Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	13D0521144	02/28/2019
Name of Provider or Supplier	**Street Address, City, State**	
St Mary's Health	701 Lewiston St, Cottonwood, ID	

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
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 a record review and an interview with the laboratory manager, the laboratory failed to document the alarm system for the refrigerator where blood products are stored as stated in the procedure manual from April 2018 through December 2018. Findings: 1. A review of the laboratory documents for blood bank revealed the laboratory failed to inspect and record the alarm system during August and November 2018. 2. A review of the laboratory's alarm system check procedure revealed the laboratory staff failed to follow the procedure to check the alarm system February, May, August, and November. 3. An interview on February 28, 2019 at 1:45 PM, with the laboratory manager, confirmed the laboratory staff failed to follow the procedure to perform and record the blood storage refrigerator alarm system.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by:

	Based on the Tosoh AIA-360 prostate-specific antigen (PSA) reagent instructions, patient test report review, and an interview with the laboratory manager, the laboratory failed to follow the Tosoh manufacturer's instructions to include the test method for PSA on the patient's test reports from the dates reviewed in November 2018. Findings: 1. A review of the Tosoh AIA-360 PSA reagent instruction sheet revealed the laboratory failed to include the identity of the PSA assay to physicians for patient's PSA test results. 2. A review of patient #C00021R final test report on November 2018, revealed the report failed to include the identity of the PSA assay used as required by the manufacturer. 3. The laboratory performs approximately 735 PSA tests per year. 4. An interview on February 28, 2019 at 11:10 AM, with the laboratory manager, confirmed the identity of the PSA assay was not included on patient test reports.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on an observation, a record review, and an interview with the laboratory manager, the laboratory failed to perform and document calibration verification procedures for blood gas analytes performed on the I-Stat since the last survey on August 16, 2017. Findings: 1. An observation on February 28, 2019 at 1:00 PM, revealed an I-Stat in use for the performance of blood gases. The laboratory tests approximately 150 a year. 2. A review of documents revealed the laboratory failed to perform and document calibration verification procedures for blood gases performed on the I-Stat since the last survey. 3. An interview on February 28, 2019 at 1:20 PM, with the laboratory manager, confirmed the laboratory failed to perform and document calibration verification activities for the blood gases.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures

	that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a record review and an interview with the laboratory manager, the laboratory failed to establish the number, type, and frequency of quality control testing materials used to monitor and detect immediate errors in blood gases performed on the I-Stat since the last survey on August 16, 2017. Findings: 1. A review of the laboratory's Individualized Quality Control Plan (IQCP) for blood gases performed on the I-Stat revealed the laboratory failed to identify the number, type, and frequency of quality control testing materials used to monitor the performance of the tests over time. 2. An interview on February 28, 2019 at 1:00 PM, with the laboratory manager, confirmed the laboratory failed to establish and identify the number, type, and frequency of quality control testing materials for blood gases in the IQCP.
D5471	CONTROL PROCEDURES CFR(s): 493.1256(e)(1)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(i) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on records review and an interview with the laboratory manager, the laboratory failed to check for a positive and negative reaction on each substrate of the gram-negative identification panel with each new lot number or shipment for the quality control performed in December 2018. Findings: 1. The laboratory performs approximately 2000 bacteriology cultures per year. 2. A review of quality control results in December 2018 for a new lot of Microscan gram-negative panels revealed the Cf8 and nitrate failed to show a positive and negative reaction for all organisms tested on the test system. 3. An interview on February 28, 2019 at 12:45 PM, with the laboratory manager, confirmed the two substrates were missing both a positive and negative reaction.
D5787	TEST RECORDS CFR(s): 493.1283(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 patient record reviews, proficiency testing (PT) records, and an interview with the laboratory manager, the laboratory failed to record the dates and all the tests performed for microbiology culture specimens to include culture set-up on media, colony description and morphology, and the personnel who performed the testing from the period reviewed between June 2018 to February 2019. Findings: 1. A review of the American Proficiency Institute bacteriology PT worksheets from June 2018, revealed the laboratory failed to document the testing for microbiology culture procedures which include: a. the type of media used; b. the colony description, quantitation, and morphology; c. the individual performing each step of testing from streaking of the plate to final reporting; 2. The laboratory performs approximately 2000 microbiology cultures per year. 3. A review of patient test records in February 20, 2019, revealed the laboratory failed to identify the dates, testing personnel, and all steps of bacteriology tests performed on a throat culture. 4. An interview on February 28, 2019 at 12:45 PM, with the laboratory manager, confirmed the laboratory failed to document all steps of bacteriology tests performed.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on a review of patient test reports and an interview with the laboratory manager, the final patient test reports failed to include the test report dates and the zip code of the laboratory which performed the test since the last survey on August 16, 2017. Findings: 1. A review of three patient test reports from June 2018, revealed the patient laboratory reports failed to include the date the test results were generated and failed to include the zip code of the laboratory. 2. An interview on February 28, 2019 at 11:10 AM, with the laboratory manager, confirmed the test report date and the zip code were not included on the patient's test report.