

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D2050413	(X3) Date Survey Completed 09/10/2026
Name of Provider or Supplier Cook Hospital Tower Lab	Street Address, City, State 415 North 2nd Street Suite #2, Tower, MN	
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	The Cook Hospital Tower Lab laboratory was found to be out of compliance with the regulations of the Clinical Laboratory Improvement Amendments of 1988 (42 C.F.R. part 493) upon completion of the recertification survey performed on September 3, 2026. The following standard-level deficiencies were cited: 493.1291 Test report 493.1413 Technical consultant responsibilities .
D5801	TEST REPORT CFR(s): 493.1291(a) (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 observation, document review, and interview with laboratory personnel, the laboratory failed to verify the accuracy of manually entered test results in 2025. Findings are as follows: 1. The laboratory performed Microbiology, Chemistry, and Hematology testing as indicated by the Laboratory Director (LD) during a tour of the laboratory at 1:05 p.m. on 09/03/26. 2. The following analyzers and equipment were observed as available for use during the tour: Sysmex XQ-320 hematology analyzer Abbott i-STAT blood analyzer Excyte 10 automated erythrocyte sedimentation analyzer MedTox Profile-V Drugs of Abuse test system Fisher Scientific Micromaster microscope 3. The laboratory manually entered test results from the above test systems and equipment into Meditech, the laboratory's Electronic Health Record software. 4. Accuracy verification of manually entered test results was required

	monthly as established in the Result Reporting procedure located in the General Policies manual. 5. Documentation of the monthly manually entered test result verification was not found in 2025 laboratory records. The laboratory was unable to provide the missing documentation upon request. 6. The laboratory released approximately 8,536 patient test results annually as indicated on the Form CMS-116 provided by the laboratory on date of survey. 7. In an interview on 6:15 p.m. on 09/03/26, the LD confirmed the above finding. .
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (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. The procedures for evaluation of the competency of the staff must include, but are not limited to-- This STANDARD is not met as evidenced by: 2025 CA missing med tox, excyte 10 and microscopic exams: man diff, KOH, WP, USed . Based on observation, document review, and interview with laboratory personnel, the Technical Consultant failed to ensure four of four tenured testing personnel were evaluated for test procedure competency in all testing areas in 2025. Findings are as follows: 1. The laboratory performed Microbiology, Chemistry, and Hematology testing as indicated by the Laboratory Director (LD) during a tour of the laboratory at 1:05 p.m. on 09/03/26. 2. The following analyzers and equipments were observed as present and available for use during the tour: Excyte 10 automated erythrocyte sedimentation analyzer (ESR) MedTox Profile-V Drugs of Abuse test system (UDS) Fisher Scientific Micromaster microscope for manual differential (Diff), KOH preparation (KOH), vaginal wet preparation (VWP) and urine sediment (USed). 3. Testing personnel were evaluated for competency in all testing areas semi-annually in the first year of testing and annually thereafter as established in the Quality Assurance Plan - Laboratory, Personnel section found in the General Policies manual. 4. Competency assessments for ESR, UDS, KOH, VWP, and USed testing were not included in the Evaluation of Competency and Performance forms completed for four of four tenured testing personnel in 2025. The laboratory was unable to provide the missing evaluations upon request. 5. In an interview at 2:45 p.m. on 09/03/26, the LD confirmed the above finding. .
D6051	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(v) (b)(8)(v) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the Technical Consultant (TC) failed to ensure two of four testing personnel (TP) were assessed annually through testing previously analyzed specimens, blind samples, or proficiency testing (PT) samples for two of four moderate complexity microscopic examinations performed in 2025. Findings are as follows: 1. The laboratory performed moderate complexity microscopic examination testing as confirmed by the Laboratory Director (LD) during a tour of the laboratory at 1:05 p.m. on 09/03/26. 2.

	An Fischer Scientific Micromaster microscope was observed as present and available for use during the tour: The laboratory performed Potassium Hydroxide (KOH) and Vaginal Wet Preparations (VWP) using this instrument. 3. Testing personnel were evaluated for competency in all testing areas semi-annually in the first year of testing and annually thereafter as established in the Quality Assurance Plan - Laboratory, Personnel section found in the General Policies manual. External proficiency testing (PT) samples were used to assess test performance. 4. Testing Personnel 1 (TP1) did not participate in KOH PT in 2025 for annual competency assessment and former TP FK (TPFK) did not participate in VWP PT in 2025 for annual competency assessment as indicated on American Proficiency Institute Attestation Statements reviewed on date of survey. 5. The laboratory was unable to provide alternative blind sample evaluation documentation completed in 2025 for TP1 and TPFK upon request. 6. In an interview at 2:45 p.m. on 09/03/26, the LD confirmed the above finding. .
D6055	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) (b)(9) unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's 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 observation, document review, and interview with laboratory personnel, the Technical Consultant (TC) failed to ensure initial training and competency evaluation was completed for one of four tenured testing personnel prior to testing patient specimens using a new Hematology analyzer in 2026. Findings are as follows: 1. The laboratory performed Hematology testing as confirmed by the Laboratory Director (LD) during a tour of the laboratory at 1:05 p.m. on 09/03/26. 2. A Sysmex XQ-320 hematology analyzer was observed as present and available for use during the tour of the laboratory. Complete Blood Count (CBC) with automated differential testing on this analyzer was implemented on 06/01/2026 as indicated by the LD and confirmed in laboratory records. 3. Sysmex XQ-320 initial training and competency evaluation documents for tenured Testing Personnel TP1, TP2, TP3, and former TP FK were not found during review of laboratory records. The laboratory was unable to provide these documents upon request. 4. The laboratory was given five business days to provide the missing training documentation. 5. In an interview at 5:30 p.m. on 09/03/26, the LD confirmed the above finding. 6. In an email received at 5:58 p.m. on 09/10/26, the LD provided training documentation for TP1, TP3, and former TP FK. No training documentation was provided for TP2. 7. 142 CBC patient test reports were released from 06/01/2026 through date of survey, 09/03/2026, as indicated by the LD in the email referenced above. See below. Month Number of patients tested June 59 July 39 August 33 September 11 .