Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2152600	07/26/2019
Name of Provider or Supplier	**Street Address, City, State**	
M&M Clinical Group	4102 Woodlawn Avenue Suite 230, Pasadena, TX	

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
D0000	The laboratory was found out of compliance with the CLIA regulations. Immediate jeopardy findings were identified. The conditions not met were: Fed - D - 5022 - 493.1213 - Toxicology Fed - D - 5300 - 493.1240 - Preanalytic Systems Fed - D - 6076 - 493.1441 - Laboratory Director Fed - D - 6108 - 493.1447 - Laboratory Technical Supervisor Fed - D - 6168 - 493.1487 - Testing Personnel The laboratory voluntarily suspended patient testing on 7/26/19 as evidenced by a letter signed my the laboratory owner on 7/26/19. Noted deficiencies and plans of correction were discussed with the laboratory representative at the exit conference. The facility representatives were given an opportunity to provide evidence of compliance with noted deficiencies and no such evidence was provided prior to survey exit. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on review of the laboratory policy, laboratory quality control records, and confirmed in interview, the laboratory failed to retain the instrument printouts for quality control performed for toxicology testing on the Microgenics MGC-240 analyzer for a minimum of 2 years. Findings were: 1. Review of the laboratory policy Record Retention (PL0002.02) revealed "it is the policy of this laboratory to maintain

	all records for the designated time frames as defined by COLA guidelines. These records will be stored in the LIS if electronic documents are obtained, and labeled sufficiently for easy retrieval at some later date for documentation on paper. Type or record: Analytic systems- QC, patient test records, instrument prin-outs, calibrations - 2 years." 2. Review of the laboratory Levy Jennings charts from May and June 2019 revealed no documentation of the instrument printouts that correspond to the values documented on the LJ charts for the following days. Amphetamine Level 1 6/07/19 - 800 6/14/19 - 798 6/20/19 - 784 6/28/19 - 805 5/02/19 - 759 5/09/19 - 804 5/16/19 - 735 5/23/19 - 726 5/30/19 - 741 Amphetamine Level 2 6/07/19 - 1300 6/14/19 - 1256 6/20/19 - 1392 6/28/19 - 1400 5/02/19 - 1300 5/09/19 - 1259 5/16/19 - 1124 5/23/19 - 1249 5/30/19 - 1276 Cocaine Level 1 6/07/19 - 250 6/14/19 - 199 6/20/19 - 226 6/28 /19 - 241 5/02/19 - 254 5/09/19 - 235 5/16/19 - 225 5/23/19 - 200 5/30/19 - 226 Cocaine Level 2 6/07/19 - 375 6/14/19 - 394 6/20/19 - 342 6/28/19 - 399 5/02/19 - 375 5/09/19 - 370 5/16/19 - 368 5/23/19 - 374 5/30/19 - 382 Opiate Level 1 6/07/19 - 200 6/14/19 - 240 6/20/19 - 216 6/28/19 - 208 5/02/19 - 197 5/09/19 - 245 5/16/19 - 220 5/23/19 - 200 5/30/19 - 240 Opiate Level 2 6/07/19 - 372 6/14/19 - 420 6/20/19 - 409 6/28/19 - 399 5/02/19 - 375 5/09/19 - 370 5/16/19 - 395 5/23/19 - 378 5/30/19 - 371 Barbiturate Level 1 6/07/19 - 168 6/14/19 - 142 6/20/19 - 150 6/28/19 - 162 5/02 /19 - 150 5/09/19 - 148 5/16/19 - 149 5/23/19 - 153 5/30/19 - 143 Barbiturate Level 2 6/07/19 - 248 6/14/19 - 264 6/20/19 - 256 6/28/19 - 265 5/02/19 - 250 5/09/19 - 248 5 /16/19 - 261 5/23/19 - 256 5/30/19 - 239 Cannabinoid Level 1 6/07/19 - 35 6/14/19 - 36 6/20/19 - 39 6/28/19 - 39 5/02/19 - 34 5/09/19 - 37 5/16/19 - 36 5/23/19 - 35 5/30 /19 - 36 Cannabinoid Level 2 6/07/19 - 62 6/14/19 - 59 6/20/19 - 60 6/28/19 - 62.5 5 /02/19 - 50 5/09/19 - 53 5/16/19 - 52 5/23/19 - 57 5/30/19 - 53 Buprenorpherine Level 1 6/07/19 - 16 6/14/19 - 15 6/20/19 - 14 6/28/19 - 17 5/02/19 - 15 5/09/19 - 13 5/16/19 - 15 5/23/19 - 16 5/30/19 - 17 Buprenorpherine Level 2 6/07/19 - 26 6/14/19 - 26 6/20 /19 - 24 6/28/19 - 26 5/02/19 - 25 5/09/19 - 23 5/16/19 - 24 5/23/19 - 26 5/30/19 - 25 Benzodiazepine Level 1 6/07/19 - 157 6/14/19 - 163 6/20/19 - 142 6/28/19 - 165 5/02 /19 - 156 5/09/19 - 145 5/16/19 - 135 5/23/19 - 130 5/30/19 - 126 Benzodiazepine Level 2 6/07/19 - 250 6/14/19 - 265 6/20/19 - 243 6/28/19 - 236 5/02/19 - 250 5/09/19 - 255 5/16/19 - 231 5/23/19 - 249 5/30/19 - 226 Urine Creatinine Level 1 6/07/19 - 76 6/14/19 - 70 6/20/19 - 69 6/28/19 - 70.2 5/02/19 - 78 5/09/19 - 86 5/16/19 - 80 5/23/19 - 77 5/30/19 - 85 Urine Creatinine Level 2 6/07/19 - 11 6/14/19 - 10 6/20/19 - 9 6/28 /19 - 10 5/02/19 - 10 5/09/19 - 12 5/16/19 - 9 5/23/19 - 11 5/30/19 - 10 3. An interview with the laboratory consultant on 7/25/19 at 1420 hours via phone confirmed the above findings.
D5022	TOXICOLOGY CFR(s): 493.1213 If the laboratory provides services in the subspecialty of Toxicology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on review of the laboratory's records, and staff interview, it was revealed the laboratory failed to meet the requirements for the subspecialty of toxicology. The findings were: 1. The laboratory failed to have documentation of monitoring the correct humidity range. (refer to D5413). 2. The laboratory failed to have documentation of performing complete establishment studies (refer to D5423). 3. The laboratory failed to have documentation of performing calibration verification (refer to D5439). 4. The laboratory failed to have documentation of establishing quality

	control (refer to D5469). 5. The laboratory failed to have documentation of a quality assessment plan that could identify and correct problems (refer to D5791).
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 a review of laboratory policy, personnel records and interview of facility personnel the laboratory failed to document the competency of the technical supervisor and general supervisor. Findings were: 1. A review of the laboratory policy Training, Competency Assessment of Technical Personnel (QM0019.02) revealed "the laboratory will assess the competency of each person to perform the duties assigned following initial training and before the person performs patient testing. Thereafter, during the first year of an individual's duties, the laboratory will assess the competency at least semiannually. After an individual has performed his/her duties for one year, the laboratory will assess competency annually. Competency assessments for the technical supervisor are conducted by the laboratory director or designee. Documents related to training and competency shall be maintained in each individual's training file." 2. A review of the facility's personnel files, revealed no documentation of the competency assessment for the technical supervisor or general supervisor for 2018 per the laboratory policy. 4. An interview of the laboratory consultant via phone on 7/25/19 at 1010 hours confirmed the above findings.
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 a review of laboratory records, laboratory policy, and confirmed in interview, the laboratory failed to verify twice annually the accuracy of all tests it performed on the Microgenics MGC-240 analyzer. The findings were: 1. A review of the laboratory records revealed the laboratory performed patient testing for the following analytes on the Microgenics MGC-240 analyzer: Amphetamine Barbiturates Benzodiazepines Buprenorphine Cocaine Opiates Oxycodone Cannabinoid Urine Creatinine 2. Review of the laboratory policy Proficiency Testing Protocol (QM0004.02) under alternative performance assessment revealed "test at least 5 challenges semiannually for alternative performance assessment...split sample analysis with reference or another laboratory." 3. Review of the 2018 laboratory records revealed no documentation of twice annual assessment for the above analytes. 4. An interview with the laboratory consultant on 7/25/19 at 1015 hours via phone confirmed the above findings.
