Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	22D2146568	04/21/2021
Name of Provider or Supplier	**Street Address, City, State**	
Primary Care Of Cape Cod	89 Lewis Bay Road, Hyannis, MA	

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	A CLIA recertification survey was conducted for the laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: . Based on record review and interview on 4/21/21 with the technical consultant (TC), the laboratory failed to follow policies and procedures in place for all tests, assays, and examinations performed by the laboratory as evidenced by the following: 1. The surveyor reviewed the Horiba Pentra 400 Clinical Chemistry User Manual on 4/21/21. The user manual under "Physical Specifications Humidity and Temperature Conditions" states that it requires 20% - 85% humidity. 2. The surveyor requested to review humidity documentation for calendar years 2020 and 2021. The TC stated that they did not check and document humidity of the room where the laboratory was located. 3. The TC confirmed in an interview on 4/21/21 at 12:00 PM that the laboratory failed to follow the Horiba Pentra 400 Clinical Chemistry User Manual and did not check humidity levels of the laboratory. 4. The laboratory performs 66,100 tests on the Horiba Pentra 400 Clinical Chemistry analyzer. .
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 record review and interview with the technical consultant on 4/21/21, the laboratory failed to perform calibration verification as appropriate as evidenced by the following: 1. The surveyor reviewed quality control records for calendar year 2020. The review revealed that calibration verifications of at least 3 points were not performed once every six months for seventeen (17) out of eighteen (18) quantitative chemistry analytes performed on the Horiba Pentra 400 analyzer and one (1) out of five (5) analytes performed on the Tosoh-AIA analyzer. 2. Calibration verifications were only performed during initial validations of the chemistry analyzers on 12/17/19 for the Horiba Pentra 400 and 12/14/19 for the Tosoh-AIA. 3. The TC interviewed on 4/21/21 at 11:15 AM confirmed that calibration verifications of at least 3 points had not been performed at least once every six months. .