Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	53D2181399	08/27/2020
Name of Provider or Supplier	**Street Address, City, State**	
Perfectus Biomed, Llc	3545 South Park Drive, Jackson, WY	

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
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on lack of a Food and Drug Administration (FDA) Emergency Use Authorization (EUA) for UBI-SARS-CoV-2 ELISA IgG test system, verification documentation reviewed as presented by the laboratory, and interview with the laboratory staff, the laboratory failed to document the test system's accuracy, analytic sensitivity specificity. The laboratory tested approximated 15 to 20 tests per week. Findings include: 1. The UBI SARS CoV-2 ELISA IgG test has not been issued an EUA or Approval from the FDA. 2. The laboratory lacked documentation of a statistically significant number of positive tests to use to verify test accuracy or analytic sensitivity. A. The total number of PCR positive specimens was thirteen. B. The laboratory failed to receive documentation that the test was accurate as compared to reference laboratory testing for test positivity (accuracy) for three of the thirteen positive tests when compared to reference laboratory test results. The laboratory failed to show documentation of the reference laboratory test reports or document through statistical analysis the measure of test accuracy. C. The laboratory failed to document it followed the specificity instructions provided to the laboratory on April 21, 2020 via

	email by FDA to confirm that: "Just for reference, if a large number of known negative samples collected (>75 "sic" in the US prior to December 2019 were from a population with a high prevalence of vaccination against the following viruses, and specificity of > 98% is observed, cross-reactivity testing for the following viruses would not be expected at this time. Your specificity plan is good to go. anti- influenza A (IgG and IgM) anti-influenza B (IgG and IgM) anti -HCV (IgG and IgM) anti- HBV (IgG and IgM) anti- haemophilus influenzae (IgG and IgM) anti- 229 E (alpha coronavirus) anti- NL63 (alpha coronavirus) anti- OC43 (beta coronavirus) ANA anti respiratory syncytial virus (IgG and IgM)" The laboratory failed to document the prevalence of vaccination of the negative samples other than the report includes the disclaimer that: anti- 229 E (alpha coronavirus), anti- NL63 (alpha coronavirus), and anti- OC43 (beta coronavirus) may cause false positive results; and failed to document they tested >75 of known negative samples collected prior to December 2019 before testing and reporting patient samples on 04/25/2020. 3. In an interview conducted on 08/27/2020 at approximately 6:00 P.M., the laboratory technical supervisor confirmed the verification studies lacked statistical valid numbers of positive tests to verify accuracy.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on test report review and interview with staff, the laboratory failed to include the name of the test performed, SARS CoV-2 ELISA IgG. The laboratory estimates an annual test volume of 4800 for 2020. Findings include: 1. The laboratory report included the test name as COVAXX ANTIBODY TEST RESULTS. 2. In an interview conducted on 08/27/2020 at approximately 6:00 P.M., staff confirmed the report included the name of the test kit instead of the detection of CoViD 19 IgG antibody from April 25, 2020 to August 27, 2020. The laboratory currently reports approximately 20 to 50 tests per week.
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 education credential documentation and confirmation by the laboratory supervisor, two of four new testing personnel lacked documentation to qualify as a high complexity testing person. (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 lack of documentation, patient test reports review, and confirmation by the laboratory supervisor, two of five new testing personnel failed to have documentation to qualify as a high complexity testing person. Findings include: 1. Test person D lacked documentation of a degree or transcript to document they met the requirements to qualify as a high complexity testing person. Testing person E failed to have a United States (US) evaluation of a foreign diploma to determine the US analogy of the educational benchmark. 2. It was not determined the number of patient tests performed by test persons D and E. 3. In an interview conducted on 08/27/2020 at approximately 6:10 P.M., the technical supervisor confirmed the laboratory failed to ensure test person D had the educational documentation and test person E had a foreign diploma evaluated to compare to US educational benchmarks to qualify to perform high complexity testing.