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 review of laboratory procedures, the lack of quality assurance documents and interview of facility personnel, the laboratory failed to monitor and assess problems in general laboratory systems. Findings are: 1. Review of the laboratory policy Quality Management Plan (QM003.02) revealed "quality assessment program activities will be reported monthly so that any indicators not meeting established threshold can be reviewed in a timely manner. Appraisal of the program will be conducted annually to ensure its continuing effectiveness and impact on patient care. Recommendations for and implementation of plans for improvement will be made at this time, if indicated. The laboratory will have a mechanism for documenting and assessing problems identified during quality assurance reviews and discussing them with the laboratory...the laboratory will maintain documentation of all quality assurance activities including problems identified and corrective actions taken." 2. Review of the laboratory records revealed no documentation of the quality assessment documents. 3. An interview with the laboratory consultant on 7/25/19 at 1030 hours via phone confirmed the above findings.
D5300	PREANALYTIC SYSTEMS CFR(s): 493.1240 Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in 493.1241 and 493.1242, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the preanalytic systems and correct identified problems as specified in 493. 1249 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: 41687 Based on review of the laboratory's procedures, , and staff interview, it was revealed the laboratory failed to identify and correct problems with preanalytic systems. The findings were: 1. The laboratory failed to establish the conditions for specimen stability and transportation of patient specimens (refer to D5311 I). 2. The laboratory failed to follow its written procedure for specimen acceptability and rejection (refer to D5311 II) 3. The laboratory exceeded the sample stability guidelines for testing urine specimens as outlined in their policy (refer to D5311 III). 4. The laboratory failed to follow its policy for the transport of patient specimens to the laboratory for testing (refer to D5311 IV). 5. The laboratory failed to provide a guideline for the specimen stability for patient samples when assaying urine creatinine (refer to D5311 V). 6. The laboratory failed to have a quality assessment plan which could detect issues in preanalytic test systems (refer to D5391).
D5309	TEST REQUEST CFR(s): 493.1241(e) If the laboratory transcribes or enters test requisition or authorization information into a record system or a laboratory information system, the laboratory must ensure the

	information is transcribed or entered accurately. This STANDARD is not met as evidenced by: Based on review of the laboratory patient requisitions and final reports and confirmed in interview, the laboratory failed to ensure the laboratory accurately transcribed date of collection of specimens into the laboratory final reports. Findings were: 1. Random review of patient requisitions from November 2018 to May 2019 with the corresponding final reports revealed 7 of 10 patient final reports with the date of collection transcribed onto the final report that did not match the information on the patient requisitions. Patient ID 2584 date of collection: 6/5/19; Final report date of collection: 6/7/19 Patient ID 2683 date of collection: 5/9/19; Final report date of collection: 5/16/19 Patient ID 1683 date of collection: 4/17/19; Final report date of collection: 4/19/19 Patient ID 2543 date of collection: 3/8/19; Final report date of collection: 3/14/19 Patient ID 406 date of collection: 2/18/19; Final report date of collection: 2/22/19 Patient ID 410 date of collection: 2/18/19; Final report date of collection: 2/22/19 Patient ID 001 date of collection: 11/26/18; Final report date of collection: 11/30/18 2. An interview with the laboratory consultant on 7/25/19 at 1435 hours via phone confirmed the above findings.