Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0188565	10/08/2020
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
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: Based on review of Laboratory procedure manuals and interview with the testing personnel (TP) #4, the laboratory failed to establish a competency assessment policy to assess the competency of 35 of 36 testing personnel (TP) who performed testing in the areas of Microbiology, Clinical Chemistry, Hematology, Serology, Urinalysis and 1 of 2 consultant competencies from 2018 to the day of survey. Findings include: 1. On the day of survey, 10/08/2020, the laboratory could not provide a competency assessment policy to assess the competency of 35 of 36 testing personnel (TP) who performed testing in the areas of Microbiology, Clinical Chemistry, Hematology, Serology, Urinalysis and 1 of 2 consultant competencies from 03/19/2018 to 10/08 /2020. 2. On the CMS 209 personnel form, TP # 11 (listed as a clinical consultant, technical consultant, technical supervisor and general supervisor) was not assessed for competency in 2018, 2019 and 2020. 3. Testing personnel performing provider preformed microscopy were not assessed for each test analyzed (Vaginal ferns, KOH, wet mounts and semen analysis) in 2018, 2019 and 2020. 3. TP #4 confirmed the findings above on 10/08/2020 around 10:50 am.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.

	This STANDARD is not met as evidenced by: Based on Medical Laboratory Evaluation (MLE) proficiency testing (PT) records and interview with the testing personnel (TP) #4, the laboratory failed to identify problems that required a corrective action for the Hematology 3rd event in 2018. Findings include: 1. On the date of survey, 10/08/2020, review of MLE PT records revealed, In 2018 the following PT result did not have a corrective action documented: - MLE 3rd event, Hematology, Glucose - 80% score. 2. TP #4 confirmed the findings above on 10 /08/2020 at 11:45 am.
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 observation of the service sticker on the Hamilton Bell Van Guard V 6500 Centrifuge and interview with testing personnel (TP) # 3, the laboratory failed to perform and document service maintenance for 1 of 1 centrifuge in 2020. Findings include: 1. On the day of survey, observation of 1 of 1 Hamilton Bell Van Guard V 6500 Centrifuge, while on tour of the laboratory revealed, service was due for the centrifuge on 05/2020. 2. The Laboratory was unable to provide documentation for the service performed on the Hamilton Bell Van Guard V 6500 Centrifuge after 05 /2020. 3. TP #3 confirmed the findings above on 10/08/2020 at 10:30 am.
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 lack of Quality Control (QC) records and interview with testing personnel (TP) #4, the laboratory failed to performed quality control (QC) each day of patient testing for potassium hydroxide (KOH), wet mount, Vaginal fern and Vasectomy Sperm microscopic examinations performed from 03/19/2018 to the day of survey. Findings include: 1. On the day of survey, 10/08/2020, TP #4 could not provide QC records for KOH, wet mount, Vaginal fern and Vasectomy Sperm microscopic examination from 03/19/2018 to 10/08/2020. 2. In 2018 (3/19/ 2018 to 12/31/18) the following microscopic examinations were performed: - Vasectomy = 10. - Wet Mount = 712. - KOH = 3. - Fern = 14. 3. In 2019 the following microscopic examinations were performed: - Vasectomy = 14. - Wet Mount = 827. - KOH = 4. - Fern = 20. 4. In 2020 (01/10/20 to 10/08/2020) the following microscopic examinations were performed: - Vasectomy = 17. - Wet Mount = 376. - KOH = 4. - Fern = 10. 5. TP# 4 confirmed the findings above on 10/08/2020 at 11:00 am.

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 review of quality control (QC) records and interview with the testing personnel (TP)# 4, the laboratory failed to check and document each batch or shipment of media its ability to support growth, select or inhibit specific organisms from 03/19/2018 to the date of survey. Findings Include: 1. The Becton Dickinson (BD) User Quality Control Procedure for Lim Broth states, "As always, QC testing should be performed in accordance with applicable local, state, federal or country regulations, accreditation requirements, and/or your laboratory's standard quality control procedures". 2. On the day of survey, 10/08/2020, review of QC records revealed, that the laboratory did not perform end user QC on the Becton, Dickinson (BD) BBL Lim Broth media used for the selective enrichment of group B streptococci (Streptococcus agalactiae) from 03/19/2018 to 10/08/2020. 3. The Laboratory could not provide written policies and procedures to perform and document QC for BD BBL Lim Broth media. 4. TP# 4 confirmed the findings above on 10/08/2020 at 10:45 am.
D5479	CONTROL PROCEDURES CFR(s): 493.1256(e)(5)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(5) Follow the manufacturer's specifications for using reagents, media, and supplies and be responsible for results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on observation of the BD Affirm kits storage, review of the laboratory's Affirm procedure manual, review of manufacture's package insert, and interview with testing personnel (TP) #4, the laboratory failed to follow the Affirm procedure manual for the storage of the BD Affirm kits for 1 of 1 box in 2020. Findings include: 1. The laboratory's affirm procedure manual and manufacture's package insert indicates," the Affirm Kits should be either store at 2 to 8 C until expiration date or store at room up to 30 C temperature no more than 3 months". 2. On the day of survey, 10/08/2020, observation on of the kit showed 1 of 1 box (Lot #0057554 exp 01/12/2021) and 26 of 26 individual cartridges (Lot#0062318 exp 02/17/2021) received in the laboratory on 7/7/2020 were kept at room temperature for more than 3 months. 3. TP# 4 confirmed the findings above on 10/08/2020 at 1:45 p.m.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are

	established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of the procedure manuals, interview with testing personnel #4, the LD failed to ensure a quality assessment (QA) programs was established and to assure the quality of laboratory services provided from 2018 to the day of survey. Findings Include: 1. On the date of survey, 10/08/2020, TP #4 could not provide a QA procedure, that assess the laboratory's pre analytical, analytical, and post analytical processes from 03/19/2020 to 10/08/2020. 2. The LD confirmed the finding above on 10/08/2020 around 11:00 am.