

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 27D0409901	(X3) Date Survey Completed 03/15/2018
Name of Provider or Supplier Rosebud Healthcare Center	Street Address, City, State 383 North 17th Avenue, Forsyth, 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 3/14/18-3/15/18, deficiencies were cited for Rosebud Health Care Center in Forsyth, MT.
D2000	<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 record review and interview, the laboratory failed to enroll in proficiency testing for serum human chorionic gonadotropin (shCG) from 4/22/16 through 3/14/18. The findings include: 1. A combination hCG kit was observed in the laboratory cupboard on 3/14/18 at 8:45 a.m. 2. On 3/14/18 at 8:45 a.m., staff member A stated both urine and serum samples were used on the kit. 3. A review on 3/14/18 at 11:00 a.m. of the American Proficiency Institute (API) documentation lacked shCG proficiency testing. 4. A review on 3/14/18 at 11:05 of the Rosebud Health Care Center test volume report included 32 shCGs performed annually. 5. On 3/14/18 at 11:10 a.m., staff member A stated the laboratory had urine hCG enrollment but not serum hCG. 6. A review on 3/15/18 at 10:40 a.m. of the Rosebud Health Care Center API 2018 Order Confirmation lacked enrollment for shCG.</p>
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p>

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 record review and interview, the laboratory failed to perform accuracy verification on potassium hydroxide (KOH) from 4/22/16 through 3/14/18. The findings include: 1. A review on 3/14/18 at 11:00 a.m. of the American Proficiency Institute (API) documentation lacked KOH proficiency testing. Accuracy verification was not documented. 2. A review on 3/14/18 at 11:05 of the Rosebud Health Care Center test volume report included 22 KOHs performed annually. 3. On 3/14/18 at 11:10 a.m., staff member A stated the laboratory did not have enrollment for KOH. 4. A review on 3/15/18 at 10:40 a.m. of the Rosebud Health Care Center API 2018 Order Confirmation lacked enrollment for KOH.

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 record review and interview, the laboratory failed to follow manufacturer directions for prostate specific antigen (PSA) from 4/22/16 through 3/14/18. The findings include: 1. A review on 3/14/18 at 2:20 p.m. of a PSA test report lacked the identity of the PSA assay used. 2. A review on 3/14/18 at 2:20 of the Siemens Dimension PSA manufacturer instructions stated the "results reported by the laboratory to the physician must include the identity of the PSA assay used." 3. On 3/14/18 at 2:20 p.m., staff member A stated the identity was not on the report.

D5447

CONTROL PROCEDURES
CFR(s): 493.1256(d)(3)(i)(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 quantitative procedure, include two control materials of different concentrations; (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 perform two levels of quality control (QC) every day of patient testing for three of twenty days reviewed for prostate specific antigen. The findings include: 1. A review on 3/14/18 at 11:05 a.m. of the Rosebud Health Care Center test volume report included 141 PSAs performed annually. 2. A review on 3/15/18 at 9:00 a.m. of the days with a patient PSA result included twenty days of patient results between 4/1/17 and 6/30/17. 3. A review on 3/15/18 at 9:08 a.m., of the PSA QC files lacked QC results for three of the twenty days with patient results. a. 4/21/17. b. 4/25/17. c. 4/28/17. 4. On 3/15/18 at 9:08 a.m.,

staff member A stated the analyzer prompts for QC to be performed every 24 hours. 5. A review on 3/15/18 at 9:15 a.m. of the Rosebud Health Care Center Quality Control Policy states "two levels of Bio-Rad Immunoassay Control will be run each 24 hours the instrument is used for patient testing."

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 record review and interview, the laboratory failed to perform positive and negative reactivity for eight reagents in microbiology identification systems for one of one lot reviewed. The findings include: 1. A review on 3/15/18 at 10:15 a.m. of the Microscan Biochemical Quality Control Report Form included eight reactions without both positive and negative reactivity documented. a. Gram negative ID panel (NBPC34 panel, lot number B1017-404, received 2/14/18). 1. Urea lacks a documented positive reaction. 2. Oxidase lacks a documented positive reaction. 3. Tartrate lacks a documented positive reaction. 4. Tobramycin lacks a documented positive reaction. b. Gram positive ID panel (PBPC20 panel, lot number B1017-206, received 2/14/18). 1. Novobiocin lacks a documented positive reaction. 2. PGR glycosidase lacks a documented positive reaction. 3. ARA carbohydrate lacks a documented positive reaction. 4. Hemolysis lacks a documented negative reaction. 2. On 3/15/18 at 10:15 a.m., staff member A stated these reactions were missing.

D6128

TECHNICAL SUPERVISOR RESPONSIBILITIES

CFR(s): 493.1451(b)(9)

The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation.

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory failed to perform annual competency assessments on two of three testing personnel from 4/22/16 through 3/14/18. The findings include: 1. A review on 3/14/18 at 12:20 p.m. of annual competency assessments were missing for 2016 for staff member A and B. A 2017 competency assessment was missing for staff member A. 2. On 3/14/18 at 12:20 p.m., staff member A stated the competency evaluations were not in the file.