Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	27D0652515	10/16/2018
Name of Provider or Supplier	**Street Address, City, State**	
Logan Health Shelby	640 Park Ave, Shelby, MT	

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	Based on an on-site recertification survey conducted on 10/15/18-10/16/18, deficiencies were cited for Marias Medical Center in Shelby, MT.
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on observation, record review, and interview, the laboratory failed to perform proficiency testing for phenytoin from 2/9/16 through 10/15/18. The findings include: 1. On 10/15/18 at 12:45 p.m., a Siemens Dimension EXL 200 analyzer was observed in the laboratory. 2. On 10/15/18 at 12:45 p.m., staff member A listed phenytoin in the tests performed on the analyzer. 3. A review on 10/15/18 at 1:25 p.m. of the 2017 and 2018 American Proficiency Institute (API) binders lacked documentation of phenytoin proficiency testing results. 4. On 10/15/18 at 1:25 p.m., staff member A stated phenytoin was ordered but they didn't perform it.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the

	manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on observation, record review, and interview, the laboratory failed to follow the manufacturer's calibration frequency instructions for six tests between 2/9/17 and 10/15/18. The findings include: 1. On 10/15/18 at 12:45 p.m., a Siemens Dimension EXL 200 analyzer was observed in the laboratory. 2. On 10/15/18 at 4:20 p.m., staff member A stated the laboratory may not perform chemistry calibrations in certain situations. 3.. A review on 10/16/18 at 9:45 a.m. of the calibration dates stored on the analyzer, the calibration frequency requirements listed on the Siemens package inserts, and a list of patient results showed patient results released after the calibrations had expired between 2/9/17 and 10/15/18. a. Acetaminophen manufacturer instructions required calibrations to be performed every 90 days for any one lot and with new lots. 1. Calibrations were performed by the laboratory on 1/26/17, 6/12/17, 11/18/17, 1/26/18, 6/28/18, and 10/1/18. 2. 5 patients were resulted when the calibration had expired. a. 6/4/17, 6/5/17, 10/24/17, 11/3/17, and 5/10/18. b. Digoxin manufacturer instructions required calibrations to be performed every month for any one lot and with each new lot. 1. Calibrations were performed by the laboratory on 1/26/17, 5/18/17, 8/16/17, 11/27/17, 12/7/17, 5/24/18, and 9/20/18. 2. 20 patients were resulted when the calibration had expired. a. 3/4/17, 3/7/17, 3/15/17, 3/22/17, 3/26/17, 4/20/17, 4/23/17, 4/25/17, 7/28/17, 2/13/18, 2/21/18 (2 patients), 2/26/18, 3/19/18, 3/21/18, 4/19/18, 7/3/18, 7/18/18, and 8/30/18 (2 patients). c. Salicylates manufacturer instructions required calibrations to be performed every three months for any one lot and with each new lot. 1. Calibrations were performed by the laboratory on 11/7/16, 3/27/17, 9/1/17, 11/7/17, 3/15/18, 8/14/18, and 10/15/18. 2. 8 patients were resulted when the calibration had expired. a. 2/10/17, 2/16/17, 3/24/17, 2/27/18, 7/25/18, 7/27/18, 8/5/18, 8/13/18. d. Phenytoin manufacturer instructions required calibrations to be performed every thirty days for any one lot and with each new lot. 1. Calibrations were performed by the laboratory on 3/24/17, 5/5/17, 6/25/17, 8/2/17, 9/1/17, 10/4/17, 3/30/18, and 10/15/18. 2. 8 patients were resulted when the calibration had expired. a. 11/22/17, 5/16/18 (2 patients), 5/29/18, 7/19/18, 8/8/18, 9/5/18, and 9/18/18. e. Cerebral spinal fluid (CSF) total protein manufacturer instructions required calibrations to be performed every two months for any one lot and with each new lot. 1. Calibrations were performed by the laboratory on 3/30/15, 2/16/18, and 4/27/18. 2. 2 patients were resulted when the calibration had expired. a. 8/24/18 and 9/3/18. f. Vancomycin manufacturer instructions required calibrations to be performed every thirty days for any one lot and with each new lot. 1. Calibrations were performed by the laboratory on 12/22/16, 3/24/17, 5/9/17, 8/31/17, 3/17/18, and 6/28/18. 2. 12 patients were resulted when the calibration had expired. a. 2/12/17, 2/14/17, 6/11/17, 6/13/17, 6/20/17, 6/23/17, 10/31/17, 1/7/18, 5/1/18, 7/31/18, 8/2/18, and 9/4/18.
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 observation, record review, and interview, the laboratory failed to document positive reactivity for 4 of 36 biochemical identification (ID) system reactions for two lots of gram negative organism ID systems. The findings include: 1. On 10/15/18 at 2: 30 p.m., two gram negative ID systems were observed in the laboratory. a. Negative /Urine Combo (NUC) 75. b. NUC 85. 2. A review on 10/15/18 at 5:30 p.m. of the MicroScan Neg ID Panel Type 2/Biochemical Quality Control Report Forms lacked documentation of positive reactivity for 4 reactions. a. NUC 75, lot number 2019-05-03. 1. Cephalothin reistance (Cf>8) lacked a documented positive reaction. 2. Colistin resistance (Cl>4) lacked a documented positive reaction. b. NUC 85, lot number 2019-05-31. 1. Cf>8 lacked a documented positive reaction. 2. Tartrate (TAR) lacked a documented positive reaction. 3. On 10/15/18 at 5:30 p.m., staff member A stated the forms were not filled out correctly.
D5537	ROUTINE CHEMISTRY CFR(s): 493.1267(b)(d) For blood gas analyses, the laboratory must perform the following: (b) Test one sample of control material each 8 hours of testing using a combination of control materials that include both low and high values on each day of testing. (d) Document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on observation, record review, and interview, the laboratory failed to test control materials every eight hours of patient testing for one of one patient reviewed. The findings include: 1. On 10/16/18 at 8:30 a.m., an Opti-CCA-TS analyzer was observed in the radiology department. 2. A review on 10/16/18 at 9:00 a.m. of one patient (#160002) blood gas results from 1/10/18 included electronic controls but lacked liquid control material performed on that day. 3. A review on 10/16/18 at 9:00 a.m. of the blood gas binder included daily electronic standard reference cassette (SRC) controls and monthly liquid control materials performed on the Opti-CCA-TS. 4. On 10/16/18 at 9:00 a.m., staff member A stated the laboratory did not have an Individual Quality Control Plan for the blood gas analyzer.