Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D0904226	08/23/2023
Name of Provider or Supplier	**Street Address, City, State**	
Ochsner Lsu Health Shreveport	1541 Kings Highway Attn Wendy Atnip, Shreveport, LA	

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 survey was performed at OCHSNER LSU HEALTH SHREVEPORT, CLIA # 19D0904226, on August 23, 2023 through August 24, 2023. OCHSNER LSU HEALTH SHREVEPORT LABORATORY was found not in compliance with the following CONDITION LEVEL DEFICIENCIES: 42 CFR 493.801 CONDITION: Enrollment and Testing of Samples 42 CFR 493.1403 CONDITION: Laboratories performing moderate complexity testing; Laboratory Director
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 review of laboratory policy, proficiency testing records and interview with personnel, the laboratory failed to perform and reporting of proficiency as required. Findings: 1. The laboratory failed to ensure that no inter-laboratory communications occurred for Amniotic Fluid pH proficiency testing samples prior to the cut-off date for five (5) of five (5) events reviewed from 2021-2023. Refer to D2011. 2. The laboratory failed to ensure that proficiency testing samples for Amniotic Fluid pH were not referred to another laboratory for analysis for five (5) of five (5) testing events reviewed from 2021-2023. Refer to D2013.

D2011	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(3) Laboratories that perform tests on proficiency testing samples must not engage in any inter-laboratory communications pertaining to the results of proficiency testing sample (s) until after the date by which the laboratory must report proficiency testing results to the program for the testing event in which the samples were sent. Laboratories with multiple testing sites or separate locations must not participate in any communications or discussions across sites/locations concerning proficiency testing sample results until after the date by which the laboratory must report proficiency testing results to the program. This STANDARD is not met as evidenced by: Based on record review and interview with laboratory personnel, the laboratory failed to ensure that no inter-laboratory communications occurred for Amniotic Fluid pH proficiency testing samples prior to the cut-off date for submission of test results for five (5) of five (5) testing events reviewed from 2021-2023. Findings: 1. Review of the laboratory Point of Care (POC) Proficiency Testing Policy revealed the Point of Care Coordinator (POCC) determines which POC testing site needs to perform the survey. This policy further stated "Referral of proficiency testing specimens to another laboratory is strictly prohibited." 2. Review of American Proficiency Institute (API) proficiency testing records for Chemistry - Miscellaneous kit revealed laboratory records for participation of Amniotic Fluid pH using the Pro-Lab Amniotest kit for five (5) consecutive PT events from 2021-2023. 3. Review of the laboratory's test menu provided to surveyor with the CMS-116 revealed the laboratory did not list Pro-Lab Amniotest, or any method of Amniotic Fluid pH testing. 4. In interview on August 23, 2023 at 1:45 pm, the Performance Improvement (PI) and Quality Coordinator stated the hospital held three CLIA certificates for the physical address specific to Point of Care testing. She further stated all proficiency testing samples for facilities under the parent organization are mailed to the main hospital's point of care department. The POCC at the main hospital then brings the appropriate PT samples to different campuses for test performance. Once testing is complete, the POCC submits PT results for all sites from the main hospital point of care department. She further stated the POCC left the organization 6 weeks prior to the survey date. 5. Review of the API Chemistry - Miscellaneous, Amniotest results from 2021 - 2023 revealed the following results: a) 2021 - 1st Event, 3 samples: 100% b) 2021 - 2nd Event, 3 samples: 100% c) 2022 - 1st Event, 3 samples: 100% d) 2022 - 2nd Event, 3 samples: 100% e) 2023 - 1st Event, 3 samples: 100% 6. Review of personnel location in the hospital computer system revealed that testing personnel that perform Amniotest proficiency testing samples were obstetrics (OB) providers at 19D2181178. 7. Continued interview with the Performance Improvement (PI) and Quality Coordinator on August 23, 2023 at 2:30 pm confirmed the Amniotest proficiency testing had been ordered and received by the main hospital point of care under CLIA 19D0904226, then taken by the POCC from the main hospital campus to a new hospital site (19D2181178) servicing OB patient for test performance by OB providers in the emergency room, then reported to API from the main campus point of care department (19D0904226) from 2021 until the 2023 validation survey. 8. In interview on August 23, 2023 at 4:45 pm, the Director of Laboratory Services and PI & Quality Coordinator for laboratory stated the POC Proficiency Testing policy prohibits PT referral. Both personnel confirmed that the Point of Care Coordinator communicated with personnel outside of the main hospital (19D0904226) for Amniotest PT samples prior to each event cutoff date from 2021-2023.