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: I. Based on review of the laboratory's establishment studies and staff interview, it was revealed the laboratory failed to establish the conditions for specimen stability and transportation of patient specimens. Findings include: 1. A review of the laboratory's establishment studies on the Mircogenics MGC-240 toxicology analyzer revealed there was no documentation of a stability and transport study for the following non FDA approved tests: Amphetamine Barbiturates Benzodiazepine Buprenorphine Cannabinoid Cocaine Opiate Creatinine 2. A review of the laboratory's establishment studies revealed a 'Stability and Transport Study' was performed for a different analyzer, the Tokyo Boeki Biolis 24i analyzer (serial number 2227980210). 3. An interview with the certified medical assistant on 7/25/19 at 13:05 in the laboratory, when asked if there was any other documentation of the establishment studies for the Microgenics MGC-240, she replied, "I do not know." This confirmed the above findings. II. Based on a review of the laboratory's policies, the laboratory's 'Urine Drug Testing (Preliminary) Order & Report Form', review of patient records from June 7- July 5, 2019, and staff interview, it was revealed the laboratory failed to follow its written procedure for specimen acceptability and rejection. Findings include: 1. A review of the laboratory's 'Specimen Handling' policy revealed the following statement: Acceptable Temperatures: 32.5-37.7C (90.5-99.9F). Do not accept urine specimen if Temperature is outside this range. 2. A review of the laboratory's 'Urine Drug Testing (Preliminary) Order & Report Form' includes the following statement: Specimen Temperature (90-100 F) with in limit: YES NO 3. A

review of patient results from June 7- July 5, 2019 revealed the following patients results were reported without the testing person indicating whether the specimen temperature was within the required temperature range of 90-100 F: Patient ID: 0 Run Date: 6/7/19 Patient ID: 1 Run Date: 6/7/19 Patient ID: 3 Run Date: 6/7/19 Patient ID: 4 Run Date: 6/7/19 Patient ID: 5 Run Date: 6/7/19 Patient ID: 6 Run Date: 6/7/19 Patient ID: 7 Run Date: 6/7/19 Patient ID: 8 Run Date: 6/7/19 Patient ID: 9 Run Date: 6/7/19 Patient ID: 10 Run Date: 6/7/19 Patient ID: 380 Run Date: 6/17/19 Patient ID: 2 Run Date: 6/17/19 Patient ID: 1 Run Date: 6/17/19 Patient ID: 1090 Run Date: 6/17 /19 Patient ID: 5 Run Date: 6/17/19 Patient ID: 1 Run Date: 7/5/19 Patient ID: 4 Run Date: 7/5/19 Patient ID: 3 Run Date: 7/5/19 Patient ID: 2 Run Date: 7/5/19 Patient ID: 1524 Run Date: 7/5/19 4. An interview with the certified medical assistant on 7/25/19 at 1:20 in the laboratory, when shown the above patient results, said, "That was missed, it should be marked." This confirms the above findings. III. Based on the laboratory's 'Specimen Stability Guidelines' policy, a review of patient results from June 7- July 5, 2019, and staff interview, it was revealed the laboratory exceeded the sample stability guidelines for testing refrigerated urine specimens as outlined in their policy. Findings include: 1. A review of the laboratory's 'Specimen Stability Guidelines' policy revealed the following analytes and the specimen stability guidelines for refrigerated urine toxicology specimens: Amphetamine 3 days Barbiturates 3 days Benzodiazepine 3 days Buprenorphine 3 days Cannabinoid 3 days Cocaine 3 days Opiate 3 days 2. A review of patient records from June 7- July 5, 2019 revealed the following patient sample's collected date to run date exceeded the 3 day stability guideline specified in the 'Specimen Stability Guidelines' policy: Patient ID: 0 Collected Date: 5/31/19 Run Date: 6/7/19 Elapsed time: 7 days Patient ID: 1 Collected Date: 5/31/19 Run Date: 6/7/19 Elapsed time: 7 days Patient ID: 3 Collected Date: 5/31/19 Run Date: 6/7/19 Elapsed time: 7 days Patient ID: 4 Collected Date: 5/31/19 Run Date: 6/7/19 Elapsed time: 7 days Patient ID: 5 Collected Date: 6/3/19 Run Date: 6/7/19 Elapsed time: 4 days Patient ID: 6 Collected Date: 6/3/19 Run Date: 6/7/19 Elapsed time: 4 days Patient ID: 7 Collected Date: 6/3 /19 Run Date: 6/7/19 Elapsed time: 4 days Patient ID: 8 Collected Date: 6/3/19 Run Date: 6/7/19 Elapsed time: 4 days Patient ID: 9 Collected Date: 6/3/19 Run Date: 6/7 /19 Elapsed time: 4 days Patient ID: 10 Collected Date: 6/3/19 Run Date: 6/7/19 Elapsed time: 4 days Patient ID: 380 Collected Date: 6/10/19 Run Date: 6/17/19 Elapsed time: 7 days Patient ID: 2 Collected