

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  27D0410237	<b>(X3) Date Survey Completed</b>  03/01/2018
<b>Name of Provider or Supplier</b>  Logan Health - Chester	<b>Street Address, City, State</b>  315 West Madison Ave, Chester, MT	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	Based on an on-site recertification survey conducted on 2/28/18-3/1/18, deficiencies were cited for Liberty Medical Center in Chester, MT.
<b>D2000</b>	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on observation, record review, and interview, the laboratory failed to enroll for proficiency testing for three of four microbiology tests from 1/1/17 through 2/28/18. The findings include: A. Gram Stain 1. On 2/28/18 at 8:30 a.m., staff member A stated the laboratory was no longer performing microbiology with the exception of gram stain, methicillin resistant staphylococcus aureus (MRSA) cultures, methicillin susceptible staphylococcus aureus (MSSA) cultures, and back up cultures for streptococcus. 2. A review on 2/28/18 at 10:30 a.m. of the 2017 and 2018 American Proficiency Institute (API) documentation lacked proficiency testing enrollment for gram stain. 3. A review on 2/28/18 at 11:00 a.m. of the Test Volume worksheet included seven gram stains performed annually. 4. On 2/28/18 at 11:00 a.m., gram stain reagents were observed in a cupboard of the laboratory. 5. On 2/28/18 at 11:00 a. m., staff member A stated gram stains were run occasionally in the laboratory but proficiency testing was not enrolled. B. MRSA 1. On 2/28/18 at 8:30 a.m., staff member A stated the laboratory was no longer performing microbiology with the</p>

exception of gram stain, MRSA cultures, MSSA cultures, and back up cultures for streptococcus. 2. A review on 2/28/18 at 10:30 a.m. of the 2017 and 2018 API documentation lacked proficiency testing enrollment for MRSA chrome agar. 3. On 2/28/18 at 11:00 a.m., staff member A stated proficiency testing was not enrolled for MRSA. 4. A review on 3/1/18 at 9:00 a.m. of the microbiology logbook included patient MRSA cultures. C. MSSA 1. On 2/28/18 at 8:30 a.m., staff member A stated the laboratory was no longer performing microbiology with the exception of gram stain, MRSA cultures, MSSA cultures, and back up cultures for streptococcus. 2. A review on 2/28/18 at 10:30 a.m. of the 2017 and 2018 API documentation lacked proficiency testing enrollment for MSSA chrome agar. 3. On 2/28/18 at 11:00 a.m., staff member A stated proficiency testing was not enrolled for MSSA. 4. A review on 3/1/18 at 9:00 a.m. of the microbiology logbook included patient MSSA cultures.

**D5217**

**EVALUATION OF PROFICIENCY TESTING PERFORMANCE**

CFR(s): 493.1236(c)(1)

At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.

This STANDARD is not met as evidenced by:  
Based on observation, record review, and interview, the laboratory failed to perform accuracy verification on three tests from 1/1/17 through 2/28/18. The findings include:  
A. Stool lactoferrin 1. On 2/28/18 at 8:30 a.m., a Leuko EZ stool lactoferrin kit was observed in the laboratory. 2. A review on 2/28/18 at 10:30 of the American Proficiency Institute (API) documentation lacked proficiency testing for the Leuko EZ kit. Accuracy verification data was not found. 3. On 2/28/18 at 10:30 a.m., staff member A stated the laboratory did not have proficiency testing for the Leuko EZ kit.  
B. Potassium hydroxide (KOH) preps 1. A review on 2/28/18 at 8:45 a.m. of the Test Volume worksheet included an annual test volume of three KOH preps. 2. A review on 2/28/18 at 10:30 of the API documentation lacked proficiency testing for KOH preps. Accuracy verification data was not found. 3. On 2/28/18 at 10:30 a.m., staff member A stated the laboratory did not perform proficiency testing for KOH preps.  
C. Wet preps 1. A review on 2/28/18 at 8:45 a.m. of the Test Volume worksheet included an annual test volume of six wet preps. 2. A review on 2/28/18 at 10:30 of the API documentation lacked proficiency testing for wet preps. Accuracy verification data was not found. 3. On 2/28/18 at 10:30 a.m., staff member A stated the laboratory did not perform proficiency testing for wet preps.

**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 record review and interview, the laboratory failed to follow a written procedure for Quality Management from 1/1/17 through 2/28/18. The findings include: A. Urine drug screens 1. A review on 2/28/18 at 3:25 p.m. of the Liberty Medical Center Urine Drug Screen patient log included controls run per new box. 2. A