D2013

TESTING OF PROFICIENCY TESTING SAMPLES
CFR(s): 493.801(b)(4)

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 record review and interview with laboratory personnel, the laboratory failed to ensure that proficiency testing samples for Amniotic Fluid pH were not referred to another laboratory for analysis for five (5) of five (5) testing events reviewed from 2021-2023. Findings: 1. Review of American Proficiency Institute (API) proficiency testing records for Chemistry - Miscellaneous kit revealed laboratory records for participation of Amniotic Fluid pH using the Pro-Lab Amniotest kit for five (5) consecutive PT events from 2021-2023. 2. Review of the laboratory's test menu provided to surveyor with the CMS-116 revealed the laboratory did not list Pro-Lab Amniotest, or any method of Amniotic Fluid pH testing. 3. Review of the laboratory Point of Care (POC) Proficiency Testing Policy revealed the Point of Care Coordinator (POCC) determines which POC testing site needs to perform the survey. This policy further stated "Referral of proficiency testing specimens to another laboratory is strictly prohibited." 4. In interview on August 23, 2023 at 1:45 pm, the Performance Improvement (PI) and Quality Coordinator stated the hospital held three CLIA certificates for the physical address specific to Point of Care testing. She further stated all proficiency testing samples for facilities under the parent organization in the city are mailed to the main hospital's point of care department. The POCC at the main hospital then brings the appropriate PT samples to different campuses for test performance. Once testing is complete, the POCC submits PT results to API for all sites from the main hospital point of care department. She further stated the POCC left the organization 6 weeks prior to the survey date. 5. Review of the API Chemistry - Miscellaneous, Amniotest results from 2021 - 2023 revealed the following results: a) 2021 - 1st Event, 3 samples (APH-01, APH-02, APH-03): 100% b) 2021 - 2nd Event, 3 samples (APH-04, APH-05, APH-06): 100% c) 2022 - 1st Event, 3 samples (APH-01, APH-02, APH-03): 100% d) 2022 - 2nd Event, 3 samples (APH-04, APH-05, APH-06): 100% e) 2023 - 1st Event, 3 samples (APH-01, APH-02, APH-03): 100% 6. Review of personnel location in the hospital computer system revealed that testing personnel that perform Amniotest proficiency testing samples were obstetrics (OB) providers at 19D2181178. 7. Continued interview with the Performance Improvement (PI) and Quality Coordinator on August 23, 2023 at 2:30 pm confirmed the Amniotest proficiency testing had been ordered and received by the main hospital point of care under CLIA 19D0904226, then taken by the POCC from the main hospital campus to

	a new hospital site (19D2181178) servicing OB patient for test performance by OB providers in the emergency room, then reported to API from the main campus point of care department (19D0904226) from 2021 until the 2023 validation survey. 8. In interview on August 23, 2023 at 4:45 pm, the Director of Laboratory Services and PI & Quality Coordinator for laboratory stated the POC Proficiency Testing policy prohibits PT referral. Both personnel confirmed the POCC took samples from the main hospital CLIA laboratory to the new hospital laboratory but did not understand that to be referral if both CLIA certificates and laboratories were in the same hospital system.
D5980	PPM LABORATORY DIRECTOR CFR(s): 493.1355 The laboratory must have a director who meets the qualification requirements of 493.1357 and provides overall management and direction in accordance with 493.1359. This CONDITION is not met as evidenced by: Based on record review and interview with personnel, the laboratory director failed to provide management and direction to the laboratory for proficiency testing processes. Refer to D5983.
D5983	PPM LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1359 The laboratory director is responsible for the overall operation and administration of the laboratory, including the prompt, accurate, and proficient reporting of test results. This STANDARD is not met as evidenced by: The laboratory director failed to ensure that the laboratory performed proficiency testing as required. Findings: 1. The laboratory failed to ensure that no inter-laboratory communications occurred for Amniotic Fluid pH proficiency testing samples prior to the cut-off date for five (5) of five (5) events reviewed from 2021-2023. Refer to D2011. 2. The laboratory failed to ensure that proficiency testing samples for Amniotic Fluid pH were not referred to another laboratory for analysis for five (5) of five (5) testing events reviewed from 2021-2023. Refer to D2013.