Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	51D0665886	02/11/2020
Name of Provider or Supplier	**Street Address, City, State**	
Pleasant Valley Hospital Laboratory	2520 Valley Drive, Point Pleasant, WV	

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 CLIA validation survey was conducted at Pleasant Valley Hospital on February 11, 2020 by the West Virginia Office of Laboratory Services. The laboratory was surveyed under 42 CFR 493 CLIA Regulations. Specific deficiencies cited are as follows:
D2087	ROUTINE CHEMISTRY CFR(s): 493.841(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Based on a reivew of laboratory College of American Pathology (CAP) proficiency testing (PT) records and an interview with the general supervisor of the Chemistry department (GS3), the laboratory failed to attain a score of at least 80 percent for each analyte in the 2019 API 1st testing event for Routine Chemistry. Findings: 1. A review of the 2019 CAP 1st testing event PT records for Routine Chemistry identified an overall successful score of 98 percent for the testing event. 2. A review of the 2019 CAP 1st testing event PT records for Routine Chemistry identified an unsatisfactory analyte performance score of 60 percent for the analyte BUN. 3. A review of the 2019 CAP 1st testing event PT records revealed an investigation into the unsuccessful performance of the analyte BUN. The documented corrective action was to calibrate the analyte on a more frequent basis as recommended from Roche service. 4. An interview with GS3, on 2/11/2020 at approximately 10:30 AM, confirmed the findings.
D2099	ENDOCRINOLOGY CFR(s): 493.843(b) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory

	performance. This STANDARD is not met as evidenced by: Based on a review of the laboratory College of American Pathology (CAP) proficiency testing (PT) records and an interview with the Chemistry general supervisor (GS3), the laboratory failed to attain an overall score of 80 percent for the 3rd CAP 2018 testing event in Endocrinology. Findings: 1. A review of the PT records for the 3rd CAP 2018 Endocrinology testing event identified the overall testing event score of 70 percent as an unsatisfactory performance. Specimens K-14 and K-15 had unsuccessful analyte performance for the analytes Free Thyroxine, T3 Uptake, TSH, and T4 (thyroxine). a. The individual analyte Free Thyroxine score was 60 percent. b. The individual analyte T3 Uptake score was 60 percent. c. The individual analyte TSH score was 60 percent. d. The individual analyte T4 (thyroxine) score was 60 percent. 2. A review of PT records for the 2018 CAP 3rd testing event in Endocrinology identified an investigation of the unsatisfactory performance. The documented investigation revealed an error in processing and testing specimens K-14 and K-15. The documented corrective action was retraining of testing personnel in the processing and testing of specimens. 3. An interview with GS3, on 2/11/2020 at approximately 10:30 AM, confirmed the findings.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of laboratory quality control (QC) records and an interview with the microbiology general supervisor (GS4), the laboratory failed to (e)(4)(i) check each batch of media in microbiology for sterility. Findings: 1. A review of 2019 and 2020 QC records identified that each batch of media in microbiology was documented as being tested for growth and inhibition as required for MTM, CHOC, MRSA, CHROME, and CANDIDA agar media. Review identified that each batch of media had no documentation of being checked for sterility. 2. An interview with GS4, on 2/11/2020 at approximately 3:00 PM, confirmed that no sterility checks were being performed on the MTM, CHOC, MRSA, CHROME, and CANDIDA microbiology media.
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met.

	This STANDARD is not met as evidenced by: Based on a review of the Immunohematology laboratory room temperature maintenance logs and an interview with the Immunohematology general supervisor (GS2), the laboratory failed to document corrective actions taken when the room temperature criteria was not met. Findings: 1. A review of Immunohematology room temperature maintenance logs identified the acceptable criteria as 20 to 24 degrees Celsius. 2. A review of 2019 and 2020 Immunohematology room temperature maintenance logs identified room temperatures out of the acceptable criteria range 8 of 31 days in January 2020 and no documentation of corrective action for 6 of the 8 out of range temperatures. a. In January 2020 temperatures were documented as out of range on 1/19, 1/25, 1/26, 1/27, 1/28, and 1/30 with no documentation of corrective action taken. b. In January 2020 temperatures were documented as out of range on 1 /18 and 1/31 with documentation of "no platelets" as the corrective action. 3. A review of 2019 and 2020 Immunohematology room temperature maintenance logs identified room temperatures out of the acceptable criteria range 3 of 11 days in February 2020 and no documentation of corrective action for all 3 out of range temperatures. 4. An interview with GS2, on 2/11/2020 at approximately 1:00 PM, confirmed the findings.
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (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 a review of written laboratory policies and procedures, personnel competency records, and an interview with the general supervisor (GS1), the technical supervisor (TS1) was not the documented evaluator for the competency of the testing personnel (TP). Findings: 1. A review of 2018 and 2019 testing personnel competency records identified the testing personnel competencies had been observed, evaluated, and signed by the general supervisors of each department for all 16 TP. The TS1 has the responsibility of performing TP competency. 2. A review of the 2018 and 2019 retired testing personnel competency forms identified the lack of all 6 required elements for each methodology performed by the testing personnel. The new competency forms have all 6 required elements for each moderate complexity and high complexity methodology. 3. An interview with GS1, on 2/11/2020 at approximately 9:30 AM, confirmed the findings. The GS1 stated that the written policy and procedure for TP competency will be revised and updated to include provisions for the TS to observe and witness TP competency and for the documentation to include the signatures of the the TS, along with the GS and lab director. The GS1 stated the new TP competency forms, with all 6 required elements, will be put into use with the performance of 2020 TP competencies.