	<p>review on 3/1/18 at 1:30 p.m. of the Liberty Medical Center Quality Management policy included "a positive and negative control will be run each day patient is tested, with the exception of weekends." 3. On 3/1/18 at 1:30 p.m., staff member B stated the Quality Management policy needs updating. B. DCA Vantage 1. A review on 2/28/18 at 2:00 p.m. of the Liberty Medical Center microalbumin/creatinine controls showed controls run per lot number. 2. On 2/28/18 at 2:00 p.m., staff member B stated the controls were run with new lots. 3. A review on 3/1/18 at 1:30 p.m. of the Liberty Medical Center Quality Management policy included "a external control will be run with each new lot number, each new shipment, or monthly-whichever is soonest before use for patient testing.</p>
<p><b>D5407</b></p>	<p><b>PROCEDURE MANUAL</b> CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory director failed to sign approval of three procedures from 8/14/17 through 2/28/18. The findings include: 1. On 2/28/18 at 8:30 a.m., staff member A stated the new Laboratory Director had not signed the policies and procedures. 2. A review on 3/1/18 at 9:30 a.m. of the Individualized Quality Control Plans (IQCPs) for the Siemens Stratus-CS, i-Stat, and DCA Vantage lacked a signature of approval from the current laboratory director. 3. A review on 3/6/18 at 9:00 a.m. of the Aspen Central Office database showed the current laboratory director was entered on 8/14/17. 4. On 3/6/18 at 11:44 a.m., staff member A emailed the facility minutes with approval of the new Laboratory Director on 11/2/17.</p>
<p><b>D5425</b></p>	<p><b>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE</b> CFR(s): 493.1253(b)(3)</p> <p>The laboratory must determine the test system's calibration procedures and control procedures based upon the performance specifications verified or established under paragraph (b)(1) or (b)(2) of this section.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to establish and maintain historical in-house performance data for three of three plans reviewed. The findings include: 1. A review on 3/1/18 at 9:35 a.m. of three Individual Quality Control Plans (IQCPs) lacked historical in-house performance data, established by the laboratory in its own environment to demonstrate the stability of the test system supports the quality control (QC) frequency. a. Siemens Stratus-CS IQCP. b. DCA Vantage IQCP. c. i-Stat IQCP. 2. On 3/1/18 at 10:30 a.m., staff member A stated the data was not in the binder.</p>
<p><b>D5441</b></p>	<p><b>CONTROL PROCEDURES</b> CFR(s): 493.1256(a)(b)(c)(g)</p> <p>(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</p>

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 record review and interview the laboratory failed to include the number, type, and frequency of testing for three of three Individual Quality Control Plans (IQCPs) reviewed. The findings include: 1. A review on 3/1/18 at 9:45 a.m. of the IQCPs for the Siemens Stratus-CS, i-Stat, and DCA Vantage lacked a quality control plan (QCP) stating the number, type, and frequency of controls. A reference to another policy was not included. 2. On 3/1/18 at 10:30 a.m., staff member A stated the information was in a policy titled "Quality Management" instead of the IQCP. 3. A review on 3/1/18 at 1:30 p.m. of the Quality Management policy included "an external control will be run with each new lot number, each new shipment, or monthly-whichever is soonest before use for patient testing."

**D5449**

**CONTROL PROCEDURES**

CFR(s): 493.1256(d)(3)(ii)(g)

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-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (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 perform a positive and negative control every day of patient testing for five tests from 1/1/17 through 2/28/18. The findings include: A. Serum human chorionic gonadotropin (shCG) 1. On 2/28/18 at 8:30 a.m. a hCG kit was observed in the laboratory cabinet. 2. On 2/28/18 at 8:30 a.m., staff member A stated serum was used on the hCG kit. 3. A review on 2/28/18 at 1:30 p.m. of the Liberty Medical Center Individualized Quality Control Plan (IQCP) binder lacked an IQCP for serum hCG. 4. A review on 2/28/18 at 2:45 p.m. of the Liberty Medical Center Quickvue Pregnancy Test patient log included nine days of patient results without controls. a. 1/12/17 b. 3/16/17 c. 3/31/17 d. 7/31/17 e. 8/30/17 f. 9/6/17 g. 9/21/17 h. 10/19/17 i. 10/28/17 5. A review on 3/1/18 at 1:30 p.m. of the Liberty Medical Center Quality Management Policy stated a "positive and a negative should be tested with each new lot or shipment" for serum pregnancy tests. B. Stool Lactoferrin 1. On 2/28/18 at 8:30 a.m. a Leuko EZ stool lactoferrin kit was observed in the laboratory. 2. A review on 2/28/18 at 1:30 p.m. of the Liberty Medical Center IQCP binder lacked an IQCP for stool lactoferrin. 3. A review on 2/28/18 at 2:58 p.m. of the Liberty Medical Center Leuko EZ patient log included five days of patient results without controls. a. 11/24/17 b. 1/2/18 c. 2/10/18 d. 2/12/18 e. 2/15/18 4. A review on 3/1/18 at 1:30 p.m. of the Liberty Medical Center Quality Management Policy lacked information on the controls for the Leuko EZ stool lactoferrin kit. C. Mononucleosis (mono) 1. On 2/28/18 at 8:30 a.m. a mono kit was observed in the laboratory cabinet. 2. On 2/28/18 at 8:30 a.m., staff member A stated

