

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  27D2095592	<b>(X3) Date Survey Completed</b>  08/04/2021
<b>Name of Provider or Supplier</b>  Big Sky Laboratory	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<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 record review and interview with Laboratory Director (LD) #1, the laboratory failed to ensure the laboratory was enrolled in an HHS-approved proficiency testing program for Mycology (KOH Preps), Chemistry (C-Reactive Protein (CRP)) and Chemistry (Hemoglobin A1c) for years 2019 and 2020. See D6015</p>
<b>D5400</b>	<p>ANALYTIC SYSTEMS CFR(s): 493.1250</p> <p>Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.</p>

This CONDITION is not met as evidenced by:  
Based on review of chemistry, hematology, virology and uranalysis procedures, the laboratory failed to include a step-by-step procedure for microscopic urinalysis and blood smear preparation for manual differential send-out (refer to D5403); failed to verify the performance specifications of COVID-19 IgG/IgM rapid test prior to reporting patient test results, (refer to D5421); failed to perform at least a three-point calibration for sodium, potassium, and chloride on the chemistry analyzer every six months (refer to D5439); and failed to include a negative and positive control material for COVID-19 IgG/IgM test for each day of patient testing (refer to D5449).

**D5403**

**PROCEDURE MANUAL**  
CFR(s): 493.1251(b)

The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:  
. Based on review of the laboratory procedures, patient reports and interview with Testing Personnel (TP) #1, the laboratory failed to have a step by step procedure for microscopic urinalysis and preparation of blood smears for manual differential send-outs. Findings: 1. No step by step procedure for microscopic urinalysis was available for review. 2. No step by step procedure for preparation of blood smear for manual differential send-outs were available for review. 3. Interview with the TP #1 on August 3, 2021 at 8:00 AM, confirmed the laboratory failed to have a step-by-step procedure of microscopic urinalysis and preparation of blood smears for manual differential send-outs.

**D5421**

**ESTABLISHMENT AND VERIFICATION OF PERFORMANCE**  
CFR(s): 493.1253(b)(1)

Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

Based on review of laboratory procedures, manufacture's insert, and interview with the Testing Personnel (TP) #1, the laboratory failed to verify the performance specifications of Healgen COVID-19 IgG/IgM Rapid Test Cassette prior to reporting patient test results. Findings: 1. No verification data to demonstrate accuracy, precision, and reportable range was available for review. 2. Review of manufacturer's product insert revealed, "Quality control - Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance." 3. Review of Validation Procedure reveals, "1 Purpose: 1.1 To validate the precision and accuracy of new or existing laboratory equipment." 4. No laboratory director review prior to introducing Healgen COVID-19 IgG/IgM Rapid Test for routine patient testing was available for review. 5. Interview with the (TP) #1 on August 3, 2021 at 10:30 AM confirmed the laboratory failed to verify the performance specifications of Healgen COVID-19 IgG/IgM Rapid Test Cassette prior to reporting patient test results.

**D5439**

**CALIBRATION AND CALIBRATION VERIFICATION**

CFR(s): 493.1255(b)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:

Based on review of the calibration records for the Siemens Dimension Xpand Plus chemistry analyzer for the analytes of sodium, potassium, and chloride, and interview with the Testing Personnel (TP) #1, the laboratory failed to perform at least a three point (a minimal, mid-point, and maximum) calibration verification every six months. Findings: 1. Review of 2019 and 2020 calibration records for the Siemens Dimension Xpand Plus chemistry analyzer for the analytes: sodium, potassium, and chloride, revealed the laboratory failed to perform a calibration including, at least, a minimal, midpoint, and maximum value for each analyte, every six months. 2. Interview with the TP #1 on August 3, 2021 at 9:30 AM confirmed the laboratory failed to perform at

least a three-point calibration for sodium, potassium, and chloride on the Siemens Dimension EXL 200 chemistry analyzer every six months.

**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 review of Serology Log (SAR-CoV-2 IgG/IgM), manufacture's insert and interview with the Testing Personnel (TP) #1, the laboratory failed to include a negative and positive control material for Healgen COVID-19 IgG/IgM Rapid Test for each day of patient testing. Findings: 1. No external positive or negative quality control results were documented in the Serology Log (SAR-CoV-2 IgG/IgM). 2. Review of manufacturer's product insert revealed, "Quality control - Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance." 3. Interview with the (TP)#1 on August 3, 2021 at 10:45 AM confirmed the laboratory failed to include a negative and positive control material for Healgen COVID-19 IgG/IgM Rapid Test for each day of patient testing.

**D6015**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(4)

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)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed.

This STANDARD is not met as evidenced by:

. Based on review of proficiency testing records from the American Proficiency Institute (API), the test volume report and interview with Laboratory Director (LD) #1, the laboratory director failed to ensure that the laboratory is enrolled in an HHS approved proficiency testing program for KOH Preps, C-Reactive Protein (CRP) and Hemoglobin A1c for years 2019 and 2020. Findings: 1. Review of Test Volume Report revealed 2 KOH Preps were performed, 168 C-Reactive Protein tests were performed, and 904 Hemoglobin A1c tests were performed in 2020. 2. Review of 2019 and 2020 API Testing Program records lacked documentation of proficiency testing for KOH Preps, C-Reactive Protein and Hemoglobin A1c. 3. Review of Quality Assessment Plan revealed, "6. Proficiency Testing - This laboratory is enrolled in formal proficiency testing appropriate to the test menu and treats all proficiency test challenge specimens the same as patient specimens." 4. Interview on August 3, 2021 at 11:00 AM with the (LD)#1 confirmed the laboratory failed to enroll

in an HHS-approved proficiency testing program for Mycology (KOH Preps), Chemistry (C-Reactive Protein) and Chemistry (Hemoglobin A1c) for years 2019 and 2020.