Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D2085402	07/18/2025
Name of Provider or Supplier	**Street Address, City, State**	
Ssm Health St Anthony Healthplex	201 S Sara Road, Mustang, OK	

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	A complaint investigation (OK00083199) was performed on 07/18/2025. The complaint was substantiated. The laboratory was found out of compliance with the following CLIA Condition: 493.801; D2000: Enrollment and Testing of Samples The findings were reviewed with the quality and safety specialist on 07/23/2025.
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on a review of records, observation, and interview with the quality and safety specialist and lead technologist, the laboratory failed to ensure they followed Subpart H for one of two Chemistry Core proficiency testing events in 2025. Findings include: (1) The laboratory sent proficiency testing samples to another laboratory for one of two Chemistry Core events in 2025. Refer to D2013.
D2013	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(4) (b)(5) The laboratory must not send proficiency testing samples or portions of proficiency testing samples to another laboratory for any analysis for which it is certified to perform in its own laboratory. Any laboratory that CMS determines

intentionally referred a proficiency testing sample to another laboratory for analysis may have its certification revoked for at least one year. If CMS determines that a proficiency testing sample was referred to another laboratory for analysis, but the requested testing was limited to reflex, distributive, or confirmatory testing that, if the sample were a patient specimen, would have been in full conformance with written, legally accurate and adequate standard operating procedures for the laboratory's testing of patient specimens, and if the proficiency testing referral is not a repeat proficiency testing referral, CMS will consider the referral to be improper and subject to alternative sanctions in accordance with 493.1804(c), but not intentional. Any laboratory that receives a proficiency testing sample from another laboratory for testing must notify CMS of the receipt of that sample regardless of whether the referral was made for reflex or confirmatory testing, or any other reason.

This STANDARD is not met as evidenced by:
Based on a review of records, observation, and interview with the quality and safety specialist and lead technologist, the laboratory sent proficiency testing samples to another laboratory for one of two Chemistry Core events in 2025. Findings include: (1) The quality and safety specialist contacted the Oklahoma State Agency on 05/29 /2025 to self-report that five specimens from the API (American Proficiency Institute) Second 2025 Chemistry Core event had inadvertently been sent to their main hospital laboratory - SSM Health St Anthony- Oklahoma City- CLIA #37D0050352. The samples had been sent by courier on 05/27/2025 which was prior to the API submission cut-off date of 05/28/2025; (2) Interview with the quality and safety specialist and lead technologist on 07/18/2025 at 09:30 am provided the following information: (a) The main hospital laboratory courier picked up patient referral specimens at 10:00 am and 04:30 pm. Specimens for pickup were stored in plastic biohazard bags on the fourth shelf of the Thermoscientific refrigerator in the laboratory; (b) The second shift technologist prepared patient samples for the 04:30 pm courier pickup on 05/27/2025 by completing a packing list and placing the specimens from the fourth shelf into a large send-out testing bag which had been placed on the top shelf of the refrigerator. It was then noticed that a plastic biohazard bag containing specimens was sitting on the first shelf of the refrigerator and without looking in the bag, assumed the specimens were intended for the courier pickup, and they were placed into the send-out testing bag; (c) When the specimens were received at the main hospital laboratory, the evening processor at the main hospital laboratory identified the samples were not patient samples and immediately set them aside in the refrigerator with a note for the day shift lead technologist; (d) The day shift technologist identified the specimens in the biohazard bag were from the second 2025 Chemistry Core event, consisting of CH-07, ALC-07, HCG-07, NB-07, and IB-07 and immediately notified the laboratory. (3) The quality and safety specialist provided the following documents for review: (a) Copies of the proficiency testing records for the Second 2025 Chemistry Core event; (b) Copies of the API Submitted Results Form for the main hospital laboratory and the laboratory; (c) Copy of the Root Cause Analysis completed by the laboratory on 05/29/2025, outlining the investigation of the occurrence with the corrective actions taken. (4) A review of the documents identified the following: (a) The proficiency testing records showed the night shift technologist had tested proficiency samples CH-07, ALC-07, HCG-07, and NB-07 on 05/14/2025; and IB-07 on 05/15/2025; (b) The API Submitted Results Form showed the following: (i) The laboratory had submitted their results to API electronically on 05/26/2025; (ii) The main hospital laboratory had submitted their results to API electronically on 05/22 /2025. (c) The Root Cause Analysis, which was signed and dated by the quality and safety specialist and laboratory director on 07/10/2025, showed the following issues:

	(i) The night shift technologist had placed the proficiency samples (CH-07, ALC-07, HCG-07, NB-07, and IB-07) in a plastic biohazard bag on the top shelf of the Thermoscientific refrigerator instead of putting them in the designated refrigerator for proficiency testing specimens, which was the bottom shelf of the Fisherbrand Isotemp refrigerator located in the storage room directly off the laboratory; (ii) The second shift technologist did not inspect the biohazard bag on the top shelf of the Thermoscientific refrigerator before including it with the courier pickup on 05/27 /2025. (d) The Root Cause Analysis showed the following actions taken: (i) Continuing education for proficiency sample handling assigned to all staff on 05/28 /2025 and completed on 06/14/2025; (ii) Proficiency testing guidelines were added to initial training and competency assessments for all staff; (iii) A plastic bin clearly labeled for the storage of proficiency testing specimens was added to the bottom shelf of the Fisherbrand Isotemp refrigerator in the storage room. (5) Observation of the laboratory on 07/18/2025 at 10:20 am identified the following: (a) The Thermoscientific refrigerator in the laboratory contained a bin on the fourth shelf designated for patient samples for courier pickup; (b) The Fisherbrand Isotemp refrigerator located in the storage room of the laboratory, contained a bin on the bottom shelf designated for proficiency samples and labeled "Proficiency Testing Samples Only". (6) Based on the provided information and documentation, it was confirmed the laboratory sent proficiency testing samples to the main hospital laboratory with the courier on 05/27/2025, however as soon as the specimens were identified the laboratory was notified and they were returned. No testing had been performed by the main hospital laboratory.