Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D0530411	07/18/2023
Name of Provider or Supplier	**Street Address, City, State**	
Honorhealth Tempe Medical Center	1500 S Mill Ave, Tempe, AZ	

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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of the laboratory's competency policies and interview with the Technical Consultant (TC-1), the laboratory failed to follow established policies and procedures to assess employee competency. Findings include: 1. The laboratory performs patient testing in the specialties of Microbiology, Diagnostic Immunology, Chemistry, Hematology, Immunohematology and Pathology, with an approximate annual test volume of 729,560. 2. The laboratory policy reviewed during the survey titled, "Employee Training and Competency (policy# GE.045)" states, " 1. The Laboratory Medical Director assures the performance of the following annually: 2. Personnel roster is updated to accurately indicate qualified individuals performing roles of testing personnel, clinical consultant, technical consultant, technical supervisor, and general supervisor, as applicable. 3. Delegation of laboratory functions document is updated and signed by the Laboratory Medical Director authorizing individuals by name and/or job title to perform functions on behalf of the Laboratory Medical Director. 4. Assessment of all personnel that have been assigned or delegated functions". 3. The laboratory failed to follow the established policy indicated above to assess employee competency, including the role of Clinical Consultant, Technical Consultant, Technical Supervisor and General Supervisor. 4. The TC-1 interviewed on July 18, 2023 at 10:55 AM confirmed the laboratory failed to follow the established personnel competency policy indicated above to assess employee competency.
D5433	MAINTENANCE AND FUNCTION CHECKS

	CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: Based on lack of pipet carryover study documentation and interview with the Technical Consultant (TC-1), the laboratory failed to perform function checks on the pipets used on the Siemens Dimension EXL chemistry analyzers as required by laboratory policy. Findings include: 1. The laboratory's established policy titled, "Pipet Carry-Over Procedure" states, "To evaluate the test system where automatic pipetting is used to check for carryover. Carryover will be performed every six months". 2. The laboratory failed to provide evidence that carryover studies were performed on the pipets contained on the Siemens Dimension EXL analyzers every six months during 2021 and 2022, as required per laboratory policy. 3. The laboratory utilizes two separate Siemens Dimension EXL analyzers, with an annual reported test volume of 475,000. 4. The TC-1 interviewed on July 18, 2023 at 3:10 PM confirmed that the pipets were not tested for carryover as required during 2021 and 2022.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on lack of calibration verification documentation for the Siemens Dimension EXL 200 chemistry analyzers and interview with the Technical Consultant (TC-1), the laboratory failed to perform and document calibration verification procedures at least

	once every 6 months during 2022. Findings include: 1. The laboratory utilizes two Siemens Dimension EXL chemistry analyzers (instrument #1 and instrument #2) to conduct patient testing in the subspecialties of Routine Chemistry and Endocrinology, with an approximate annual test volume of 475,000. 2. No documentation was presented for review to indicate the laboratory performed a calibration verification on each chemistry analyzer at least once every six months during 2022, including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results. 3. Review of calibration verification records for each chemistry analyzer revealed the laboratory performed a calibration verification on each analyzer on 10/10/2021, 8/10/2022 and 01 /15/2023. 4. The TC-1 interviewed on July 18, 2023 at 2:15 PM confirmed the laboratory failed to perform a calibration verification on each chemistry analyzer at least once every 6 months.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on lack of test comparison results from 2021 and 2022 and interview with the Technical Consultant (TC-1), the laboratory failed to evaluate and define the relationship between test results using two separate Chemistry and two separate Hematology instruments, twice a year Findings include: 1. The laboratory utilizes two separate Siemens Dimension EXL instruments to perform chemistry testing on patient specimens. The laboratory's approximate annual test volume in the specialty of Chemistry is 475,000. The laboratory distinguishes each analyzer as EXL 1 and EXL 2. 2. The laboratory failed to evaluate and define the relationship between test results generated from each EXL chemistry analyzer twice a year during 2021 and 2022. 3. The laboratory utilizes two separate Sysmex XN 2000 instruments to perform Complete Blood Count (CBC) testing on patient specimens. The laboratory's approximate annual test volume in the specialty of Hematology is 244,000. The laboratory distinguishes each analyzer as XN-1 and XN-2. 4. The laboratory failed to evaluate and define the relationship between CBC test results generated from each Sysmex XN 2000 (XN-1 and XN-2) analyzer twice a year during 2021 and 2022. 5. The laboratory failed to evaluate and define the relationship between test results obtained from an automated white blood cell (WBC) differential versus a manual WBC differential on each analyzer (XN-1 and XN-2) twice a year during 2021 and 2022. 6. The TC-1 interviewed on July 18, 2023 at 2:35 PM confirmed the laboratory failed to evaluate and define the relationship between test results twice a year for results generated from the chemistry and hematology analyzers as indicated above, including a comparison of test results between the manual and automated WBC differential.
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to

	ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: Based on review of patient test reports and interview with the Technical Consultant (TC-1), the laboratory failed to have a system in place to ensure the accuracy of test results that are manually entered and electronically interfaced into the Laboratory Information System (LIS) and the patient's electronic medical record (EMR). Findings include: 1. The laboratory performs approximately 729,560 patient tests annually under the specialties of Microbiology, Diagnostic Immunology, Chemistry, Hematology, Immunohematology and Pathology. 2. No documentation was presented for review during the survey to indicate the laboratory has a system in place to ensure the accuracy of patient test results that are electronically interfaced from the analyzers to the LIS and from the LIS to the EMR, or for test results that are manually entered into the LIS and then electronically interfaced from the LIS to the patient's EMR. 3. The TC-1 interviewed on July 18, 2023 at 4:05 PM confirmed the laboratory did not have a system in place to verify the accuracy of patient test results that are electronically interfaced or manually entered into the LIS, and then electronically interfaced to the EMR.
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 review of Activated Clotting Time (ACT) test reports maintained in the patients' Electronic Medical Record (EMR) and interview with the Technical Consultant (TC-1), the laboratory failed to include documentation of positive patient identification as required on the final test report for one patient. Findings include: 1. One out of two ACT test reports (TL0006037493) reviewed in the EMR during the survey failed to include either the patient's name and identification number, or a unique patient identifier and identification number on the final test report. 2. The TC-1 interviewed on July 18, 2023 at 12:45 PM acknowledged the test report indicated above was missing at least two positive patient identifiers.
D5813	TEST REPORT CFR(s): 493.1291(g)

	The laboratory must immediately alert the individual or entity requesting the test and, if applicable, the individual responsible for using the test results when any test result indicates an imminently life-threatening condition, or panic or alert values. This STANDARD is not met as evidenced by: Based on review of test results for CG8+testing performed on the i-Stat analyzer and interview with the Technical Consultant (TC-1), the laboratory failed to immediately alert the individual or entity requesting the test when the test result indicates an imminently life-threatening condition, or panic or alert values. Findings include: 1. Review of blood gas and chemistry test results for patient ID# TL0005967922 performed on 04/09/2023 at 13:22:16 indicated three critical test results: pH = 7.005 (critical low); TCO2 = 7 mmol/L (critical low); and Potassium (K) = 6.4 mmol/L (critical high). 2. No documentation was presented for review to indicate the laboratory notified the entity requesting the test of the critical test results for the testing indicated above. 3. The TC-1 interviewed on July 18, 2023 at 1:35 PM confirmed the laboratory failed to provide documented evidence that the critical test results referenced above were communicated to the entity requesting the test.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on review of competency records and interview with the Technical Consultant (TC-1), the technical consultant failed to evaluate the annual competency assessment of 14 out of 14 testing personnel who perform testing on the i-Stat analyzer. Findings include: 1. The laboratory performs Arterial Blood Gas (ABG) and Activated Clotting Time (ACT) testing on the i-Stat analyzer. 2. The technical consultant failed to evaluate the annual competency evaluations for 14 out of 14 testing personnel during 2022, for testing personnel who perform testing on the i-Stat analyzer. 3. Review of annual competency evaluations from 2022 for the testing personnel referenced above indicated the competency evaluations were performed by an individual who does not meet the qualification requirements of Technical Consultant as listed under 493.1411. 4. The TC-1 interviewed on July 18, 2023 at 10:30 AM acknowledged the competency evaluations performed during 2022 for the testing personnel indicated above were not performed by an individual listed as Technical Consultant on the CMS-209, Laboratory Personnel Form.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must 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 lack of education records for two out of two testing personnel and interview with the technical supervisor, the laboratory director failed to ensure that all testing personnel have the appropriate education prior to testing patients' specimens. Findings include: 1. During the survey performed on July 18, 2023, documentation of a foreign diploma was presented for review for two out of two testing personnel. 2. No documentation was presented for review during the survey to indicate the laboratory had the diploma and corresponding transcripts evaluated by a foreign transcript evaluation agency to ensure the equivalent education requirements for the two testing personnel indicated above. 3. The technical supervisor interviewed on July 18, 2023 at 10:05 AM confirmed the laboratory failed to complete the process of having the foreign transcripts evaluated for the testing personnel indicated above, prior to the individual testing patients' specimens.