Date: 6/7/19 Run Date: 6/17/19 Elapsed time: 10 days Patient ID: 1 Collected Date: 6/7/19 Run Date: 6/17/19 Elapsed time: 10 days Patient ID: 1090 Collected Date: 6/13/19 Run Date: 6/17/19 Elapsed time: 4 days Patient ID: 5 Collected Date: 6/13/19 Run Date: 6/17/19 Elapsed time: 4 days Patient ID: 1 Collected Date: 6/28/19 Run Date: 7/5/19 Elapsed time: 7 days Patient ID: 4 Collected Date: 7/1/19 Run Date: 7/5/19 Elapsed time: 4 days Patient ID: 3 Collected Date: 7/1/19 Run Date: 7/5/19 Elapsed time: 4 days Patient ID: 2 Collected Date: 7/1/19 Run Date: 7/5/19 Elapsed time: 4 days Patient ID: 1524 Collected Date: 7 /1/19 Run Date: 7/5/19 Elapsed time: 4 days 3. An interview with the certified medical assistant on 7/25/19 at 11:15 in the nurse's station, when asked about the storage of their patient specimens, said, "We batch the specimens. Everything is stored here in the refrigerator prior to testing." This confirmed the above findings. IV. Based on the laboratory's 'Specimen Handling' policy and staff interview, it was revealed that laboratory failed to have a mechanism in place to ensure patient specimens were transported at the acceptable temperature for testing. Findings include: 1. A review of the laboratory's 'Specimen Handling' policy states the following: "The urine specimen is transported to M&M Clinical Group at refrigerated temperature." 2. An interview with the certified medical assistant on 7/25/19 at 1:20 in the nurse's station, when asking her about how patient specimens are transported to the laboratory, said, "When I pick up samples from the other locations, I use a

	Styrofoam cooler and place ice packs in the cooler for the samples." When asked if the temperature of the Styrofoam cooler is monitored, she replied, "I do not monitor the temperature in the cooler." This confirmed the above findings. V. Based on the laboratory's 'Specimen Stability Guidelines' policy and staff interview, it was revealed that the laboratory failed to provide a guideline for the specimen stability for patient samples when assaying urine creatinine. Findings include: 1. 1. A review of the laboratory's 'Specimen Stability Guidelines' policy revealed the following analytes and the specimen stability guidelines for urine toxicology specimens: Amphetamine 3 days Barbiturates 3 days Benzodiazepine 3 days Buprenorphine 3 days Cannabinoid 3 days Cocaine 3 days Opiate 3 days Urine Creatinine 2. An interview with the certified medical assistant on 7/25/19 at 1:10 in the laboratory, when asked if there was documentation of the stability of urine samples when assaying creatinine, said, "I don't know." This confirmed the above findings.
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(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 preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and quality assessment records from 2018 and 2019, it was revealed the laboratory's quality assessment plan failed to identify issues with preanalytic systems. Findings include: 1. A review of the laboratory's policy titled 'Specimen Handling' states: 3.0 Principle It is necessary that the technical staff at M&M Clinical Group be assured of the specific requirements for collecting, processing and maintenance of integrity of patient specimens analyzed in the laboratory. Any deviation from these requirements can jeopardize the accuracy of test results, thereby affecting proper clinical diagnosis and treatment of clinical patients. The laboratory director ensures that these procedural steps and requirements are followed by the technical staff at the laboratory at all times. 2. The laboratory failed to establish the conditions for specimen stability and transportation of patient specimens (refer to D5311 I). 3. The laboratory failed to follow its written procedure for specimen acceptability and rejection (refer to D5311 II) 4. The laboratory exceeded the sample stability guidelines for testing urine specimens as outlined in their policy (refer to D5311 III). 5. The laboratory failed to have a mechanism in place to ensure patient specimens were transported at the acceptable temperature for testing. (refer to D5311 IV). 6. The laboratory failed to provide a guideline for the specimen stability for patient samples when assaying urine creatinine (refer to D5311 V).
