Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D2154337	01/22/2019
Name of Provider or Supplier	**Street Address, City, State**	
Statim, Llc	213 Nancy Lynn Lane Ste 2, Knoxville, TN	

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
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 of the centrifuge used for urine microscopic analysis, review of the urine microscopic procedure and interview with the laboratory supervisor, determined the centrifuge speed and spin time were not appropriate for testing performed since laboratory opened for testing 10/08/2018. The findings include: 1. Observation of the centrifuge used for urine microscopic analysis was a blood separation centrifuge with RPM (revolutions per minute) setting of 3300 and spin time of 15 minutes. 2. Review of urine microscopic procedure states to spin for 5 minutes at 1800-2000 RPM's. 3. Interview at approximately 4:00 p.m. 1/22/19 with laboratory supervisor confirmed the urine centrifuge used for spinning urine sediment for microscopic analysis was not appropriate for testing performed since 10/08/2018. ==========
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 of stored reagents for use with the Access 2 chemistry analyzer and the Microbiology MicroScan Test System, review of manufacturer's storage requirements, review of temperature charts and interview with laboratory supervisor, determined the laboratory failed to ensure proper storage for chemistry and microbiology reagents since October 2018. The findings include: 1. Observed stored reagents for use with the Access 2 Chemistry Analyzer and reagent beads for the MicroScan microbiology system in freezer 1/22/19. 2. Review of storage temperature requirements for the Access 2 controls is minus 20 degrees Celsius or colder and for the MicroScan system reagent beads is minus 70 degrees Celsius or colder. 3. Review of freezer temperature charts from October 2018 to January 2019 revealed temperature readings documented at minus 14 degrees Celsius and warmer. 4. Interview with the laboratory supervisor at approximately 5:00 p.m. 1/22/19 confirmed the freezer temperature where Access 2 and MicroScan reagents are stored, failed to meet proper storage requirements since October 2018. ==========
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 review of operator's manual for the RENOK dispense system (for use with the MicroScan Test System) for checking the dispense volume, lack of documentation of dispense volume checks and interview with the laboratory supervisor, determined the laboratory failed to document monthly dispense checks per manufacturer's instructions since November 2018. The findings include: 1. Review of the operator's manual for the RENOK dispense system states the dispense volume should be checked at least once per month. 2. Lack of documentation of dispense volume checks since testing began in November 2018. 3. Interview with the laboratory supervisor at approximately 5:00 p.m. 1/22/19 confirmed that dispense volumes had been checked but failed to be documented. ==========
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.

	This STANDARD is not met as evidenced by: ========== Based on observation of 2 microscopes in use, lack of maintenance protocol upon review of procedure manual and upon interview with the laboratory supervisor, determined the laboratory failed to establish a maintenance protocol to ensure proper equipment function prior to use in October 2018. The findings include: 1. Observation of 2 microscopes during lab tour 1 /22/19, one used for manual blood cell differentials and urine microscopy and one used for gram stains, with no documentation of professional maintenance since in use date in October 2018. 2. Lack of maintenenance protocol upon review of procedure manual for servicing microscopes. 3. An interview with the laboratory supervisor at approximately 4:00 p.m. 1/22/19 confirmed there was no maintenance protocol in place and no maintenance on the 2 microscopes had been performed since testing began in October 2018. ==========
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: ========== Based on lack of IQCP's (Individualized Quality Control Plan's) for Clostridium Difficille (D. Diff), Helicobacter Pylori (H. Pylori), Trypticase Soy Agar (TSA), MacConkey Media and MicroScan Test System (used for urine culture identification and sensitivity) and upon interview with the laboratory supervisor, determined the laboratory failed to establish written policies for these tests to establish equivalent quality control procedures since testing began in November 2018. The findings include: 1. Lack of approved equivalent IQCP policies for C. Diff, H. Pylori, TSA, MacConkey Media and MicroScan Test System, since testing began in November 2018. 2. Interview with laboratory supervisor at approximately 5:00 p.m. 1/22/19 confirmed the laboratory failed to have IQCP policies in place since testing began in November 2018. ==========
D5471	CONTROL PROCEDURES CFR(s): 493.1256(e)(1)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(i) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable. (g) The laboratory must document all control procedures performed.

	This STANDARD is not met as evidenced by: ========== Based on review of catalase testing, lack of quality control documentation and interview with the laboratory supervisor, determined quality control was not being performed since testing began 11/24/18. The findings include: 1. Review of catalase testing since 11/24/18 revealed no quality control documentation. 2. Interview with the laboratory supervisor at approximately 5: 00 p.m. 1/22/19 confirmed there had been no quality control performed for catalase testing since 11/24/18. ==========
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: ========== Based on patient test audit for 12/20 /18, quality control review and interview with the laboratory supervisor, determined control results failed to meet criteria for acceptability prior to reporting patient Vancomycin. The findings include: 1. Patient test audit on 12/20/18 included Vancomycin Trough results. 2. Quality control review for 12/20/18 of Vancomycin results revealed level 2 control was not within acceptable limits prior to reporting patient results. 3. Interview with laboratory supervisor at approximately 5:00 p.m. 1/22 /19 confirmed that level 2 Vancomycin quality control was not within acceptable limits with one patient test reported out on 12/20/18. ==========
D5503	BACTERIOLOGY CFR(s): 493.1261(a)(2) (a) The laboratory must check the following for positive and negative reactivity using control organisms: (a)(2) Each week of use for gram stains. This STANDARD is not met as evidenced by: ========== Based on review of gram stain testing with lack of quality control documentation and interview with the laboratory supervisor, determined quality control was not being performed weekly for gram stains since testing began 11/24/18. The findings include: 1. Review of gram stain testing revealed no quality control documented since patient testing began 11/24/18. 2. Interview with the laboratory supervisor at approximately 5:00 p.m. 1/22/19 confirmed there had been no quality control performed for gram stain testing since 11 /24/18. ==========
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.

