Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	50D2175974	05/25/2023
Name of Provider or Supplier	**Street Address, City, State**	
Swedish Edmonds Laboratory Poct	21601 76th Ave W, Edmonds, WA	

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
D3027	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(1) Test requisitions and authorizations. Retain records of test requisitions and test authorizations, including the patient's chart or medical record if used as the test requisition or authorization, for at least 2 years. This STANDARD is not met as evidenced by: Based on a record review, and an interview with the Technical Consultant #2 (TP-2) on 05/25/2023, the laboratory failed to ensure there was a procedure established to document and record patient test requests for point-of-care testing (POCT) on the Abbott i-STAT and the Werfen GEM 5000. Findings include: 1. Review and request for POCT testing analytic quality assessments for the Abbott i-STAT and the Werfen GEM 5000 during a validation survey on 05/25/2023, revealed a lack of documentation for test requests for POCT tests. 2. Review of the laboratory's policies and procedures reveal a lack of establishment of a procedure for documenting POCT tests. 3. The TC-2 confirmed by an interview on 05/25/2023, at 11:55 AM, the lack of procedure for documentation and reporting of POCT test requisitions, and the lack of a policy or procedure to ensure all POCT test requisitions are retained for two years. 4. The laboratory reports performing 86,208 patient POCT tests annually.
D5307	TEST REQUEST CFR(s): 493.1241(d) The patient's chart or medical record may be used as the test requisition or authorization but must be available to the laboratory at the time of testing and available to CMS or a CMS agent upon request. This STANDARD is not met as evidenced by:

	Based on the lack of documentation of laboratory test requests, and an interview with the Technical Consultant #2 (TP-2) on 05/25/2023, the laboratory failed to ensure there was a policy and procedure established to document and retain a record of patient test requisitions for point-of-care testing (POCT) on the Abbott i-STAT and the Werfen GEM 5000. Findings include: 1. Request for patient test requisitions for POCT testing on the Abbott i-STAT and the Werfen GEM 5000 during the validation survey on 05/25/2023, revealed a lack of documentation for requisition and time of order for POCT tests. 2. The TC-2 verbally stated that POCT test requests are entered into the EPIC nursing orders, and once the test is marked collected, the order disappears. 3. The TC-2 confirmed the lack of retention of POCT test requests by interview on 05/25/2023, at 11:55 AM. 4. The laboratory reports performing 86,208 patient POCT tests annually.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on a review of the laboratory policies and procedures, the lack of a procedure for reporting and documenting life-threatening patient results, and an interview with the Technical Consultant #2 (TP-2) on 05/25/2023, the laboratory failed to ensure there was a procedure established to document and record patient life-threatening test results for point-of-care testing (POCT) on the Abbott i-STAT and the Werfen GEM 5000. Findings include: 1. Review of the laboratory's policies and procedures revealed a lack of establishment of a policy or procedure for reporting and documenting patient life-threatening test results for the Abbott i-STAT and the Werfen GEM 5000 during a validation survey conducted on 05/25/2023. 3. The TC-2 confirmed by an interview on 05/25/2023, at 11:55 AM, the lack of procedure for documentation and reporting of POCT life-threatening test results, and the lack of a policy or procedure to ensure all POCT test requisitions are retained for two years. 4. The laboratory reports performing 86,208 patient POCT tests annually.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12)

	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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on a review of the laboratory's policy and procedures, testing personnel (TP) and technical consultants competency assessments, and interview with the Technical Consultant #2 (TC-2), listed on the CMS-209 on May 25, 2023, the laboratory failed to establish policies and procedures for evaluating testing personnel and technical consultants that included the six critical elements listed in 42 C.F.R. 493 subpart M. The findings include: 1. Review of the laboratory CMS-209 submitted for survey conducted on 05/25/2023, identified four (4) technical consultants for training and monitoring of testing TP. 2. Request for competency assessments for 2021 and 2022, revealed a lack of documentation for two (2) of four (4) technical consultant competencies for TC responsibilities. 3. Review of 12 testing personnel's (TP) competency records, revealed that two (2) of the 12 testing personnel's annual competency's lacked the element of direct observations for the Abbott i-STAT and Werfen GEM 5000 patient test performance. 4. Review of 12 testing personnel's competency records for 2021, and 2022, 12 of 12 TP lacked documentation of evaluation for the element of troubleshooting for years 2021, and 2022. 5. The TC-2 confirmed by an interview on 05/25/2023 at 11:55 AM, the lack of establishing policy and procedures for evaluating and documenting personnel competency which included the six elements required for TP competency assessments for the years 2021, and 2022, and the lack of competency assessment for TC Responsibilities.