Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0183623	06/21/2018
Name of Provider or Supplier	**Street Address, City, State**	
Titusville Area Hospital	406 West Oak St, Titusville, 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
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 Laboratory Quality Control record review and interview with the Laboratory Manager, the laboratory failed to document a positive and negative control each day patients specimens were examined for microscopic elements for 17 of 17 months. Findings include: 1. The laboratory failed to document Quality Control for 13 of 13 specimens tested for sperm morphology between 01/01/2017 and 06/20/2018. 2. The laboratory failed to document Quality Control for 145 of 145 wet prep specimens tested between 01/02/2017 and 06/13/2018. from January 2017 through the date of the survey, 12/20/2017. 3. The laboratory failed to document Quality Control for all Urine Sediment Examinations, performed from 01/01/2017 through 06/20/2018. 4. During the survey, the Laboratory Manager, confirmed the above findings. .
D5517	MYCOLOGY CFR(s): 493.1263(a)(c) The laboratory must check each batch (prepared in-house), lot number (commercially prepared), and shipment of lactophenol cotton blue when prepared or opened for intended reactivity with a control organism(s). (c) The laboratory must document all control procedures performed, as specified in this section.

	This STANDARD is not met as evidenced by: By review of microbiology quality control records and interview of Technical Supervisor 2 , at the time of survey (09:30 06/20/2018), the laboratory failed to document control procedures for each shipment of lactophenol cotton blue when opened, for 9 of 9 specimens tested between 02/21/2017 and 06/13/2018. Findings include: 1.. On the date of the survey (06/20/2018), there was no documentation of lactophenol cotton blue intended reactivity, for 9 of 9 specimens tested between 02/21 /2017 and 06/13/2018. 2. During the survey Technical Supervisor 2 confirmed the above finding.
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation. This STANDARD is not met as evidenced by: By review of personnel records and interview of Technical Supervisor 2 , at the time of survey (09:30 06/20/2018), the Technical Supervisor did not document the performance of 11 of 13 high complexity testing personnel annually, Findings include: 1.. On the date of the survey (06/20/2018), there was no documentation of competency assessment for 11 of 13 high complexity testing personnel in 2017. 2. During the survey Technical Supervisor 2 confirmed the above finding.