serum was used on the mono kit. 3. A review on 2/28/18 at 1:30 p.m. of the Liberty Medical Center IQCP binder lacked an IQCP for mono. 4. A review on 2/28/18 at 3:08 p.m. of the Liberty Medical Center Infectious Mononucleosis patient log included fifteen days of patient results without controls. a. 2/9/17 b. 2/17/17 c. 4/5/17 d. 5/10/17 e. 6/19/17 f. 7/12/17 g. 8/12/17 h. 8/30/17 i. 10/3/17 j. 10/20/17 k. 11/1/17 l. 11/10/17 m. 11/16/17 n. 1/3/18 o. 2/14/18 5. A review on 3/1/18 at 1:30 p.m. of the Liberty Medical Center Quality Management Policy lacked information on the frequency of controls for the mono kit. D. Clostridium difficile (C. diff) 1. On 2/28/18 at 8:30 a.m. a Wampole C. diff kit was observed in the laboratory. 2. A review on 2/28/18 at 1:30 p.m. of the Liberty Medical Center IQCP binder lacked an IQCP for C. diff. 3. A review on 2/28/18 at 3:08 p.m. of the Liberty Medical Center C. diff patient log included one day of patient results without controls. a. 3/23/17 4. A review on 3/1/18 at 1:30 p.m. of the Liberty Medical Center Quality Management Policy included to perform a positive and negative control with each new lot or shipment. E. Urine drug screen 1. On 2/28/18 at 8:30 a.m. a Bio-Rad Tox/See urine drug screen kit was observed in the laboratory cabinet. 2. A review on 2/28/18 at 1:30 p.m. of the Liberty Medical Center IQCP binder lacked an IQCP for urine drug screens. 3. A review on 2/28/18 at 3:25 p.m. of the Liberty Medical Center Urine Drug Screen patient log included 45 days of patient results without controls. a. 1/27/17 b. 2/14/17 c. 3/17/17 d. 3/25/17 e. 3/31/17 f. 4/6/17 g. 4/19/17 h. 4/26/17 i. 5/25/17 j. 6/13/17 k. 6/17/17 l. 7/10/17 m. 7/29/17 n. 7/31/17 o. 8/1/17 p. 8/11/17 q. 8/13/17 r. 8/30/17 s. 8/31/17 t. 9/6/17 u. 10/5/17 v. 10/10/17 w. 10/18/17 x. 10/19/17 y. 10/25/17 z. 10/27/17 aa. 10/28/17 bb. 11/13/17 cc. 11/16/17 dd. 11/30/17 ee. 12/2/17 ff. 12/6/17 gg. 12/14/17 hh. 12/15/17 ii. 12/22/17 jj. 12/29/17 kk. 1/4/18 ll. 1/19/18 mm. 1/21/18 nn. 1/25/18 oo. 1/30/18 pp. 2/1/18 qq. 2/16/18 rr. 2/18/18 ss. 2/22/18 4. A review on 3/1/18 at 1:30 p.m. of the Liberty Medical Center Quality Management Policy stated a "positive and a negative control will be run each day patient is tested."

**D5469**

**CONTROL PROCEDURES**  
CFR(s): 493.1256(d)(10)(g)

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-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory failed to establish criteria to determine acceptable quality control results in three of three Individual Quality Control Plans (IQCPs) reviewed. The findings include: 1. A review on 3/1/18 at 9:45 a.m. of the IQCPs for the Siemens Stratus-CS, i-Stat, and DCA Vantage lacked the criteria for acceptable quality control (QC) results. 2. On 3/1/18 at 10:30 a.m., staff

member A stated the information was in the Quality Management policy. 3. A review on 3/1/18 at 1:30 p.m. of the Quality Management policy lacked the criteria for acceptable QC results for the Siemens Stratus -CS, i-Stat, and DCA Vantage.

**D5555**

**IMMUNOHEMATOLOGY**

CFR(s): 493.1271(c)(f)

(c) Blood and blood products storage. Blood and Blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented. (f) Documentation. The laboratory must 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 regularly inspect the alarm on the blood bank refrigerator from 1/1/17 through 2/28/18. The findings include: 1. A review on 2/28/18 at 4:30 p.m. of the electronic temperature monitoring system on the blood bank refrigerator lacked abnormal temperatures from high and low alarm checks from 1/1/17 through 2/28/18. The temperature at which alarms went off was not documented due to the absence of alarm checks. 2. On 2/28/18 at 4:30 p.m., staff member B stated the check on the alarm is the maintenance staff looking at the box every day.

**D5791**

**ANALYTIC SYSTEMS QUALITY ASSESSMENT**

CFR(s): 493.1289(a)(c)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory failed to document the quality assessment plan (QAP) in three of three Individual Quality Control Plans (IQCPs) reviewed. The findings include: 1. A review on 3/1/18 at 10:00 a.m. of the IQCPs for the Siemens Stratus-CS, i-Stat, and DCA Vantage lacked a QAP. 2. On 3/1/18 at 10:30 a.m., staff member A stated the QAP was not in the IQCPs.