Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0645096	06/13/2024
Name of Provider or Supplier	**Street Address, City, State**	
Ascension St Vincent's Riverside	1 Shircliff Way, Jacksonville, FL	

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	Validation survey was conducted in conjunction with a complaint survey #2024002109 from 03/19/2024 to 6/13/2024 at Ascension St. Vincent's Riverside. The clinical laboratory was not in compliance with 42 CFR Part 493, requirements for clinical laboratories. The following Conditions were cited: D5400-Analytic Systems 493.1250 D6063- Laboratory Testing Personnel 493.1421
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on observation, record review and interview, the laboratory failed to follow their own procedure of releasing incompatible blood to patients (See D5401) and failed to complete performance specifications for Simplexa DiaSorin Herpes simplex virus (HSV) 1 & 2 Direct use on patients (See D5421).
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: Based on review of the procedure manual, Blood Bank Comments from Patient #4's medical chart, and interviews, the laboratory failed to follow their procedures for issuing incompatible red blood cells (RBCs) by not documenting the notification from the Laboratory to the Pathologist for 1 (#4) of 1 Patients records with transfusion reactions that received incompatible RBCs. Findings included: Review of the procedure titled Dispensing Incompatible Blood Components and Conditional Release noted "a pathologist must approve use of incompatible products. Authorization by the pathologist may be verbal, and must be documented by the transfusion service associate who spoke directly with the pathologist." Review of the Blood Bank Comments for Patient #4 revealed there was no documentation of the notification of the pathologist from the laboratory of the request for the release of incompatible RBC's. On 03/21/2024 at 11:25 AM, the Blood Bank Supervisor acknowledged that the notification to the pathologist of the second unit (unit number W036823563541) of incompatible blood was not documented. On 03/21/2024 at 2:06 PM, the Technical Supervisor of Blood Bank (Pathologist) stated he remembered being called for the second unit and confirmed that there was no documentation.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to do a limit of detection (LOD) study for Simplexa DiaSorin Herpes simplex virus HSV 1 Direct in their verification study prior to testing patient specimens. Findings Included: Review of Simplexa HSV 1 & 2 direct polymerase chain reaction (PCR) verification study summary signed by LD on 4/14/2021 revealed they performed a bridge study to use saline as a specimen transport media since there were shortages of the FDA approved UTM (Universal Transport Media) and VTM (Viral Transport Media) media. The laboratory tested only HSV 2 positive controls in 1:1 UTM, 1:8 UTM 1:1 saline and 1:8 saline used for specimen media comparison. The bridge study for transportation media was missing the LOD for HSV-1 positive controls detected in saline specimens. During an interview on 05/09/2024 at 10:00 AM, the laboratory manager confirmed that the verification study was incomplete for Simplexa DiaSorin Herpes simplex virus HSV 1 Direct.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.

	This CONDITION is not met as evidenced by: Based on observation, review of Clinical Laboratory Personnel Roster, the Florida Department of Health (FDOH) License Verification website, and interview, the laboratory failed to ensure the Testing Personnel (TP) had licenses for 43 (Medical Laboratory Assistant A-N, Phlebotomist A-U, G-8, I-8, M-8, S-8, L-5, M-5, N-5, and O-5) out of 242 (Medical Laboratory Assistant A-N, Phlebotomist A-U, A1-Z1, A2-Z2, A3-Z3, A4-Z4, A5-Z5, A6-Z6, A7-Z7, and A8-T8) moderate complexity Testing Personnel (See D6064) and failed to verify the education Testing Personnel (TP) prior to testing for 11 (J-1, W-1, U-5, K-6, T-5, X-5, C-7, I-8, J-8, M-8, and R-8) out of 207 (A1-Z1, A2-Z2, A3-Z3, A4-Z4, A5-Z5, A6-Z6, A7-Z7, and A8-T8) Testing Personnel (See D6065).
D6064	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(a) Each individual performing moderte complexity testing must possess a current license issued by the State in which the laboratory is located, if such licensing is required. This STANDARD is not met as evidenced by: Based on observation, review of Clinical Laboratory Personnel Roster, the Florida Department of Health (FDOH) License Verification website, and interview, the laboratory failed to ensure the Testing Personnel (TP) had licenses for 43 (Medical Laboratory Assistant A-N, Phlebotomist A-U, G-8, I-8, M-8, S-8, L-5, M-5, N-5, and O-5) out of 242 (Medical Laboratory Assistant A-N, Phlebotomist A-U, A1-Z1, A2-Z2, A3-Z3, A4-Z4, A5-Z5, A6-Z6, A7-Z7, and A8-T8) moderate complexity Testing Personnel. Finding included: On 05/07/2024 at 10:30 AM a MLA (Medical Laboratory Assistant) was seen loading a chemistry specimen onto the automated track system that ran chemistry tests. Interview on 05/07/2024 at 10:30 AM the Laboratory Administrative Director confirmed that MLA's and phlebotomists load the specimens onto trays and put on the track system for testing. Interview on 05/09/2024 at 3:25 PM the Laboratory Administrative Director confirmed that when the trays are loaded on the track the test is performed without a licensed testing person. Review of the Clinical Laboratory Personnel Roster showed no license number for TP - G-8, I-8, M-8, S-8, L-5, M-5, N-5, and O-5. Review of the FDOH website noted "No records found" for TP - G-8, I-8, M-8, S-8, L-5, M-5, N-5, and O-5. Interview via email on 04/15/2024 at 2:02 PM, the Quality Manager confirmed that TP-G-8, I-8, M-8, S-8, L-5, M-5, N-5, and O-5 did not have a Florida license, and the hospital did not have alternate-site testing locations on their license to allow moderate complexity to be performed by unlicensed personnel in the alternate-sites.
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at

	least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on the review of CMS 209 Laboratory Personnel Report, record review, and interview, the Laboratory failed to verify the education Testing Personnel (TP) prior to testing for 11 (J-1, W-1, U-5, K-6, T-5, X-5, C-7, I-8, J-8, M-8, and R-8) out of 207 (A1-Z1, A2-Z2, A3-Z3, A4-Z4, A5-Z5, A6-Z6, A7-Z7, and A8-T8) Testing Personnel. Finding included: Review of the CMS 209 Laboratory Personnel Report signed by the Laboratory Director 03/21/2024 revealed 207 Testing Personnel. Review of Testing Personnel education revealed foreign diplomas with no US equivalency for Testing personnel J-1, W-1, U-5, and K-6. Review of Testing Personnel education revealed no proof of education for T-5, X-5, C-7, I-8, J-8, M-8, and R-8. Interview via email on 04/15/2024 at 2:02 PM, the Quality Manager confirmed that TP-J-1, W-1, U-5, K-6, T-5, X-5, C-7, I-8, J-8, M-8, and R-8 did not have proof of education.