Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0714948	04/29/2021
Name of Provider or Supplier	**Street Address, City, State**	
Brian D Ardel Md Pa	3417-D Tamiami Tr, Port Charlotte, FL	

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	An announced recertification survey was conducted on 4/29/21 at Brian D Ardel Md Pa, a clinical laboratory in Port Charlotte, Florida. Brian D Ardel Md Pa is not in compliance with Code of Federal Regulations (CFR) 42, Part 493, Laboratory Requirements. The following is a description of the noncompliance.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (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. This STANDARD is not met as evidenced by: Based on American Proficiency Institute (API) proficiency record review, and interview with Testing Personnel #B, the laboratory failed to retain instrument printouts and documentation of signed attestation statements for the Chemistry Core proficiency testing for two of two years reviewed (2019-2021). The findings included: Review of the API instructions revealed that "Testing Personnel and the laboratory director must physically sign an attestation statement for all PT results and retain the signed statement (or a copy) for a minimum of 2 years." Review of API Chemistry core proficiency records for 2019-2021 (1st, 2nd, and 3rd Events for 2019 and 2020 and 1st Event 2021) revealed that 2 assigned attestation statements (2020 #3rd Event and 2nd Event of 2021) out of 7 (1st, 2nd, and 3rd Event 2019 and 2020, and 1st

	Event 2021) were missing from the proficiency testing records. Review of the API Chemistry core proficiency records showed that 1 event (2nd Event 2019) out of 7 (1st, 2nd, and 3rd Event 2019 and 2020, and 1st Event 2021) were missing instrument printouts. Interview on 04/29/21 at 1:30 p.m., Testing Personnel #B stated she did not know that the attestation statements were missing for Chemistry core 3rd Event for 2020 and 1st Event for 2021 and the instrument printouts for the Chemistry 2nd Event for 2019.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on review of the American Proficiency Institute (API) proficiency testing results, and interview with Testing Personnel # B, the laboratory director failed to review the API Chemistry Core proficiency testing results for 1 (2019 3rd Event) out of 7 API Chemistry Core (1st, 2nd, 3rd 2019 and 2020 events and 2021 1st Event) proficiency testing events The findings included: Review of API Chemistry Core proficiency testing results revealed that the Laboratory Director did not review the results for one (3rd testing event in 2019) out of 7 (events 1st, 2nd, and 3rd 2019 and 2020 events and, 1st event 2021). Interview on 4/29/21 at 1:35 p.m., Testing Personnel #B stated she did not know the Laboratory Director had not reviewed the API Chemistry 3rd 2019 event.
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 Chemistry Calibration Verification (linearity) record review, and interview

	with Testing Personnel #B, the laboratory did not perform calibration verifications on the chemistry analyzer at least every six months for two out two years (2019 - 2020). The findings included: 1. Review of calibration verification records for the Chemistry analyzer revealed that calibration verifications had been performed 4/5/19 and 2/6/20. 2. Interview on 4/29/21 at 1:40 p.m., Testing Personal #B stated she thought calibration verifications needed to be performed once a year.