

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 27D2095592	(X3) Date Survey Completed 04/23/2019
Name of Provider or Supplier Big Sky Laboratory	Street Address, City, State 2509 7th Ave South Suite C1, Great Falls, 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 4/23/19, deficiencies were cited for Big Sky Laboratory in Great Falls, MT.
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <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.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to verify the accuracy of the potassium hydroxide (KOH) test from 5/4/17 through 4/23/19. The findings include: 1. A review on 4/23/19 at 10:45 a.m. of the American Proficiency Institute (API) binders lacked documentation of proficiency testing enrollment for KOH. 2. A review on 4/23/19 at 10:45 a.m. of the API 2019 Order Confirmation form lacked enrollment for KOH. 3. On 4/23/19 at 10:45 a.m., staff member A stated the lab did not have enrollment for KOH and did not perform accuracy verification.</p>
D5437	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a)</p> <p>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</p>

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 perform calibration procedures with the frequency required by the manufacturer for four of five analytes (vitamin B12, vitamin D, free thyroxine (FT4), and free triiodothyronine (FT3)) performed on the TOSOH analyzer. The findings include:

- a. Vitamin B12
 1. On 4/23/19 at 8:00 a.m. a TOSOH AIA-900 analyzer was observed in the laboratory.
 2. A review on 4/23/19 at 1:00 p.m. of a patient (#18050059) report included results for B12 performed on 5/11/18.
 3. A review on 4/23/19 at 1:50 p.m. of the TOSOH Calibration Data log sheet documented a B12 calibration performed on 3/23/18 with an expiration date of 30 days later on 4/23/18. No calibrations were recorded after the 3/23/18 calibration.
 4. On 4/23/19 at 1:50 p.m., staff member A stated the B12 test was discontinued around that date and sent out to a reference lab.
 5. A review on 4/23/19 at 2:25 p.m. of the Big Sky Laboratory Data Log for B12 included 21 patients with B12 results reported from Big Sky Lab between the expired calibration on 4/23/18 and 6/14/18 when the B12 began to be sent out to a reference laboratory.
 6. On 4/23/19 at 4:30 p.m., staff member A stated the TOSOH analyzer prints an error code on the printout when the calibration expires but will not prohibit testing until the date is twice the acceptable calibration date.
- b. Vitamin D
 1. On 4/23/19 at 8:00 a.m. a TOSOH AIA-900 analyzer was observed in the laboratory.
 2. A review on 4/23/19 at 1:50 p.m. of the TOSOH Calibration Data log sheet included:
 - a. Calibration performed on 10/13/17 with a 90 day stability and a recalibration due on 1/13/18.
 - b. Calibration performed on 3/6/18 with a 90 day stability and a recalibration due on 6/6/18.
 - c. Calibration performed on 8/10/18 with a 90 day stability and a recalibration due on 11/10/18.
 - d. Calibration performed on 1/18/19 with a 90 day stability and a recalibration due on 4/18/19.
 3. A review on 4/23/19 at 2:05 p.m. of the vitamin D package insert included the calibration curve for vitamin D is "stable for up to 90 days."
 4. A review on 4/23/19 at 2:25 p.m. of the Big Sky Laboratory Test Tally report documented the number of patients with vitamin D resulted during expired calibrations.
 - a. 96 patients were resulted during the expired calibration between 1/13/18 through 3/6/18.
 - b. 93 patients were resulted during the expired calibration between 6/6/18 through 8/10/18.
 - c. 40 patients were resulted during the expired calibration between 11/10/18 through 1/8/19.
 5. On 4/23/19 at 4:30 p.m., staff member A stated the TOSOH analyzer prints an error code on the printout when the calibration expires but will not prohibit testing until the date is twice the acceptable calibration date.
- c. FT4
 1. On 4/23/19 at 8:00 a.m. a TOSOH AIA-900 analyzer was observed in the laboratory.
 2. A review on 4/23/19 at 1:50 p.m. of the TOSOH Calibration Data log sheet included:
 - a. Calibration performed on 8/24/18 with a 90 day stability and a recalibration due on 11/24/18.
 - b. Calibration performed on 2/1/19 with a 90 day stability and a recalibration due on 5/1/19.
 3. A review on 4/23/19 at 2:05 p.m. of the FT4 package insert included the calibration curve for FT4 is "stable for up to 90 days."
 4. A review on 4/23/19 at 2:45 p.m. of the Big Sky Laboratory Test Tally report documented 40 patients with resulted FT4 between the expired calibration on 11/24/18 and recalibration on 2/1/19.
 5. On 4/23/19 at 4:30 p.m., staff member A stated the TOSOH analyzer prints a error code on the printout when the calibration expires but will not prohibit testing until the date is twice the acceptable calibration date.
- d. FT3
 1. On 4/23/19 at 8:00 a.m. a TOSOH AIA-900 analyzer was observed in the laboratory.
 2. A review on 4/23/19 at 1:50 p.m. of the TOSOH Calibration Data log sheet included:
 - a. Calibration performed on 5/16/18 with a 90 day stability and a recalibration due on 8/16/18.
 - b. Calibration performed on 10/12/18 with a 90 day stability and a recalibration due on 1/12/19.
 - c. Calibration performed on 3/6/19 with a

90 day stability and a recalibration due on 6/6/19. 3. A review on 4/23/19 at 2:05 p.m. of the FT3 package insert included the calibration curve for FT3 is "stable for up to 90 days." 4. A review on 4/23/19 at 2:55 p.m. of the Big Sky Laboratory Test Tally report documented the number of patients with FT3 resulted during expired calibrations. a. 15 patients were resulted during the expired calibration between 8/16 /18 through 10/12/18. b. 21 patients were resulted during the expired calibration between 1/12/19 through 3/6/19. 5. On 4/23/19 at 4:30 p.m., staff member A stated the TOSOH analyzer prints an error code on the printout when the calibration expires but will not prohibit testing until the date is twice the acceptable calibration date.

D6021

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(5)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:
Based on record review and interview, the laboratory director failed to maintain a quality assessment program from 5/4/17 through 4/23/19. The findings include: 1. A review on 4/23/19 at 11:00 a.m. of the Big Sky Laboratory binders lacked documentation of QA projects. 2. On 4/23/19 at 4:15 p.m., staff member A stated QA projects were not done but the Laboratory Director had discussed starting them.