	This STANDARD is not met as evidenced by: ========== Based on review of two urinalysis test reports for January 2019 and interview with the laboratory supervisor, determined the test reports failed to contain reference ranges since October 2018. The findings include: 1. Review of two urinalysis test reports for January 2019 revealed no reference ranges. 2. Interview with the laboratory supervisor at approximately 5:00 p. m. 1/22/19 confirmed the computer system did not have a way of documenting reference ranges for urinalysis test reports since October 2018. ==========
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: ========== Based on review of two of two testing personnel files for training and competency and interview with the laboratory supervisor, determined the laboratory personnel failed to have documented training for microscopy procedures to include manual blood cell differentials, urine sediment analysis and reading of gram stains since hire dates and patient testing began. The findings include: 1. Review of personnel files for testing personnel #1 and #2 revealed no training or competency for microscopy procedures to include manual blood cell differentials, urine sediment analysis and reading of gram stains was documented since hires dates in August 2018 for testing personnel #1 and September 2018 for testing personnel #2. 2. Interview with the laboratory supervisor at approximately 5: 00 p.m. 1/22/19 confirmed there was no documentation of training or competency for microscopy procedures since patient testing began in October 2018. ==========
D6143	GENERAL SUPERVISOR QUALIFICATIONS CFR(s): 493.1461 (a) The general supervisor must possess a current license issued by the State in which the laboratory is located, if such licensing is required; and (b) The general supervisor must be qualified as a-- (b)(1) Laboratory director under 493.1443; or (b)(2) Technical supervisor under 493.1449. (c) If the requirements of paragraph (b)(1) or paragraph (b)(2) of this section are not met, the individual functioning as the general supervisor must-- (c)(1)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; and (c)(1)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing; or (c)(2)(i) Qualify as testing personnel under 493.1489(b)(2); and (c)(2)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing; or (c)(3)(i)

	Except as specified in paragraph (3)(ii) of this section, have previously qualified as a general supervisor under 493.1462 on or before February 28, 1992. (c)(3)(ii) Exception. An individual who achieved a satisfactory grade in a proficiency examination for technologist given by HHS between March 1, 1986 and December 31, 1987, qualifies as a general supervisor if he or she meets the requirements of 493. 1462 on or before January 1, 1994. (c)(4) On or before September 1, 1992, have served as a general supervisor of high complexity testing and as of April 24, 1995-- (c) (4)(i) Meet one of the following requirements: (c)(4)(i)(A) Have graduated from a medical laboratory or clinical laboratory training program approved or accredited by the Accrediting Bureau of Health Education Schools (ABHES), the Commission on Allied Health Education Accreditation (CAHEA), or other organization approved by HHS. (c)(4)(i)(B) Be a high school graduate or equivalent and have successfully completed an official U.S. military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician). (c)(4)(ii) Have at least 2 years of clinical laboratory training, or experience, or both, in high complexity testing; or (c) (5) On or before September 1, 1992, have served as a general supervisor of high complexity testing and-- (c)(5)(i) Be a high school graduate or equivalent; and (c)(5) (ii) Have had at least 10 years of laboratory training or experience, or both, in high complexity testing, including at least 6 years of supervisory experience between September 1, 1982 and September 1, 1992. (d) For blood gas analysis, the individual providing general supervision must-- (d)(1) Be qualified under 493.1461(b)(1) or (2), or 493.1461(c); or (d)(2)(i) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; and (d)(2)(ii) Have at least one year of laboratory training or experience, or both, in blood gas analysis; or (d)(3) (i) Have earned an associate degree related to pulmonary function from an accredited institution; and (d)(3)(ii) Have at least two years of training or experience, or both in blood gas analysis. (e) The general supervisor requirement is met in histopathology, oral pathology, dermatopathology, and ophthalmic pathology because all tests and examinations, must be performed: (e)(1) In histopathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(l)(1); (e)(2) In dermatopathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(l) or (2); (e)(3) In ophthalmic pathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(1)(3); and (e)(4) In oral pathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(m). This STANDARD is not met as evidenced by: ========== Based on review of laboratory supervisor's State of Tennessee License issued by the Medical Laboratory Board and upon interview with the supervisor, determined the supervisor did not possess a supervisor's license issued by the State of Tennessee since patient testing began in October 2018. The findings include: 1. Review of laboratory supervisor's State of Tennessee License reveals it is not for a General Supervisor's License which is required by the State of Tennessee. 2. Interview with the laboratory supervisor at approximately 5:00 p.m. 1/22/19 confirmed she does not possess a supervisor's license issued by the State of Tennessee. ==========