

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 27D0665300	(X3) Date Survey Completed 04/25/2018
Name of Provider or Supplier Livingston Healthcare	Street Address, City, State 320 Alpenglow Lane, Livingston, 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 4/25/18, deficiencies were cited for Livingston HealthCare in Livingston, MT.
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on observation, record review, and interview, the laboratory failed to retain chemistry calibration data and prothrombin time (PT) mean calculation data from 4/45/16 to 4/25/18. The findings include: 1. PT patient mean a. A Sysmex CA-600 coagulation analyzer was observed in the laboratory on 4/25/18 at 8:45 a.m. b. A review of the test volume report on 4/25/18 at 9:15 a.m. included an annual test volume of 1564 PTs. c. On 4/25/18 at 2:45 p.m. a PT mean patient time of 10.1 seconds was observed on the Sysmex CA-600 analyzer to calculate the patient International Normalized Ratio (INR). d. On 4/25/18 at 2:45 p.m., staff member A stated the data used to calculate the patient mean was logged into the analyzer and overwritten with each new reagent change. e. A review on 4/25/18 at 2:45 p.m. of the coagulation binder lacked the data for the calculation of the patient mean. New lots requiring a patient mean to be re-calculated were started in approximately 3/2018, 3/2017, and 4/2016. 2. Siemens Advia Centaur CP a. A Siemens Advia Centaur CP analyzer was observed in the laboratory on 4/25/18 at 8:45 a.m. b. On 4/25/18 at 8:45 a.m., staff member B stated the Centaur CP analyzer performs carcinoembryonic antigen (CEA), cortisol, free triiodothyronine (FT3), parathyroid hormone (PTH), prolactin, rubella, total testosterone, vitamin B12, folate, and hepatitis B surface antigen. c. An observation of the calibration data stored on the analyzer on 4/25/18 at 3:15 p.m. for the ten analytes lacked calibration data prior to 4/2017. d. On 4/25/18 at</p>

3:15 p.m., staff member B stated the calibrations are printed daily for review and then thrown away.

D6127

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 semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

Based on record review and interview, the technical supervisor failed to evaluate and document semiannual competency assessments for two of three new testing personnel. The findings include: 1. A review on 4/25/18 at 12:05 p.m. of the Livingston HealthCare competency documentation lacked semiannual assessments for staff members C and D. 2. On 4/25/18 at 12:05 p.m., staff member E stated the lab did not perform competency assessments within the first year.