Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D0716928	01/16/2018
Name of Provider or Supplier	**Street Address, City, State**	
Bipin P Desai Md	136 Kissane Suite A, Brighton, MI	

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
D5002	BACTERIOLOGY CFR(s): 493.1201 If the laboratory provides services in the subspecialty of Bacteriology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1261, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: . Based on document review and interview, the laboratory failed to meet Bacteriology requirements as specified in 493.1230 through 493.1256. Findings include: 1. The laboratory failed to ensure written competency policies were established and implemented. Refer to D5209. 2. The laboratory failed to verify the accuracy of testing for the bacteriology urine culture colony count. Refer to D5217. 3. The laboratory failed to follow written policies and procedures for an ongoing mechanism to monitor, assess, and correct problems as specified for the laboratory systems. Refer to D5291. 4. The laboratory failed to follow their written procedure for annual patient chart audits. Refer to D5401. 5. The laboratory failed to monitor and document the incubator temperature each day of laboratory operation. Refer to D5413. 6. The Troy Biologicals Uri-Check urine culture testing paddles stored in the cupboard and available for use exceeded the manufacturer's expiration date. Refer to D5417. 7. The laboratory failed to establish, perform, and document thermometer calibrations . Refer to D5433. 8. The laboratory failed to perform and document media checks for the Uri-Check with each new batch, lot, or shipment of media for sterility, the ability to support growth, selectivity/inhibition or biochemical responses if appropriate, and document physical characteristics. Refer to D5477.
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 record review and interview, the laboratory failed to ensure written competency policies were established and implemented for two (#1 and #2) of two testing personnel and one (clinical consultant and technical consultant) of one non-testing technical personnel federal regulatory responsibilities. Findings include: 1. On January 16, 2018 at 9:47 a.m., record review of the annual competency revealed there was no documentation as follows: a. testing personnel #1 - no annual competency for 2016 and 2017 b. testing personnel #2 - no annual competency for 2017 2. On January 16, 2018 at 9:47 a.m., lack of records revealed for one of one non-testing technical personnel the laboratory failed to establish and implement a competency for the clinical and technical consultant federal regulatory responsibilities for 2016 and 2017. 3. During the interview on January 16, 2018 at 9:47 a.m., the laboratory director and the staff nurse confirmed the annual competency was not completed as required and that the laboratory failed to establish and implement a competency for the non-testing technical personnel federal regulatory responsibilities for 2016 and 2017. ***Repeat Deficiency from February 10, 2016 survey***
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: . Based on record review and interview, the laboratory failed to verify the accuracy of testing for the bacteriology urine culture colony count testing at least twice annually for 2016 and 2017. Findings include: 1. On January 16, 2018 at 9:52 a.m., record review for the verification of accuracy of the urine culture colony counts revealed there was no documentation to show the testing was completed at least twice annually in 2016 and 2017. 2. During the interview on January 16, 2018 at 9:52 a.m., the laboratory director as listed on the CMS-209 confirmed the testing was not completed.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: . Based on procedure review, record review, and interview, the laboratory failed to follow written policies and procedures for an ongoing mechanism to monitor, assess, and correct problems as specified for the laboratory systems for six (July and November 2016 and January to December 2017) of eight quarterly reviews. Findings include: 1. On January 16, 2018 at 9:53 a.m., procedure review for the "Quality Assurance Program" revealed the laboratory did establish a quality assurance policy