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 review of instrument operator manuals, laboratory environmental records, and confirmed in interview, the laboratory failed to define the acceptable humidity range for 8 of 8 months reviewed. The findings included: 1. Review of the operator's manual for the Microgenics MGC-240 (10008776; 2004-9), under operating conditions, states: "ambient humidity of between 40 to 80% no condensation." 2. Review of the laboratory policy Instrument Analytical Preparation (PR0002.02) revealed under Acceptable Temperatures "Hygrometer (humidity) 40-80%." 3. Review of laboratory environmental records from November 2018 through July 2019 revealed that the laboratory was recording humidity but had not defined acceptable values. The laboratory acceptable humidity documented for 8 of 8 months was 30-85%. 4. In an interview with the laboratory consultant on 7/25/19 at 1040 hours via phone confirmed the above findings.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: A. Based on manufacturer's instructions, laboratory policies, surveyor observations, and confirmed in interview, the laboratory failed to document the revised expiration dates for calibrators and controls stored in the laboratory refrigerator. Findings were: 1. Review of the package insert for the UDT Multi Control (UDT-CNTL pi.06 AUG-2016) under storage and stability revealed "all controls are stable until expiration date on the label wehn stored at 2-8 C. Once opened vials of controls are stable for 30 days when stored tightly capped at 2 - 8 C." 2. Review of the laboratory policy Quality Control Program (QM0002.02) revealed "control material must be labeled with the date prepared, date opened (or when placed into service) and expiration date." 3. Surveyor observations on 7/25/19 at 1010 hours revealed the following controls stored in the laboratory refrigerator with no documentation of the opened date or revised expiration date per the laboratory policy. Carolina Liquid Chemistries UDT Multi-Drug Control A Level 1 lot M1829, exp 12/31/19 Level 2 lot M1829, exp 12/31/19 Control B Level 1 lot M1829, exp 12/31/19 Level 2 lot M1829, exp 12/31/19 4. Random review of the patient test records from June 2019 and July 2019 revealed the laboratory performed toxicology testing. Date Patient ID 6/07/19 0 6/07/19 1 6/07/19 3 6/07/19 4 6/07/19 6 6/07/19 8 6/07/19 9 6/17/19 1601 6/17/19 333 6/17/19 1398 7/05 /19 2604 7/05/19 846 7/05/19 2948 7/05/19 2995 7/05/19 1 7/05/19 4 7/05/19 3 7/05 /19 2 7/05/19 2570 7/05/19 2491 7/05/19 1524 7/05/19 2258 7/05/19 2048 7/05/19 202 7/05/19 256 7/05/19 2451 7/05/19 73 5. An interview with the laboratory consultant on 7/25/19 at 1415 hours via phone confirmed the above findings. B. Based on manufacturer's instructions, laboratory policy, surveyor observations, and confirmed in interview, the laboratory failed to document the revised expiration dates for assay reagents stored on the Microgenics MGC-240 laboratory analyzer. Findings were: 1. Review of the package insert for the Carolina Liquid Chemistries Buprenorphine Urine Enzyme Immunoassay reagent (BL424pi.10 JUL-2017) under preparation and storage revealed "the expiration date of the kit is tated on the label.

