deficiencies was created as a result of an on-site initial CLIA certification survey conducted at your facility on February 15, 2023. The findings and conclusions of any investigation by the Division of Public and Behavioral Health shall not be construed as prohibiting any criminal or civil investigations, actions or other claims for relief that may be available to any party under applicable federal, state, or local laws.
D5215	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2)</p> <p>The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).</p> <p>This STANDARD is not met as evidenced by: Based on a review of the 2021 and 2022 American Proficiency Institute (API) Proficiency Testing (PT) records, a review of the director approved proficiency testing policy and procedure, and an interview with Technical Consultant #1, the laboratory failed to ensure that the ungraded proficiency testing results were evaluated for accuracy. Findings include: 1. A review of the 2021 Hematology/Coagulation test Event 3 records revealed that the laboratory failed to evaluate the ungraded results for the Educational Blood Cell Identification for samples ECI-11, ECI-12, ECI-13, ECI-14, and ECI-15. 2. A review of the 2022 Hematology/Coagulation test Event 1 records revealed that the laboratory failed to evaluate the ungraded results for the Educational Blood Cell Identification for samples ECI-01, ECI-02, ECI-03, ECI-04, and ECI-05. 3. A review of the 2022 Hematology/Coagulation test Event 3 records revealed that the laboratory failed to evaluate the ungraded results for the Educational Blood Cell Identification for samples ECI-11, ECI-12, ECI-13, ECI-14, and ECI-15. 4. A review</p>

of the 2022 Hematology/Coagulation test Event 3 records revealed that the laboratory failed to evaluate the ungraded result for the Blood Cell Identification for sample BCI-14. 5. A review of the 2022 Chemistry Core test Event 1 records revealed that the laboratory failed to evaluate the ungraded Total Iron Binding Capacity (TIBC) results for samples CH-02, CH-04, and CH-05 6. The director approved policy and procedure entitled, "Proficiency Testing" stated, "Proficiency tests not graded due to errors in submission or lack of consensus among the PT participants will be compared to the Participant Summary for assessment and corrective action if required or needed." 7. The findings were confirmed during an interview with Technical Consultant #1 conducted on February 15, 2023 at approximately 10:30 AM. The laboratory performs approximately 111,322 chemistry tests and 34,741 hematology tests annually.

D5413

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(b)

The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:
Based on a review of the 2021 and 2022 laboratory temperature and humidity records, and an interview with Technical Consultant #1, the laboratory failed to ensure that the laboratory room, refrigerator and freezer temperatures, and the laboratory humidity records were documented. Findings include: 1. There were no records available at the time of the survey for the laboratory room, refrigerator, and freezer temperatures, and no records of the laboratory humidity for the month of December, 2021. 2. The findings were confirmed during an interview with Technical Consultant #1 on February 15, 2023 at approximately 12:00 PM. The laboratory performs approximately 111,322 chemistry tests and 34,741 hematology tests and 48 general immunology tests annually.

D5429

MAINTENANCE AND FUNCTION CHECKS
CFR(s): 493.1254(a)(1)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:
Based on a review of the 2021 and 2022 laboratory maintenance records for the Sysmex XN-550 hematology analyzer, a review of the maintenance records for the Sysmex CA-600 coagulation analyzer, a review of the Vitros 5600 chemistry and immunoassay analyzer, and an interview with Technical Consultant #1, the laboratory failed to ensure that the analyzer maintenance was performed and documented in accordance with the manufacturer's instructions. Findings include: 1. There were no maintenance records available at the time of the survey of the for the Sysmex XN-550 hematology analyzer, for the Sysmex CA-600 coagulation analyzer, and for the Vitros

5600 chemistry and immunoassay analyzer for the month of December, 2021. 2. The findings were confirmed during an interview with Technical Consultant #1 on February 15, 2023 at approximately 12:00 PM. The laboratory performs approximately 111,322 chemistry tests and 34,741 hematology tests and 48 general immunology tests annually.

D5805

TEST REPORT
CFR(s): 493.1291(c)

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) 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 random patient audit of eight patients tested between the dates of January 4, 2021 and December 20, 2022, and an interview with Technical Consultant #1, the laboratory failed to ensure that the test report included the name and address of the laboratory where the test was performed. Findings include: 1. A random patient audit revealed that the name and address of the laboratory where the tests were performed was not on the test report for three of eight patients tested between the dates of January 4, 2021 and December 20, 2022. 2. On the three reports that did not indicate the name and address of the performing laboratory, there was a comment indicating the initials of the personnel who performed the testing, the date and time of the testing, and that the testing was performed at "Location 4." There was no interpretive guidance to indicate the name and address of the laboratory designated as "Location 4." 3. The findings were confirmed during an interview with Technical Consultant #1 on February 15, 2023 at approximately 12:30 PM. The laboratory performs approximately 111,322 chemistry tests and 34,741 hematology tests and 48 general immunology tests annually.

D6021

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(5)

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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

Based on a review of the laboratory quality assessment records between the dates of January 2021 and January, 2023 and an interview with Technical Consultant #1, the director failed to ensure that the quality assessment was performed and documented between the dates of December, 2021 and April, 2022. Findings include: 1. There were no records of quality assessment between the months of December, 2021 and

April, 2022 available for review at the time of the survey. 2. The findings were confirmed during an interview with Technical Consultant #1 on February 15, 2023 at approximately 11:30 AM. The laboratory performs approximately 111,322 chemistry tests and 34,741 hematology tests and 48 general immunology tests annually.

D6029

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(11)

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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:

Based on a review of the 2022 American Proficiency Institute (API) Proficiency Testing (PT) Chemistry Core test Event 2 attestation form, and an interview with Technical Consultant #1, the director failed to ensure that all personnel possessed the appropriate level of education, received the appropriate training and demonstrated competency to perform all testing to provide accurate and reliable results. Findings include: 1. There were no records of the highest level of education and initial training and competency assessment for one of five testing personnel who signed the attestation for the 2022 API PT Chemistry Core test Event 2 attestation form indicating that the personnel had performed Vitamin D and Parathyroid Hormone on specimen IAS-06 and IAS-07, and the Hemoglobin A1c (HbA1c) on specimens Gly-06 and Gly-07. 2. An interview with Technical Consultant #1 conducted on February 15, 2023 at approximately 9:30 AM confirmed the findings and revealed that the personnel had also performed patient testing. The laboratory performs approximately 111,322 chemistry tests and 34,741 hematology tests and 48 general immunology tests annually.