Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D2181178	08/24/2023
Name of Provider or Supplier	**Street Address, City, State**	
Olhs St Mary Place Medical Center Laboratory	911 Margaret Place, Suite 1a314, 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 OLHS ST MARY PLACE MEDICAL CENTER LABORATORY, CLIA # 19D2181178, on August 23, 2023 through August 24, 2023. OLHS ST MARY PLACE MEDICAL CENTER 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 proficiency testing records and interview with personnel, the laboratory failed to ensure testing and reporting of proficiency samples of another CLIA laboratory did not occur. Findings: 1. The laboratory failed to ensure that no inter-laboratory communications occurred for Amniotic Fluid pH proficiency testing samples prior to the performance of testing and submission of results for five (5) of five (5) testing events reviewed from 2021-2023. Refer to D2011. 2. The laboratory failed to ensure the receipt of proficiency testing samples from another laboratory was reported to the Center of Medicaid & Medicare Services (CMS) for five (5) of five (5) consecutive proficiency testing events in 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 review of the laboratory's plan of correction documents and proficiency testing records and interview with personnel, the laboratory failed to ensure that no inter-laboratory communications occurred for Amniotic Fluid pH proficiency testing samples prior to the performance of testing and submission of results for five (5) of five (5) testing events reviewed from 2021-2023. Findings: 1. Review of the laboratory's plan of correction from a validation survey conducted on January 23, 2023 through January 27, 2023 revealed "The laboratory had proficiency testing for 2021 and 2022. The CLIA ID #19D0904226 on the proficiency documents is incorrect. PT was actually performed at CLIA ID #19D2181178. Testing was originally performed at main campus (19D0904226) which is on the documents. In 2020, a new hospital was quickly opened so that OB/GYN and other patients could be housed and main campus hospital could open beds for COVID patients. When transfer of patients occurred in April 2020, testing performed by the providers went with it, but Point of Care Coordinators failed to change the CLIA ID# with American Proficiency Institute (API) so that the paperwork reflected the change." 2. In interview on August 24, 2023 at 9:15 am, the Laboratory Supervisor stated that prior to the validation survey, she was unaware Amniotest was listed under the CLIA ID #19D2181178. The Laboratory Supervisor further stated that the Point of Care Coordinator was in charge of the Amniotest which is performed in the labor and delivery department. The Laboratory Supervisor further stated the plan of correction responsibility for the validation survey (19D2181178) was handled by the Point of Care department. 3. Review of the laboratory's American Proficiency Institute (API) proficiency testing records for 2021, 2022 and 2023 revealed the CLIA ID number indicated on the paper work, CLIA ID 19D0904226, was the main hospital campus point of care department. 4. Further review of the laboratory's American Proficiency Institute (API) proficiency testing records for 2021, 2022 and 2023 revealed the laboratory (19D2181178) received, tested, and provided results to the point of care coordinator of the main hospital point of care department (19D0904226) for reporting results to API of Amniotest for the following five (5) of five (5) testing events: a) Chemistry - Miscellaneous 2021 1st event, 3 samples (APH-01, APH-02, and APH-03) b) Chemistry - Miscellaneous 2021 2nd event, 3 samples (APH-04, APH-05, and APH-06) c) Chemistry - Miscellaneous 2022 1st event, 3 samples (APH-01, APH-02, and APH-03) d) Chemistry - Miscellaneous 2022 2nd event, 3 samples (APH-04, APH-05, and APH-06) e) Chemistry - Miscellaneous 2023 1st event, 3 samples (APH-01, APH-02, and APH-03) 5. In interview on August 24, 2023 at 9:35 am, Testing Personnel that was documented on API proficiency testing 1st event stated that she performed one of the Amniotest proficiency samples for the 2023 Chemistry Miscellaneous 1st event in the labor unit. Testing Personnel further stated labor unit charge nurse provided the samples for testing as part of the residency training

