Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0011492	05/10/2018
Name of Provider or Supplier	**Street Address, City, State**	
Corry Memorial Hospital	965 Shamrock Lane, Corry, 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
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, review of Siemens Complete pH/Blood Gas, ISE, Co-oximeter and Metabolite Quality Control package insert, and interview Technical Consultant (TC) #1, the laboratory failed to monitor and document the condition for storage of Siemens Complete pH/Blood Gas, ISE, Co-oximeter and Metabolite Quality Control, Levels #1, #2 and #3 from 2016 to the date of survey. Findings Include: 1. According to Siemens Complete pH/Blood Gas, ISE, Co-oximeter and Metabolite Quality Control Package insert, Storage and Handling state, "Store complete solution at room temperature (18 - 25 degrees Celsius) away from sunlight. You may also store Complete at 2 - 25 degrees Celsius without out verse effects". 2. On the day of survey, 05/09/2018, it was discovered that one box each level (1-3) of Siemens Complete pH /Blood Gas, ISE, Co-oximeter and Metabolite Quality Controls were stored in a wall cabinet by the instrument, but room temperature was not recorded and documented. 3. 2016 Annual volume (May 2016 to April 2017), 126 patient Blood Gas tests were analyzed. 4. 2017 Annual volume (May 2017 to April 2018), 139 patient Blood Gas tests were analyzed. 5. TC #1 confirmed the findings above on 05/09/2018 around 02: 45 pm
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 the review of Urine Microscopic Analysis, Post Vasectomy Semen Analysis and Osom hcg Combo Test Serum Quality Control (QC) logs and interview with the Technical Consultant (TC) #2, the laboratory failed to document QC for Urine Microscopic Analysis, Post Vasectomy Semen Analysis and perform hcg serum patient testing each day of patient testing in 2016 to the date of survey. Findings Include: A). 1. On the date of survey 05/09/2018, review of Urine Microscopic QC records, revealed the laboratory has reference material available for Urine Microscopic analysis QC but QC was not documented in 2016 and 2017. 2. 2016 Annual volume (May 2016 to April 2017), 2828 Urine Microscopic Analysis tests were analyzed. 3. 2017 Annual volume (May 2017 to April 2018), 2122 Urine Microscopic Analysis tests were analyzed. 4. The TC#2 confirmed the findings above on 05/09/2018 around 09:15 am. B). 1. On the date of survey 05/09/2018, review of Osom hcg Combo Test Serum QC frequency, revealed the laboratory was performing QC on a weekly bases instead of each day of patient testing in 2016 and 2017. 2. No IQCP was developed to support the laboratory weekly frequency for performing Osom hcg Combo Test for Serum QC. 3. Annual volume (May 2016 to April 2017), 198 Serum hcg tests were analyzed. 4. Annual volume (May 2017 to April 2018), 161 Serum hcg tests were analyzed. 5. The TC #2 confirmed the findings above on 05/09 /2018 around 12:00 pm. C). 1. On the date of survey 05/10/2018, review of Semen QC records, revealed the laboratory has reference material available for Semen analysis QC but QC was not documented in 2016 and 2017. 2. 2016 Annual volume (May 2016 to April 2017), 5 Post Vasectomy Semen Analysis tests were analyzed. 3. 2017 Annual volume (May 2017 to April 2018), 5 Post Vasectomy Semen Analysis tests were analyzed. 4. The TC#2 confirmed the findings above on 05/10/2018 around 09:30 am.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of Manual Differential Stain Quality control (QC) and interview with the Technical Consultant (TC) #1 and #2, the laboratory failed to test the manual differential stain (Quick III Stain) for reactivity each day of patient use from 2016 to the date of survey. Finding Include: 1. On the day of survey, 05/09/2018, while on the initial tour of the laboratory, surveyor #2 asked "if the laboratory documents wright stain QC?", TC#1 and #2 replied that the stain check is performed but not documented

	in 2016 and 2017. 2. 2016 Annual volume (May 2016 to April 2017), 13433 Manual Differential tests were analyzed. 3. 2017 Annual volume (May 2017 to April 2018), 12474 Manual Differential tests were analyzed. 4. The TC #1 and #2 confirmed the findings above on 05/09/2018 around 9:45 am.
