Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D0888296	03/30/2023
Name of Provider or Supplier	**Street Address, City, State**	
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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
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: A. Based on review of the written procedure manual and interview with the testing person, the afternoon of the day of survey, the laboratory did not have a written procedure for direct use of the TAXO A disk on initial inoculation of a throat swab to perform throat culture testing. Findings: 1. The written throat culture procedure instructs the laboratory to subculture throat cultures and then perform TAXO A disk testing on the subculture, but the laboratory was performing throat culture testing by placing the TAXO A disk directly on an initial inoculation (from throat swab) of strep selective agar (direct throat culture test). 2. The laboratory did not have a written procedure for direct throat culture testing and this was confirmed by interview with the testing person. B. Based on review of the written procedure manual and interview with the testing person, the afternoon of the day of survey, the laboratory did not follow written procedures to receive Uricult test media for bacteriology testing. Findings: 1. The written laboratory procedure states that the laboratory checks each shipment of Uricult media for contamination and substandard media and also maintain a copy of the manufacturer's quality control testing results for the lot(s) of media received. The laboratory did not document the condition of each shipment of Uricult media received and did not keep the manufacturer's quality control testing report for each lot received. 2. This was confirmed with the testing person during interview. C. Based on observation and interview with the testing person the afternoon of the day of survey, the laboratory did not have an approved written procedure for testing performed on the TOSOH chemistry analyzer. Findings: 1. The laboratory did not

	have a written procedure approved by the laboratory director to perform chemistry testing on the TOSOH chemistry analyzer. 2. The laboratory was using the manufactures instruction manual as the written procedure, this manual was not reviewed and approved and dated by the laboratory director and was not reviewed to ensure that it was specific in describing activities performed by the laboratory, such as storage of patient samples prior to testing, labeling and separation of serum or plasma from samples prior to testing, if applicable. 3. The laboratory did not have copies of the manufacturer instructions for each test performed using the TOSOH. These reagent instructions may be used as part of the written procedure, provided they are reviewed and approved and dated by the laboratory director to show when they were palced in use and date of discontinuence if needed. D. Based on review of the laboratory written procedure manual, and interview with the testing person on the afternoon of the day of survey, the laboratory did not have a wrtitten procedure to test proficiency testing samples like a patient specimen. Findings: 1. The written procedures did not state that proficiency test samples must be tested the same number of times a patient sample is tested, and repeat testing may only be performed if the proficiency test sample meets the same requirements to test a patient specimen. 2. This was confirmed during interview with the testing person.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of proficiency testing, the laboratory did not ensure that corrective actions were complete and reviewed by the laboratory director. findings: 1. The proficiency test event #2 in 2022 for urine crystals was 75% no corrective action was documented and the proficiency testing was not reviewed by the laboratory director to provide corrective actions.