	program. 6. In phone interview on August 24, 2023 at 11:05 am, the Quality Manager of the sister laboratory (19D0904226) stated the proficiency testing from 2021, 2022 and 2023 was sent by the Point of Care Coordinators via courier from the main campus laboratory to a contact person in the labor department (19D2181178). 7. In further phone interview on August 24, 2023 at 11:05 am, the Quality Manager of the sister laboratory (19D0904226) stated the proficiency records for point of care testing was stored in the Point of Care Coordinator's office on the main campus laboratory. The Quality Manager further stated that the Point of Care Coordinator was responsible for updating the CLIA ID with the opening of another facility (19D2181178) in April of 2020.
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 review of the laboratory's plan of correction documents and proficiency testing records and interview with personnel, the laboratory failed to ensure the receipt of proficiency testing samples from another laboratory was reported to the Center of Medicaid & Medicare Services (CMS) for five (5) of five (5) consecutive proficiency testing events in 2021-2023. Findings: 1. Review of the laboratory's plan of correction from a validation survey conducted on January 23, 2023 through January 27, 2023 revealed "The laboratory had proficiency testing for 2021 and 2022. The CLIA ID #19D0904226 on the proficiency documents is incorrect. PT was actually performed at CLIA ID #19D2181178. Testing originally performed at main campus (19D0904226) which is on the documents. In 2020, a new hospital was quickly opened so that OB/GYN and other patients could be housed and main campus hospital could open beds for COVID patients. When transfer of patients occurred in April 2020, testing performed by the providers went with it, but Point of Care Coordinators forgot to change the CLIA ID# with American Proficiency Institute (API) so that the paperwork reflected the change". 2. In interview on August 24, 2023 at 9:15 am, the Laboratory Supervisor stated that prior to the validation survey, she was unaware Amniotest was listed under the CLIA ID #19D2181178. The Laboratory Supervisor further stated that the Point of Care Coordinator was in charge of the Amniotest proficiency testing which is performed in the labor and delivery department. 3. In further interview on August 24, 2023 at 9:15 am, the Laboratory Supervisor stated the plan of correction responsibility for the validation survey (19D2181178) was handled

	by the Point of Care department. 4. Review of the laboratory's American Proficiency Institute (API) proficiency testing records for 2021, 2022 and 2023 revealed the CLIA ID number indicated on the paper work was that of the sister laboratory (19D0904226) located on the main campus, not the laboratory (19D2181178) that opened in April 2020 for the following five (5) of five (5) testing events: a) Chemistry - Miscellaneous 2021 1st event, 3 samples (APH-01, APH-02, and APH-03) b) Chemistry - Miscellaneous 2021 2nd event, 3 samples (APH-04, APH-05, and APH-06) c) Chemistry - Miscellaneous 2022 1st event, 3 samples (APH-01, APH-02, and APH-03) d) Chemistry - Miscellaneous 2022 2nd event, 3 samples (APH-04, APH-05, and APH-06) e) Chemistry - Miscellaneous 2023 1st event, 3 samples (APH-01, APH-02, and APH-03) 5. In phone interview on August 24, 2023 at 11:05 am, the Quality Manager for the sister laboratory (19D0904226) stated the proficiency testing from 2021-2023 was sent by the Point of Care Coordinators via courier from the main campus laboratory to a contact person in the labor department (19D2181178). The Quality Manager (19D0904226) further stated the proficiency testing samples were given to the attending obstetrician or the labor unit nurse manager from facility (19D2181178) for testing. 6. In further phone interview on August 24, 2023 at 11:05 am, the Quality Manager of the sister laboratory (19D0904226) stated the proficiency records for point of care testing were stored in the Point of Care Coordinator's office on the main campus laboratory. The Quality Manager further stated that the Point of Care Coordinator was responsible for updating the CLIA ID with the opening of another facility (19D2181178) in April of 2020.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on review of laboratory proficiency testing records and interview with personnel, the Laboratory Director failed to provide overall management and direction. Refer to D6016.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on review of proficiency testing records and interview with personnel, the Laboratory Director failed to ensure proficiency samples are tested 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 performance of testing and submission of results for five (5) of five (5) testing events reviewed

	from 2021-2023. Refer to D2011. 2. The laboratory failed to ensure the receipt of proficiency testing samples from another laboratory was reported to the Center of Medicaid & Medicare Services (CMS) for five (5) of five (5) consecutive proficiency testing events in 2021-2023. Refer to D2013.