Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0946050	09/10/2019
Name of Provider or Supplier	**Street Address, City, State**	
Berkley Hills Lab	322 Warren Street, Johnstown, 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
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 calibration verification documentation and interview with testing personnel (TP) #1, the laboratory failed to perform calibration verification on 1 of 1 Abbott Architect i1000 and 1 of 1 Beckman Coulter AU480 used to perform chemistry and endocrinology tests at least once every 6 months from 2018 to the date of survey. Finding Include: 1. On the day of survey, 9/10/2019, the laboratory failed to perform calibration verification on 1 of 1 Abbott Architect i1000 and 1 of 1

	Beckman Coulter AU480 used to perform chemistry and endocrinology tests at least once every 6 months in 2018 and 2019. 2. Calibration Verification was performed on the Abbott Architect i1000 on: - 03/23/2018 - 08/28/2019 3. Calibration Verification was performed on the Beckman Coulter AU480 on: - Not performed in 2018 - 08/28 /2019 4. In 2018: 77,181 patient tests were analyzed on the Beckman Coulter AU480 chemistry analyzer. 5. In 2019: 59,118 patient tests were analyzed on the Beckman Coulter AU480 chemistry analyzer. 6. In 2018: 5,640 patient tests were analyzed on the Abbott Architect i1000 chemistry analyzer. 7. In 2019: 4,004 patient tests were analyzed on the Abbott Architect i1000 chemistry analyzer. 8. TP#1 confirmed the findings above on 9/10/2019 around 10:10 am.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based on review of laboratory procedures, and interview with the testing personnel (TP) #1, the laboratory director failed to ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process from 2017 to the date of survey. Findings Include: 1. On the date of survey, 9/10/2019, the laboratory could not provide the following procedures: - Quality Assurance /Assessment Policy. - Competency Assessment Policy. 2. The following analyzer polices did not include measures for quality control: - Beckman Coulter AU480 analyzer used to perform Routine Chemistry testing. - Sysmex i1000 XS analyzer used to perform Complete Blood Count testing. - Abbott Architect i1000 analyzer used to perform Endocrinology testing. 3. The following polices were not signed by the LD: - Revised Serum Pregnancy Procedure. - Revised Erythrocyte Sedimentation Rate procedure (ESR). 4. TP#1 confirmed the findings above on 9/10/2019 around 10: 00 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 review of testing personnel competency assessment records, review of the competency assessment policy and interview with TP #1, the technical consultant (TC) failed to evaluate the competency of 1 of 5 TP performing Hematology, chemistry and Immunology testing in 2019. Findings Include: 1. On the day of survey, 9/10/2019, the laboratory could not provide competency assessment documentation for 1 of 5 TP (TP# 4). All TP were assessed for competency on January of 2019. 2. TP#1 confirmed the finding above on 9/10/2019 around 9:40 am.