Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0656672	04/16/2026
Name of Provider or Supplier	**Street Address, City, State**	
Ascension St John Jane Phillips Nowata	237 S Locust Street, Nowata, 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	The validation survey was performed on 04/15/2026-04/16/2026. The laboratory was found out of compliance with the following CLIA Conditions: 493.1215; D5024: Hematology 493.1487; D6168: Testing Personnel
D5024	HEMATOLOGY CFR(s): 493.1215 If the laboratory provides services in the specialty of Hematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1269, and 493. 1281 through 493.1299. This CONDITION is not met as evidenced by: Based on a review of records and interview with technical consultant #2, the laboratory failed to ensure the requirements were met for the specialty of Hematology for D-Dimer testing during the review period of September 2025 through the current date. Findings include: (1) The laboratory failed to ensure records provided definitive proof that QC had been performed as stated in the IQCP for D-dimer testing for five of eight months reviewed from September 2025 through the current date. Refer to D5445; (2) The laboratory failed to ensure instrument printouts were maintained that reflected actual dates of D-Dimer QC (Quality Control) testing for two of two analyzers reviewed from September 2025 through the current date. Refer to D5787.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by:

	Based on a review of records and interview with technical consultant #1, the laboratory failed to review and evaluate proficiency testing results for one of four Chemistry proficiency testing events reviewed in 2025 and 2026. Findings include: (1) On 04/15/2026, a review of Chemistry proficiency testing from API (American Proficiency Institute) records for 2025 (first, second, and third events) and 2026 (first event) identified the following biases (biases were identified using the SDI (Standard Deviation Index) values assigned by the proficiency program) for one of four events: (a) 2025 - API Chemistry Core 3rd Event (i) pH - five of five results exhibited a negative bias: (aa) Sample IB-11 - SDI of -3.6 (bb) Sample IB-12 - SDI of -1.5 (cc) Sample IB-13 - SDI of -2.6 (dd) Sample IB-14 - SDI of -1.3 (ee) Sample IB-15 - SDI of -1.5 (2) There was no evidence in the records to prove the biases had been identified and addressed; (3) The records were reviewed with technical consultant #1, who stated on 04/15/2026 at 11:40 am, the biases had not been identified and addressed.
D5409	PROCEDURE MANUAL CFR(s): 493.1251(e) (e) The laboratory must maintain a copy of each procedure with the dates of initial use and discontinuance as described in 493.1105(a)(2). This STANDARD is not met as evidenced by: Based on a review of the procedure manual and interview with technical consultant #1, the laboratory failed to ensure that two of two written procedures no longer in use had been discontinued. Findings include: (1) A review of the manual titled, "Technical Procedures" identified the following procedures: (a) "Complete Blood Counts on the Sysmex XS-1000i"; (b) "QC/QM Hematology Sysmex XS-1000i". (2) The procedures were reviewed with technical consultant #1 who stated on 04/16/2026 at 01:30 pm that the laboratory discontinued the use of the XS-1000i analyzer on 01/31 /2025 and the procedures were not indicated as discontinued.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) (d) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493. 1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (d)(3) At least once each day patient specimens are assayed or examined perform the following for: This STANDARD is not met as evidenced by: Based on a review of records and interview with technical consultant #2, the laboratory failed to ensure records provided definitive proof that QC had been performed as stated in the IQCP (Individualized Quality Control Plan) for D-dimer testing for five of eight months reviewed from September 2025 through the current date. Findings include: (1) On 04/16/2026 at 09:00 am, the technical consultant stated the following: (a) The laboratory performed D-Dimer testing using two Biosite Triage

	Meter Pro analyzers (analyzer serial number 75157 denoted by the laboratory as meter #1 and analyzer serial number 75122 denoted by the laboratory as meter #2); (b) The laboratory performed two levels of QC (Quality Control) materials every 30 days according to the IQCP. (2) A review of "D-dimer QC Log" records for Meter #1 and Meter #2 from September 2025 through the current date identified that, although QC had been performed every 30 days (according to handwritten documentation), the instrument printouts that were attached to the records with tape, did not reflect the actual dates of testing: (a) Meter #1 - The following was identified for two of eight months: (i) The record showed a handwritten date of "9/1/25" and the instrument printouts showed a test date of 10/04/2021 for level 1 and level 2 QC materials; (ii) The record showed a handwritten date of "10/2/25" and the instrument printouts showed a test date of 11/04/2021 for level 1 and level 2 QC materials. (b) Meter #2 The following was identified for five of eight months reviewed: (i) The record showed a handwritten date of "9/1/25" and the instrument printouts showed a test date of 10/13 /2023 for level 1 and level 2 QC materials; (ii) The record showed a handwritten date of "10/2/25" and the instrument printouts showed a test date of 11/12/2023 for level 1 and level 2 QC materials; (iii) The record showed a handwritten date of "11/9/25" and the instrument printouts showed a test date of 12/20/2023 for level 1 and level 2 QC materials; (iv) The record showed a handwritten date of "12/2/25" and the instrument printouts showed a test date of 01/12/2024 for level 1 and level 2 QC materials; (v) The record showed a handwritten date of "1/1/26" and the instrument printouts showed a test date of 02/11/2024 for level 1 and level 2 QC materials. (3) The records were reviewed with technical consultant #2 who confirmed on 04/16/2026 at 11:12 am, the instrument printouts did not reflect the actual dates of testing as stated above; (4) The following were examples of patient testing performed: (a) Patient # 25-247-002450C - testing performed on 09/04/2025; (b) Patient # 25-257-003168A - testing performed on 09/14/2025; (c) Patient #25-269-005025A - testing performed on 09/26 /2025; (d) Patient #25-276-004621A - testing performed on 10/03/2025; (e) Patient #25-284-002785A - testing performed on 10/11/2025; (f) Patient #25-301-003550A - testing performed on 10/28/2025; (g) Patient #25-306-002266B - testing performed on 11/02/2025; (h)Patient #25-315-002580B - testing performed on 11/11/2025; (i) Patient #25-322-002280A - testing performed on 11/26/2025; (j) Patient #25-340-000596A - testing performed on 12/06/2025; (k) Patient #25-349-005058A - testing performed on 12/15/2025; (l) Patient #25-356-002631H - testing performed on 12/22 /2025; (m) Patient #26-018-001948C - testing performed on 01/18/2026; (n) Patient #26-019-001924A - testing performed on 01/19/2026.
D5787	TEST RECORDS CFR(s): 493.1283(a) (a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: Based on a review of records and interview with technical consultant #2, the laboratory failed to maintain instrument printouts that reflected actual dates of D-Dimer QC (Quality Control) testing for two of two analyzers reviewed from September 2025 through the current date. Findings include: (1) On 04/16/2026 at 09:

