Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0188565	03/19/2018
Name of Provider or Supplier	**Street Address, City, State**	
Susquehanna Valley Women's Health Care	694 Good Drive, Suite 112, Lancaster, 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
D2006	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b) The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing. This STANDARD is not met as evidenced by: Based on the record review and interview with the General Supervisor (GS), the laboratory failed to examine the Hematology and Chemistry Medical Laboratory Evaluation (MLE) proficiency testing (PT) specimens (all 2017 and 2018 events) , in the same manner as it tests patient specimens. Findings including: 1. The laboratory's Attestation Statement of PT testing policy reviewed at the time of investigation, and signed by the former laboratory director states" Under my direction as laboratory director, all PT samples received, are tested and reported within the same guideline as patient specimens". 2. At the time of investigation on 3/19/2018, a review of MLE PT records and instrument print outs revealed that Hematology and Chemistry PT specimens were tested 2 - 5 times before reporting. a. On 2/7/18, ALT (MLE 2018, Event #1) sample #CH3 was tested twice with the results (286 and 287). The laboratory reported 285 (the average) on the MLE test report sheet. b.White blood count PT (MLE 2017 event 1, Sample HD - 5) was tested 3 times with the following results (7.7, 7.9, 7.7). On the MLE test report the laboratory reported 7.8. 3. The General Supervisor stated that the laboratory tested their proficiency specimens multiple times and sometimes averaged the results reported to MLE, while patient specimens were usually tested once. 4. The annual volume for Chemistry tests from 3

	/9/16 through 3/9/17 - 43, 927. The annual volume for Hematology tests from 3/9/16 through 3/9/17 - 15, 305. ALT - Alanine Transaminase.
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on Medical Laboratory Evaluation (MLE) Proficiency Testing (PT) record review and interview with the General Supervisor and Testing Personnel #1, the Laboratory failed to test the MLE PT Microscopy Procedure samples for (all events 2017 - 2018), with the laboratory's regular patient workload by personnel who routinely performed the testing in the Laboratory. Findings include: 1. Only medical providers routinely perform Microscopy Procedures. 2. Review of the MLE attestation statements, revealed only Testing Personnel who do not routinely perform Microscopy Procedures, ran the samples and signed the MLE attestation statements for (all events 2017 - 2018). 3. 34 of 34 medical providers did not participate in proficiency testing for Microscopy Procedures from 2017-2018. 4. During the survey on March 19, 2018 at 11:30 am, the Laboratory Supervisor confirmed the above findings.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: By personnel interview of the General Supervisor and Testing Personell #1 and review of the Competency Records, the Laboratory failed to follow the Laboratory's written policies and procedures to assess competency, for 37 of 37 Testing Personnel from 2017 through the date of the survey (03/19/2018). Findings: 1. 3 of 3 Laboroatory Testing Personnel performing microbiology, diagnostic immunology, chemistry, and hematology had documentation of all platforms on a single sheet, which did not indicate the 6 Centers for Medicare and Medicaid Services (CMS) required procedures for competency as per the Laboratory Competency Policy in use. 2. 5 of 19 medical providers who performed Provider Performed Microscopy (PPM), had no director signature or date documented on competency performed between 09 /25/2017 and 01/11/2018. 3. 15 o f 34 medical providers who performed PPM, had no competency documented for 2017 through the date of the survey (03/19/2018). 4. The Quality Assessment Review Form used to document medical provider competency did not indicate the 6 CMS required procedures for competency. 5. During the survey, the General Supervisor confirmed, the above findings.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)

	Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on observation and interview with the General Supervisor (GS), at the time of complaint investigation, the laboratory failed to monitor and document the incubation time for the Group B Strep specimens from 2016 to the day of investigation. There was no written proof that the laboratory followed manufacturer's instruction for the incubation time. Findings include: 1. The BD Max system used for Group B Strep (GBS) tests package insert (Principles of the procedure) states " Following incubation for over 18 hours at 37C in ambient air or 5% CO2 (Carbon dioxide), a 15 uL aliquot of Lim Broth is used for detecting the presence of GBS". 2. The laboratory was unable to provide documentation of the incubation time before adding the aliquot of Lim Broth to ensure manufacturer's instruction was followed. 3. 2318 patient specimens had Group B Strep tests from 3/19/16 through 3/19/17. 4. The GS interviewed on 3/19 /18 at 10:15 am revealed that the laboratory did not document the incubation time. Based on review of the Centaur manufacturer's instructions and a patient report, at the time of complaint investigation, the laboratory failed to follow manufacturer's instructions for the B HCG tests performed on all the Advia Centaur XP analyzer from 2016 through the day of investigation. Findings include: 1. The manufacturer stated linearity (assay range) of the Centaur for B Hcg (Beta human chorionic gonadotropin) is 2.0 mIU/mL 2. A patient report reviewed at the time of survey showed a value of less than 1 mIU/mL. 3. 2378 patients specimes had B Hcg tests from 3/19/16 through 3/19/17. 4. The GS confirmed the findings above on 3/19/18 at 10:24 am.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on observation and interview with the General Supervisor (GS), at the time of complaint investigation, the laboratory failed to monitor and document the temperature of the only Boekel Scientific complete culture control incubator used for Group B strep specimens from 2016 to the day of investigation. Findings include: 1. The GS interviewed on 3/19/18 at 10:05 am revealed that the laboratory did not document the temperature of the incubator. The laboratory could not produce the temperature record for the incubator from 2016 to the day of investigation.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)

	Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on observation of expired reagent, and interview with the General Supervisor (GS), at the time of complaint investigation, the laboratory failed to ensure 8 different laboratory testing reagents, were not used after exceeding the expiration date. Findings include: 1. While on a tour of the laboratory with the GS at the time of survey, the following expired (exp)reagents and control materials were observed: 1 kit of Ora Quick HCV control lot# 006641747 exp. 06/30/2015 1 HIV Rapid test control pack lot#151000034 exp. 09/2017 1 bottle of DIL T4 reagent lot# 03D2836 exp. 10/09 /2016 1 bottle of FOB (Fecal Occult Blood) test control kit T1 - TCO2 negative control (Hemosure reagent) lot# LO210167796 exp. 02/2017 1 bottle of FOB test control kit T1 - TCO2 positive control (Hemosure reagent) lot# LO210167795 exp. 02 /2017 1 bottle of resolve microscope Immersion oil low viscosity lot# 123370 exp. 12 /2010 10 of 10 bottles of Siemens Advia Centaur total Hcg calibration material lot# 36600 exp. 02/05/2017 1 kit of CBC line Lot # CL120 Exp. 05/25/2017 2. General Supervisor interviewed around 10:25 am on March 19, 2018 confirmed the findings above.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of quality control (QC) records and interview with General Supervisor (GS), the laboratory failed to document a complete IQCP for the Amnisure, Gardnerella, Candida and Trichomonas tests performed from 2016 through the day of complaint investigation. Findings include: 1. A review of the IQCP for the Affirm analyzer used for Gardnerella, Candida and Trichomonas test, showed there was no Quality Assessment plan (QA). 2. A review of the IQCP for the Amnisure test, showed there was no QA plan. 3. The laboratory performed one risk assessment for multiple tests. It did not address each test system. 4. The IQCP did not have the signature of the current Laboratory director. 5. According to the GS at the time of survey, Gardnerella, Candida and Trichomonas tests were performed on 3056 specimens and Amnisure test performed on 144 specimens from 3/19/16 through 3/19 /17. 4. The GS interviewed on 3/19/2018 at 09:45 am confirmed the findings above. Note: IQCP: Individualized quality control plan
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291.

	This STANDARD is not met as evidenced by: Based on review of patient records, and interview with the General Supervisor (GS), at the time of a complaint investigation, the laboratory failed to establish and follow written policies for an ongoing mechanism to monitor, assess amd when indicated, correct problems identified in the analytic systems specified in 493.1291. Findings include: 1. On 08/16/17, a patient CO2 result was reported as 3 mEq/L on the ABX Pentra 400 analyzer. The General Supervisor interviewed at 9:40 am on 3/19/18 said the ordering physician was notified and the result was removed completely from the patient's chart. The 08/18/17 report reviewed at the time of survey indicates that the CO2 result was removed from the patient's final report. 2. Investigation carried out at the time of survey revealed that the incident was not documented. There was no documentation of corrective action taken, and no policy for preventing problems identified. 3. At the time of the investigation, there was no quality assessment policy to ensure continous improvement. Note: CO2 - Carbon dioxide
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on observation,and review of records, and interview with the General Supervisor (GS) and the Chief Executive Officer (CEO), the laboratory director failed to provide overall management and direction in accordance with 42 CFR 493.1445. Refer D2006, D5413, D5891, D5449, and D5411.