

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2262174	(X3) Date Survey Completed 04/19/2024
Name of Provider or Supplier Ascension St Vincent's St Johns County	Street Address, City, State 205 Trinity Way, St Johns, 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	An unannounced complaint survey #2024004230, was conducted on 04/09/2024 - 04/19/2024 at Ascension St Vincent's St John County. The facility was not in compliance with the CLIA regulations surveyed at 42 CFR 493, Requirement for clinical laboratories. The following Conditions were cited: D5400- Analytic Systems 493.1250 D6063- Laboratory Testing Personnel 493.1421
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on review of the procedure manual and laboratory personnel competency records; and interview, the laboratory failed to document the six month competency assessments on five (A, B, D, I, L) of ten (A - I, L) Testing Personnel (TP). Findings included: Review of the Blood Banking policy titled Performance and Competency Evaluations noted "Written competency assessments for each associate are performed: post-training, prior to performing duties; six months post-hire; annually thereafter." Review of "The Laboratory Personnel Report" signed and dated by the Laboratory Director on 04/10/2024, showed there were 12 testing personnel. On 04/10/24 at 4:15 PM, the Blood Bank Supervisor stated TP - J and TP - K did not work in blood banking. Review of the Blood Banking competency assessments showed the following; TP - A's initial competency assessment was on 08/12/2022 and the annual competency assessment was on 11/24/2023. TP- B's initial competency assessment was on 07/08/2022 and the annual competency assessment was on 02/19/2024. TP - D's initial competency assessment was on 07/05/2022 and the annual competency assessment was on 11/29/2023. TP - I's initial competency assessment was on 02/10/2022 and the annual competency assessment was on 01/30/2024. TP - L's initial</p>

competency assessment was on 08/17/2022 and the annual competency assessment was on 11/22/2023. No documentation of a six month post hire competency assessment were available for review for TP - A, TP - B, TP -D, TP - I, and TP - L. On 04/10/2024 at 4:23 PM, the Blood Bank Supervisor stated the six month competency assessments were not done.

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 record review and interview the laboratory failed to perform the verification studies on "Grifols ABORh Validation-Bench" at the testing location and failed to use in-date reagents for the verification studies on manual blood bank testing prior to Patient Testing (See D5421).

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 perform the verification studies on "Grifols ABORh Validation-Bench" at the testing location and failed to use in-date reagents for the verification studies on manual blood bank testing prior to Patient Testing. Findings Included: Interview on 04/10/2024 at 11:00 AM the Administrative Laboratory Director stated that verification studies began mid-May 2022 after the hospital was built and the laboratory opened for patient testing July 2022. Review of the "Grifols ABORh Validation-Bench" (signed by the Pathologist 07/01/2022) had testing dates from 09/2021. Interview on 04/19/2024 at 10:00 AM the Pathologist confirmed that the testing was not performed at the St. John's location. Review of the "Grifols Data-Cyte Validation-Bench" (signed by the Pathologist 07/01/2022) used the following expired reagents: Panel C-expired 06/14/2022, 0.8% Data-Cyte Plus-expired 06/11/2022, 0.8% Data-Cyte Plus 2-expired 05/28/2022, and 0.8% Data-Cyte Extended-expired 06/11/2022. Verification study testing was performed with the expired reagents on 06/18/2022, 06/19/2022, and 06/28/2022. Review of "Grifols Search-Cyte Validation-Bench" (signed by the Pathologist 07/01/2022) used the following expired reagents: 3% Surgiscreen-expired 06/14/2022, Coombs Control-expired 05/24/2022, 3% Search-Cyte-expired 06/11/2022, Coombs Control-expired 06

/11/2022, 0.8% Surgiscreen-expired 06/14/2022, and 0.8% Search-Cyte-expired 05/28/2022. Verification study testing was performed with expired reagents 06/28/2022. Review of "Rare AntiSera Validation" (signed by the Pathologist 07/21/2022) used the following expired reagents: Anti-K-expired 01/24/2022, Panocell#1-expired 08/31/2021, and Panocell#2-expired 08/13/2021. Verification study testing was performed with expired reagents on 07/19/2022. Review of the verification study cover worksheets state "Reagents are current and not expired" under prerequisites for testing. Review of the manufacturers' instructions for each of the expired reagents state under precautions to "Do not use beyond expiration date." Interview on 04/19/2024 at 10:00 AM the Pathologist confirmed that expired reagents should not be used in verification studies.

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 the review of Clinical Laboratory Personnel Roster and the Florida Department of Health (FDOH) License Verification website; and interview, the laboratory failed to ensure the Testing Personnel (TP) had licenses for one (W) of 23 (A - W) moderate complexity testing personnel (See D6064).

D6064

TESTING PERSONNEL QUALIFICATIONS
CFR(s): 493.1423(a)

Each individual performing moderate 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 the review of Clinical Laboratory Personnel Roster and the Florida Department of Health (FDOH) License Verification website; and interview, the laboratory failed to ensure the Testing Personnel (TP) had licenses for one (W) of 23 (A - W) moderate complexity testing personnel. Finding included: Review of the Clinical Laboratory Personnel Roster showed for the license number listed for TP - W was a certificate number. Review of the FDOH website noted "No records found" for TP - W. Interview via email on 04/15/2024 at 2:02 PM, the Quality Manager confirmed that TP- W 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.