	and a quarterly checklist that covered the general, pre-analytic, analytic, and post-analytic systems in the laboratory. 2. On January 16, 2018 at 9:53 a.m., record review revealed the laboratory did not have any documentation to show the quarterly review for six of eight quarters in 2016 and 2017 was completed. When queried, the laboratory director as listed on the CMS-209 was unable to provide documentation showing the quarterly checklists that monitored the laboratory systems were completed. 3. During the interview on January 16, 2018 at 9:53 a.m., the laboratory director confirmed the quarterly checklists were not completed.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: . Based on document review and interview, the laboratory failed to follow written protocol to review the "Laboratory Procedure Manual" annually for two (2016 and 2017) of two years and audit patient charts annually for two (2016 and 2017) of two years. Findings include: 1. On January 16, 2018 at 9:28 a.m., document review of the "Laboratory Procedure Manual" showed for two of two years the laboratory director failed to review and sign the cover page for the manual. 2. On January 16, 2018 at 9: 53 a.m., document review of the annual "Quality Assurance Audit" revealed for two of two years there was no documentation to show the audits were performed and documented. 3. During the interview on January 16, 2018 at 9:28 a.m., the laboratory director as listed on the CMS-209 confirmed the manual was not signed and the patient chart audits were not completed annually in 2016 and 2017.
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 record review and interview, the laboratory failed to monitor and document the incubator temperature each day of laboratory operation for seven (April 25, October 25, November 21 and 28, and December 30 in 2016 and May 30 and 31 in 2017) of seven days reviewed in 2016 and 2017 and five (July, August, September, October, and December) of 19 months reviewed in 2016 and 2017 to ensure reliable incubation temperature for the urine culture colony counts. Findings include: 1. On January 16, 2018 at 11:05 a.m., record review of the monthly temperature charts revealed the laboratory failed to monitor and document the temperature for seven of seven days in 2016 and 2017 and for five of 19 months in 2016 and 2017 as follows:

	a. Daily temperature readings not monitored in 2016 1. April 25 2. October 25 3. November 21 and 28 4. December 30 b. Daily temperature readings not monitored in 2017 1. May 30 and 31 c. Daily temperature readings not monitored for the month in 2017 1. July to October and December 2. During the interview on January 16, 2018 at 11:05 a.m., the nursing staff confirmed the incubator temperatures were not monitored and recorded daily.
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 and interview, the Troy Biologicals Uri-Check urine culture testing paddles stored in the cupboard and available for use exceeded the manufacturer's expiration date. Findings include: 1. On January 16, 2018 at 9:15 a.m., during a tour of the laboratory, the surveyor observed the Uri-Check urine culture testing paddles lot # 7D19A stored in the cupboard that exceeded the manufacturer's expiration (December 19, 2017). 2. During the interview on January 16, 2018 at 9:15 a.m., the laboratory director as listed on the CMS-209 confirmed the Uri-Check paddles had exceeded the manufacturer's expiration date. ***Repeat Deficiency from January 12, 2012 survey***
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 lack of records and interview, the laboratory failed to establish, perform, and document thermometer calibrations for two (2016 and 2017) of two years to ensure proper incubation storage of the bacteriology urine culture specimens. Findings include: 1. On January 16, 2018 at 11:05 a.m., lack of records to show the laboratory established, performed and documented incubator thermometer calibrations for two of two years to ensure the thermometer is reading between 20 to 50 C as stated on the outside label of the Streck Laboratories thermometer located in the Pfizer incubator. 2. During the interview on January 16, 2018 at 11:05 a.m., the nursing staff confirmed the laboratory did not establish, perform and document thermometer calibration for the incubator thermometer for 2016 and 2017.
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 record review and interview, the laboratory failed to perform and document media checks for the Uri-Check with each new batch, lot, or shipment of media for sterility, the ability to support growth, selectivity/inhibition or biochemical responses if appropriate, and physical characteristics for four (lot # 6H10A, 6C23A, 5L25A, and 7D19A) of four lots received in 2016 and 2017. Findings include: 1. On January 16, 2018 at 9:58 a.m., record review for four of four Uri-Check "Quality Control Certificates" revealed there was no documentation to show the sterility, the ability to support growth, selectivity/inhibition or biochemical responses if appropriate, and the physical characteristics of the media for each new batch, lot or shipment was performed in 2016 and 2017. 2. During the interview on January 16, 2018 at 9:58 a.m., the nursing staff confirmed the media checks were not performed and documented with each new batch, lot or shipment of media in 2016 and 2017.