D5523	PARASITOLOGY CFR(s): 493.1264(a)(d) The laboratory must have available a reference collection of slides or photographs and, if available, gross specimens for identification of parasites and use these references in the laboratory for appropriate comparison with diagnostic specimens. (d) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review of the laboratory's Scabies Wet Mount Quality Control (QC) references material and interview with Technical Consultant (TC) #1, the laboratory failed to document Trichomonas vaginalis Wet Mount QC from 2016 to the date of survey. Findings Include: 1. At the time of the survey 05/09/2018, the laboratory did have Trichomonas vaginalis reference material available for laboratory personnel to review, but QC was not documented in 2016 and 2017. 2. 2016 Annual volume (May 2016 to April 2017), 11 Trichomonas vaginalis Wet Mount tests were analyzed. 3. 2017 Annual volume (May 2017 to April 2018), 14 Trichomonas vaginalis Wet Mount tests were analyzed. 4. TC #1 confirmed the findings above on 05/08/2018 around 10:45 am.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must 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 Blood Gas Procedure Manual and interview with Technical Consultant #1 and #2, the laboratory director (LD) failed to ensure that all the procedure manuals have been signed and approved from 2016 to the date of survey. Findings Include: 1. On the day of survey, 05/09/2018, review of the Blood Gas procedure Manual, revealed that the current LD did not sign and approve the current Blood gases manual in use for patient testing since their start date of 10/11/2016. 2. TC #1 and #2 confirmed the findings above on 05/09/2018 around 02:15 pm.
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, the review of records and interview with the Technical Consultant (TC) #1 and #2, the Technical Supervisor failed to evaluate the competency of 2 of 9 Testing Personnel (TP) who perform, Bacteriology, Chemistry, Hematology, Immunohematology, Parasitology, Virology, and Urinalysis testing in 2017. Findings Include: 1. On the date of survey 05/09/2018, review of personnel's annual competency assessments, revealed that 2 of 9 TP who perform Bacteriology, Chemistry, Hematology, Immunohematology, Parasitology, Virology, and Urinalysis patient tests, were not assessed for competency in 2017. 2. The Laboratories Annual Volume (May 2016 to April 2017), 355,381 patient tests were performed. 3. The Laboratories Annual Volume (May 2017 to April 2018), 331,927 patient tests were performed. 4. The TC #1 and #2 confirmed the findings above on 05/09/2018 around 10:15 am
D6125	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(v) The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. This STANDARD is not met as evidenced by: Based on, the review of testing personnel competency assessment records, American Proficiency Institute (API) proficiency records and interview with Technical Consultant #1 and #2 (TC), the Technical Supervisor failed to evaluate the assessment of all testing personnel (TP) for the assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples from 2016 to the date of survey. Findings Include: A. 1. On the day of survey, 05/09/2018, review of the laboratory's API attestation statements from Event 1-3 in 2016 and 2017, revealed that each year, 3 of 7 Laboratory TP perform PT for the categories of Microbiology, Clinical Chemistry, Hematology, Immunohematology and Urinalysis. 2. 4 of 7 Laboratory TP were not evaluated through external proficiency testing samples or internal blind testing samples on non-waived tests in 2016 and 2017. 3. TC#1 and TC#2 confirmed the findings above on 05/09/2018 around 10:00 am. B. 1. On the day of survey, 05/09/2018, review of Blood Gases PT records revealed that 2 of 2 Respiratory therapy TP perform in PT testing for blood gases in 2016 and 2017. 2. 7 of 7 laboratory TP who also periodically run Blood Gases patients samples have not been evaluated through external proficiency testing samples or internal blind testing samples for Blood Gases in 2016 and 2017. 3. TC#1 and TC#2 confirmed the findings above on 05/09/2018 around 02:30 pm.