	00 am, technical consultant #2 stated the following: (a) The laboratory performed D-Dimer testing using two Biosite Triage Meter Pro analyzers (analyzer serial number 75157 denoted by the laboratory as meter #1 and analyzer serial number 75122 denoted by the laboratory as meter #2); (b) The laboratory performed two levels of QC materials every 30 days according to the IQCP (Individualized Quality Control Plan). (2) A review of "D-dimer QC Log" records for Meter #1 and Meter #2 from September 2025 through the current date identified that although QC had been performed every 30 days (according to handwritten documentation), the instrument printouts, that were attached to the records with tape, did not reflect the actual dates of testing: (a) Meter #1 - The following was identified for two of eight months: (i) The record showed a hand written date of "9/1/25" and the instrument printouts showed a test date of 10/04/2021 for level 1 and level 2 QC materials; (ii) The record showed a hand written date of "10/2/25" and the instrument printouts showed a test date of 11/04 /2021 for level 1 and level 2 QC materials. (b) Meter #2 The following was identified for five of eight months reviewed: (i) The record showed a hand written date of "9/1 /25" and the instrument printouts showed a test date of 10/13/2023 for level 1 and level 2 QC materials; (ii) The record showed a hand written date of "10/2/25" and the instrument printouts showed a test date of 11/12/2023 for level 1 and level 2 QC materials; (iii) The record showed a hand written date of "11/9/25" and the instrument printouts showed a test date of 12/20/2023 for level 1 and level 2 QC materials; (iv) The record showed a hand written date of "12/2/25" and the instrument printouts showed a test date of 01/12/2024 for level 1 and level 2 QC materials; (v) The record showed a hand written date of "01/1/26" and the instrument printouts showed a test date of 02/11/2024 for level 1 and level 2 QC materials. (3) The records were reviewed with technical consultant #2 who confirmed on 04/16/2026 at 11:12 am, the instrument printouts did not reflect the actual dates of testing as stated above. Refer to D5445 for examples of patient testing.
D6168	TESTING PERSONNEL CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: Based on review of records and interview with the technical consultant #1, the laboratory failed to ensure four of five testing persons met the qualification requirements to perform high complexity testing. Findings include: (1) The laboratory failed to ensure that each person performing high complexity testing met the qualification. Refer to D6171.
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; or (b)(2)(i) Have earned a doctoral, master's, or bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(2)(ii) Be qualified under the requirements of 493.1443(b)(3) or 493.1449(c)(4) or (5); or (b)(3)(i) Have earned an associate degree in a laboratory science or medical laboratory

technology from an accredited institution or (b)(3)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes (b)(3)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, includes either (b)(3)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(3)(ii)(A)(2) 24 semester hours of science courses that include (b)(3)(ii)(A)(2)(i) 6 semester hours of chemistry; (b)(3)(ii)(A)(2)(ii) 6 semester hours of biology; and (b)(3)(ii)(A)(2)(iii) 12 semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(3)(ii)(B) Have laboratory training that includes: (b)(3)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES or the CAAHEP (this training may be included in the 60 semester hours listed in paragraph (b)(3)(ii)(A) of this section); or (b)(3)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing; or (b)(4) Successful completion of an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and having held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(5) Notwithstanding any other provision of this section, an individual is considered qualified as a high complexity testing personnel under this section if they were qualified and serving as a high complexity testing personnel in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024. (b)(6) For blood gas analysis (b)(6)(i) Be qualified under paragraph (b)(1), (2), (3), (4), or (5) of this section; or (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution. (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (f) to perform tissue examinations.

This STANDARD is not met as evidenced by:
Based on a review of records, FDA database, and interview with technical consultant #1, the laboratory failed to ensure that each person performing high complexity testing met the qualification requirements for four of five persons listed on the CMS-209. Findings include: (1) On 04/16/2026 at 10:30 am, technical consultant #1 stated the following: (a) Multi-Drug Screen Test Panels (Amphetamine, Benzodiazepines, Cocaine, Methadone, Marijuana, Phencyclidine, Methamphetamine, Opiate, Barbiturates, and Benzodiazepines) were performed using the One Step Drug Screen Test Card method; (2) A review of the FDA (Food and Drug Administration) database did not include a categorization for the test which defaults the test to high complexity; (3) A review of the Laboratory Personnel Report (Form CMS-209) and education records for five testing persons identified four of five testing persons did not meet the qualification requirements to perform high complexity testing; (4) The findings were reviewed with technical consultant #1 who stated on 04/16/2026 at 10:30 am, they were not aware the test had not been FDA categorized.