Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 39D0189114	**(X3) Date Survey Completed** 11/09/2018
Name of Provider or Supplier Dr Jessica Pagana-Defazio Fpc	**Street Address, City, State** 1072 Market Street, Sunbury, PA	
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**
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on laboratory tour, review of the Unico Power Spin Centrifuge Manuel and interview with the Laboratory Director, the laboratory failed to perform RPM (revolution per minute) function checks on the Unico Power Spin Centrifuge from April 2017 to the date of survey. Findings include: 1. Unico Power Spin Centrifuge Manuel, under the Calibartion section states, "It is recommended that your centrifuge's RPM be calibrated at least every 6 months". 2. On the day of survey, 11/09/2018, the labortaory was unable to provide documentation of RPM checks performed on the Unico Power Spin Centrifuge every 6 months. 3. The Unico Power Spin Centrifuge is used to spin chemistry specimen: - In 2017, 35,752 specimen were analyzed. - In 2018, (01/01/2018 to 10/31/2018) 34,310 specimen were analyzed. 4. The LD confirmed the findings above on 11/09/2018 around 9:00 am.
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 Ace Alera calibration verification records and interview with the Labortaory Director (LD), the laboratory failed to perform calibration verification (CV) on the Ace Alera chemistry analyzer according to manufacturer's instructions in 2018. Findings include: 1. on the day of survey, 11/09/2018, according to the the Ace Alera's manufacturer's instructions, calibration verification criteria should be performed at least every six months. The laboratory last performed CV on 1/24/2018 and was due to be performed by 07/24/2018. The labortaory was unable to provide documentation of a CV performed before 07/24/2018. 2. In 2018 - 31,699 specimen were analyzed on the Ace Alera. 3. The LD confirmed the findings above on 11/09 /2018 around 09:55 am.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on testing personnel (TP) competency assessment record review and interview with the Laboratory Director (LD), the laboratory technical consultant (the LD) failed to assess the competency assessment of 2 of 4 TP for each analyzer (Ace Alera, Tosoh AIA 360 and Cell Dyn Emerald CBC) they perform testing on from 2017 to the date of survey. Findings include: 1. On the day of survey, 11/09/2018, review of competency assessment records revealed, CLIA's 6 points of competency is only assessed for testing personnel's 6 month competency and 1st yearly competency. 2. Thereafter, the LD performs a "Performance Appraisal" yearly, which does not cover all 6 points of CLIA's competency assessment and does not assess TP (2 of 4) for each analyzer (Ace Alera, Tosoh AIA 360 and Cell Dyn Emerald CBC) they perform testing on. 3. The LD confirmed the findings above on 11/09/2018 around 8:45 am.