

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 46D2086447	<b>(X3) Date Survey Completed</b> 02/10/2021
<b>Name of Provider or Supplier</b> Physician Laboratory Services	<b>Street Address, City, State</b> 2051 E Red Hills Parkway, Suite 7, St George, UT	
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>D2015</b>	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by: Based on proficiency testing records review, lack of documentation and confirmation by the technical supervisor, the laboratory failed to retain complete blood count (CBC) instrument printouts from 1 of 5 events reviewed, the 3rd event of 2019; pentra 400 routine chemistry instrument printouts for 1 of 5 events reviewed, the 3rd event of 2020, and attestation statements 2 of 5 hematology testing events the 2nd and 3rd of 2019. Findings include: 1. Proficiency records review failed to include documentation the laboratory retained ABX Micros 60 instrument printouts from the 3rd Hematology CBC event of 2019; pentra 400 routine chemistry instrument printouts from the 3rd event of 2020, and attestation statements from the 2nd and 3rd hematology testing events of 2019. 2. In an interview conducted on 02/20/2021 at approximately 6:00 P. M. the technical supervisor confirmed some of the proficiency testing records could be missing from those provided for review.</p>
<b>D5217</b>	<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 lack of documentation and confirmation by the technical supervisor, the laboratory failed to verify test accuracy twice annually for approximately 34 of 44 drugs and 10 of 10 antinuclear antibodies for 2 years of testing reviewed (2019 and 2020). The laboratory performed approximately 1625 drug assays per year and 1040 Antinuclear antibody (ANA) tests per year. Findings include: 1. The laboratory participation in College of American Pathology (CAP) urine drug testing UT module failed to include detection of approximately 34 of the drugs reported each year of testing. 2. The laboratory performed reflex testing for ANA testing for the subgroups Anti: IgA, IgG, and IgM, SM-96, RnP 96, SB-20, Jo 1, Centromere 96CE, Sci-70, 96 SC, SS-B, SS-A, and DNA 96 DS. Proficiency testing for these subgroups if included in the testing events for the CAP - S module were not graded by the proficiency testing agency and not self graded by the laboratory in 2019 and 2020. 3. In an interview on 02/10/2021 at approximately 6:15 P.M. the technical supervisor confirmed the laboratory did not self grade proficiency test results when not graded by the proficiency testing agency and did not have a method to verify test accuracy for reflex ANA tests. ,

**D5433**

**MAINTENANCE AND FUNCTION CHECKS**

CFR(s): 493.1254(b)(1)

For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.

This STANDARD is not met as evidenced by:

Based on direct observation, lack of documentation, and interview with the technical supervisor, the laboratory failed to establish a maintenance protocol to verify they followed the manufacturer's requirement that Quantiferon specimens be vortexed using 30 RPM'S. The laboratory performed approximately 10 to 15 Quantiferon TB Gold tests per week. Findings include: 1. Direct observation of the Vortemp vortex mixer on 02/10/2021 at approximately 8:45 A.M. lead to an interview with the technical supervisor for the test the instrument was used for. 2. In an interview on 02 /10/2021 at approximately 1:00 P.M. the technical supervisor stated the vortex mixer was used for TB Quantiferon and the laboratory did not document instrument maintenance that included verification of the 30 RPM rotations of the flat bed used to mix microtiter trays containing the specimen, reagents, and antibody coated tests wells.

**D5467**

**CONTROL PROCEDURES**

CFR(s): 493.1256(d)(9)(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-- When using calibration material as a control material, use calibration material from a different lot number than that used to establish a cut-off value or to calibrate the test system. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on quality control (QC) records review, lack of documentation, and interview with the technical supervisor, the laboratory failed to ensure they used calibration materials from different lot numbers as the standards used for standard curve determination for approximately 64 of 64 drugs the laboratory reported. The laboratory performed approximately 10 to 30 drug concentration analyses twice a week. Findings include: 1. Quality control records review included the lot numbers of quality control materials in use from February 2019 to February 2021. Quality control records review included documentation for stock solution verification of control concentrations made from dilutions of Cerilliant drug standards used to establish a standard curve for each day of gas chromatography, tandem mass spectrometry testing. 2. The laboratory lacked documentation they used two different lot number of standards to make controls and standard curve dilutions points used to compare instrument reading for the calculation of drug concentrations for the determination of the presence or absence (by cut off concentrations) of drugs in patient's urine specimens. 3. In an interview conducted on 02/10/2021 the technical supervisor confirmed at approximately 6:15 P.M. the laboratory used the same lot numbers of standards for creating the standard curve and for controls.

**D6086**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1445(e)(3)(ii)

The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method.

This STANDARD is not met as evidenced by:

Based on lack of test specification verification of analytical specificity and sensory for Anti: nuclear antibody, Cyclic Citrulinated Peptide, dsDNA, P, S-SA, S-SB Sm, Sm RNP, Sci-70, Jo-1. Centromere, and RNP 70 reflex tests following a positive Anti nuclear Antibody test; and Qiagen QfTB Gold Quantiferon test for the presence or absence of Mycobacterium Tuberculosis, the director failed to ensure verification procedures were adequate to determine analytic sensitivity and specificity. (See D5423)

**D6094**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:

Based on proficiency testing records review, lack of documentation, quality assessment plan review, and interview with the general immunology technical

supervisor, the laboratory failed to maintain their quality assessment policy the end of 2019 and the first of 2020 when the laboratory failed to self grade Antinuclear antibody (ANA) proficiency tests. Findings include: 1. College of American Pathology (CAP) failed to actually grade ANA tests for the S-C event of 2019 and for event S-A of 2020 due to less than 10 participants using the same methodology for the tests. 2. The quality assessment plan included acceptable participation in proficiency testing that is sent 3 times per year. 3. In an interview conducted on 02/10/2021 at approximately 6:30 P.M. staff confirmed the proficiency company did not grade the ANA test results and the laboratory did not have a procedure for lack of a graded proficiency test acceptable participation.

**D6168**

**TESTING PERSONNEL**  
CFR(s): 493.1487

The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493.1495 of this subpart for the volume and complexity of testing performed.

This CONDITION is not met as evidenced by:  
Based on lack of documentation and confirmation by the technical supervisor the laboratory failed to ensure 1 of 2 high complexity testing personnel met the requirements for high complexity testing personnel for mass spectrometry and immunoassay testing. (See D6171)

**D6171**

**TESTING PERSONNEL QUALIFICATIONS**  
CFR(s): 493.1489(b)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical

laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations.

This STANDARD is not met as evidenced by:

Based on personnel records review, lack of documentation, and interview with the laboratory technical supervisor for toxicology, routine chemistry, and endocrinology, one of two testing personnel failed to have at least six semester hours in chemistry to qualify as a high complexity testing person for toxicology, general immunology, or hematology testing. Findings include: 1. Personnel records review of the transcript presented for qualification included zero chemistry credit hours for test person 2. 2. Training records included documentation the laboratory trained test person 2 for immunoassay testing on 10/06/2020 and mass spectrometry testing on 01/26/2021. 3. In an interview conducted on 02/10/2021 at approximately 10:30 A.M. the laboratory technical supervisor for routine chemistry, endocrinology, and toxicology confirmed the transcript did not include 6 semester hours of chemistry to qualify test person 2 as a high complexity test person. The laboratory technical supervisor confirmed test person 2 was trained for high complexity testing and stated that to date had not performed any mass spectrometry high complexity tests. The number of high complexity immunoassay tests performed was not determined.