Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D0530411	04/01/2025
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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. In addition, retain the following: This STANDARD is not met as evidenced by: Based on review of manual cell count test records on April 1, 2025, lack of the manufacturer's assay sheet for Quality Control (QC) material and interview with the Technical Supervisor (TS-2), the laboratory failed to retain the manufacturer's QC assay sheets for at least 2 years for each lot of Body Fluid Cell Count QC used in January 2025. Findings include: 1. The laboratory performs one level of Control material every 8 hours of patient testing for manual cell counts performed on body fluid specimens. The laboratory utilizes 2 levels of control material which are alternated equally. 2. Review of the laboratory's monthly 'Cell Count Control Log Sheet' for January 2025 indicated the laboratory performed one manual cell count on 1 /12/25 for one patient (#781732) and tested one level of quality control material (Level 1-UC, lot# 42320412). 3. The laboratory failed to produce evidence of the manufacturer's QC assay sheet for the control materials that were in use during January 2025: Streck Cell-Chex Body Fluid Cell Count Control, Level 1-UC, lot# 42320412, expiration date: 2/19/25; and Level 2-L2, lot# 42320413, expiration date: 2 /19/25. 4. The TS-2 interviewed on 4/01/25 at 2:15 PM confirmed the laboratory failed to retain the manufacturer's assay information sheet for at least 2 years for each lot of QC material used by the laboratory in January 2025.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)

	(a)(1) 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 review of maintenance logs for the Siemens CS-2500 Coagulation Analyzer and interview with the Technical Supervisor (TS-2), the laboratory failed to perform and document the monthly maintenance activity of cleaning the filters as required by the manufacturer for 18 out of 20 months between August 2023 and March 2025. Findings include: 1. Review of the monthly maintenance logs for the Siemens CS-2500 analyzer indicated the laboratory failed to perform and document the monthly maintenance activity of 'cleaning the filters' for 18 out of 20 months between August 2023 and March 2025. 2. The TS-2 interviewed on 4/01/25 at 2:35 PM acknowledged the maintenance activities listed above were not performed and documented each month on the CS-2500 analyzer as required by the manufacturer. 3. The laboratory's reported annual test volume for the specialty of Hematology is 160,116.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) (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-2), the laboratory failed to perform and document calibration verification procedures at least once every 6 months during 2024. Findings include: 1. The laboratory utilizes two Siemens Dimension EXL chemistry analyzers (instrument #1 - Serial# SN12252743 and instrument #2 - Serial# SN DE271590) to conduct patient testing in the subspecialties of Routine Chemistry, Toxicology and Endocrinology, with a reported annual test volume of 182,186. 2. No documentation was presented for review to indicate the laboratory performed calibration verification procedures on each chemistry analyzer at least once every six months during 2024 for the analytes Sodium (Na), Potassium (K) and Chloride (Cl), 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. The laboratory's policy titled, Dimension EXL Linearity/Calibration Verification, states, "Linearity or calibration

	verification must be performed when any of the following conditions are met: D. Every six months....The only methods that require a separate AMR verification are the electrolytes (Na, K, Cl) will be verified using Maine Standards and assayed according to the manufacturer's instructions." 4. The TC-1 interviewed on 4/01/25 at 10:15 AM confirmed the laboratory failed to perform calibration verification procedures on each chemistry analyzer at least once every 6 months during 2024 for the analytes indicated above. **This is a repeat deficiency from the previous inspection conducted on July 18, 2023.
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. This STANDARD is not met as evidenced by: (A) Review of 2024 instrument comparisons for Activated Clotting Time (ACT) testing performed under the specialty of Hematology and interview with the technical consultant (TC-1), the laboratory failed to perform instrument comparisons for four of four i-Stat analyzers. Findings include: A1. The laboratory performs ACT testing utilizing i-Stat analyzers to perform patient testing under the specialty of Hematology. The laboratory rotates the testing among four i-Stat analyzers. A2. No evidence was presented for review from 2024 to indicate the laboratory evaluated and defined the relationship between test results for four of four i-STAT analyzers in December 2024. A3. The TC-1 interviewed on 4/1/25 at 1:00 PM confirmed the laboratory failed to perform instrument comparisons for four of four i-Stat analyzers in December 2024. A4. The number of patients affected could not be determined at the time of the survey. **(B) Based on lack of test comparison results from 2024 for two Dimension EXL chemistry analyzers and interview with the Technical Consultant (TC-2), the laboratory failed to, twice a year, evaluate and define the relationship between test results using two separate Chemistry analyzers. Findings include: B1. The laboratory utilizes two separate Siemens Dimension EXL analyzers to perform testing in the specialty of Chemistry, with a reported annual test volume of 182,186. The laboratory distinguishes each analyzer as EXL 1 (Serial# SN 12252743) and EXL 2 (Serial# SN DE271590). B2. The laboratory failed to, twice a year, evaluate and define the relationship between test results generated from each EXL chemistry analyzer during 2024. B3. The TC-2 interviewed on 4/01/25 at 10:19 AM confirmed the laboratory failed to, twice a year, evaluate and define the relationship between test results generated from the two EXL chemistry analyzers during 2024. **This is a repeat deficiency from the previous inspection performed on July 18, 2023.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) (b)(9) Thereafter, evaluations must be performed at least annually This STANDARD is not met as evidenced by: Based on lack of documentation of an annual competency evaluation from 2023 and interview with the Technical Supervisor (TS-5), the technical consultant failed to

	evaluate and document the performance for six out of six individuals responsible for moderate complexity testing at least annually after the first year the individual tested patient specimens. Findings include: 1. No evidence of an annual competency evaluation was presented for review from 2023 for six out of six testing personnel who performs moderate complexity testing performed in the specialties of Diagnostic Immunology, Hematology, Microbiology, and Chemistry. 2.. The TS-5 interviewed on 4/1/25 at 12:00 PM confirmed the technical supervisor failed to evaluate and document an annual competency evaluation for the testing personnel indicated above.
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) (b)(9) Thereafter, evaluations must be performed at least annually unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individuals performance must be reevaluated to include the use of the new test methodology or instrumentation. This STANDARD is not met as evidenced by: Based on lack of documentation of an annual competency evaluation from 2023 and interview with the Technical Supervisor (TS-5), the technical supervisor failed to evaluate and document the performance for six out of six individuals responsible for high complexity testing at least annually after the first year the individual tested patient specimens. Findings include: 1. No evidence of an annual competency evaluation was presented for review from 2023 for six out of six testing personnel who performs high complexity testing performed in the specialties of Hematology, Immunohematology, and Microbiology. 2.. The TS-5 interviewed on 4/1/25 at 12:00 PM confirmed the technical supervisor failed to evaluate and document an annual competency evaluation for the testing personnel indicated above.