	The kit can be expected to perform satisfactorily until the expiration date if stored in the refrigerator at 2-8 C. The kits is table for 18 months when stored at 2-8 C. The reagents are stable opened when stored on-board the instrument for 28 days at 2-8 C." 2. Review of the package insert for the Carolina Liquid Chemistries Creatinine Reagent (Urine) (BL-343pi.03 JUN 2017) under reagent stability and storage revealed "unopened CREA reagetn materials are stable until the date of expiration on the kits when stored tightly capped at 2 - 8 C. Reagent on-board stability is at least 30 days." 3. Review of the laboratory policy Quality Control Program (QM0002.02) revealed "all analytical testing materials, including reagents, assay kits, biochemical supplies, internal and external controls reagent preparations, containers, instrumentation and ancillary equipment shall be proprly labeled and inventoried." 4. Surveyor observations on 7/25/19 at 1010 hours revealed the following reagents on board the Microgenics MGC-240 analyzer with no documentation of the opened date or revised expiration date. The Microgenics MGC-240 also had no mechanism to monitor the on-board stability of the reagents. Buprenorphine - lot A1903, exp 4/30/19 Urine Creatinine - lot H1804, exp 6/30/19 5. Random review of the patient test records from June 2019 and July 2019 revealed the laboratory performed Buprernorphine and Urine creatinine. Date Patient ID 6/07/19 0 6/07/19 1 6/07/19 3 6/07/19 4 6/07/19 6 6/07/19 8 6/07/19 9 6/17/19 1601 6/17/19 333 6/17/19 1398 7/05/19 2604 7/05/19 846 7/05/19 2948 7/05/19 2995 7/05/19 1 7/05/19 4 7/05/19 3 7/05/19 2 7/05/19 2570 7/05/19 2491 7/05/19 1524 7/05/19 2258 7/05/19 2048 7/05/19 202 7/05/19 256 7/05/19 2451 7/05/19 73 6. An interview with the laboratory consultant on 7/25/19 at 1415 hours via phone confirmed the above findings.
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 surveyor observations, review of the manufacturer's instructions, and confirmed in interview, the laboratory failed to ensure the laboratory did not use expired assay reagents for patient testing on the Microgenics MGC-240 laboratory analyzer. Findings were: 1. Surveyor observations on 11/25/19 at 1010 hours revealed the following reagents on board the Microgenics MGC-240 analyzer: Benzodiazepines - lot H1804, exp 6/30/19 Buprenorphine - lot A1903, exp 4/30/19 Urine Creatinine - lot H1804, exp 6/30/19 2. Review of the package insert for the Carolina Liquid Chemistries Buprenorphine Urine Enzyme Immunoassay reagent (BL424pi.10 JUL-2017) under preparation and storage revealed "the expiration date of the kit is tated on the label. The kit can be expected to perform satisfactorily until the expiration date if stored in the refrigerator at 2-8 C. The kits is table for 18 months when stored at 2-8 C. The reagents are stable opened when stored on-board the instrument for 28 days at 2-8 C." 3. Review of the package insert for the Carolina Liquid Chemistries Benzodiazepine Assay reagent (BL418pi.10 SEP-2018) under reagent preparation and storage revealed "all assay components when stored at 2-8 C, are stable until the expiration date indicated on the label. Do not use reagents beyond the expiration dates." 4. Review of the package insert for the Carolina Liquid Chemistries Creatinine Reagent (Urine) (BL-343pi.03 JUN 2017) under reagent stability and storage revealed "unopened CREA reagetn materials are stable until the date of expiration on the kits when stored tightly capped at 2 - 8 C. Reagent on-board

	stability is at least 30 days." 5. Review of the laboratory records available revealed the laboratory performed patient testing on 7/5/19 using the above expired reagents. Patient ID 2604 846 2948 2995 1 4 3 2 2570 2491 1524 2258 2048 202 256 2451 73 22 1522 1239 1238 2729 3053 3066 366 3025 2951 2542 2470 10 9 3061 3052 2824 2612 1843 1892 3080 2823 2226 1365 1070 6. An interview with the laboratory consultant on 7/25/19 at 1415 hours via phone confirmed the above findings.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on the laboratory's establishment studies for the Microgenics MGC-240 and staff interview, it was revealed that the laboratory failed to have documentation of a completed establish the performance specifications for the analytes run on the Microgenics MGC-240 toxicology analyzer before reporting patient test results. Findings include: 1. A review of the establishment studies for the Microgenics MGC-240 (approved by the laboratory director on 11/1/2018) revealed the following: I. No documentation of pre analytic studies for sample stability (refer to D5311 I). II. No documentation of evaluating the effects of interfering substances in positive samples to ensure there were no false negative results. III. No documentation of evaluating the effects of interfering substances with the creatinine assay. 2. An interview with the certified medical assistant on 7/25/19 at 13:05 in the laboratory, when asked if there was any other documentation of the establishment studies for the Microgenics MGC-240, she replied, "I do not know." This confirmed the above findings.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or

	replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on a review of the laboratory's calibration and quality control records from 2018 to 2019, the laboratory's 'Quality Management Plan' policy, and staff interview, it was revealed the laboratory failed to have documentation of performing calibration verifications on the Microgenics MGC-240 toxicology analyzer. Findings include: 1. A review of the laboratory's calibration records revealed the laboratory used 2 levels of calibrator material. A review of the laboratory's quality control records revealed the laboratory ran 2 levels of quality control material one time a day. 2. The laboratory's 'Quality Management Plan' policy states, "the laboratory director ensures that calibration verification is performed every 6 months." 3. According to the laboratory's records, testing started in November 2018. Atleast one calibration verification should have been performed by the time of the survey. 3. An interview with the certified medical assistant on 7/25/19 at 1:50 in the laboratory revealed, when asked about documentation of calibration verifications for the Mircogenics MGC-240 analyzer, said, "I do not believe there are records for calibration verification. I have never done one." This confirmed the above findings.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(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 quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of laboratory policy, quality control records, patient test records, and confirmed in interview, the laboratory failed to document two control materials of different concentrations for each day of toxicology testing on the Microgenics MGC-240 analyzer. Findings were: 1. Review of the laboratory policy Quality Control Program (QM0002.02) revealed "quality control materials are included in each test assay in order to assess and monitor the analytical performance of the specific test assay. The assay test results of these internal quality control samples is evaluated by the technologist or by the instrument soft-ware program to assess acceptable performance and to reach a decision that assists in the validation of the assay test run. The internal assessment of each assay run includes specified controls, either qualitative or quantitative, which are used to help validate the test before any patient results are accepted for reporting. The laboratory technologist or programmed instrumentation software assesses the performance of these controls based on pre-accepted ranges (mean +/- 2 SD)...All QC data must be within acceptable limits in order to validate the assay run." 2. Random review of the laboratory records from November 2018 to July 2019 revealed documentation the laboratory performed patient testing with no documentation of corresponding quality control for 10 of 20

	days reviewed. Date Patient ID 6/07/19 9 6/17/19 1601 6/17/19 333 6/17/19 1398 7/05 /19 2604 7/05/19 846 7/05/19 2948 7/05/19 2995 7/05/19 1 7/05/19 4 7/05/19 3 7/05 /19 2 7/05/19 2570 6/28/19 2721 6/28/19 2121 6/28/19 1908 5/16/19 2683 5/16/19 2131 5/09/19 1710 5/09/19 1763 3/14/19 2543 3/14/19 2 2/22/19 406 2/22/19 410 1/25 /19 4 1/25/19 1 11/30/18 197 11/30/18 28 11/30/18 2572 3. An interview with the laboratory consultant on 7/25/19 at 1410 hours via phone confirmed the above findings.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(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--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory policy, quality control records, patient test records, and confirmed in interview, the laboratory failed to establish the quality control ranges for the toxicology testing on the Microgenics MGC-240 analyzer. Findings were: 1. A review of the laboratory records revealed the laboratory performed patient testing for the following analytes on the Microgenics MGC-240 analyzer: Amphetamine Barbiturates Benzodiazepines Buprenorphine Cocaine Opiates Oxycodone Cannabinoid Urine Creatinine 2. Review of the quality control records revealed the laboratory used UDT Multi Control for Barbiturate, Amphetamine, Cannabinoid (THC50), Cocaine, and Opiate toxicology testing on the Microgenics MGC-240 analyzer. 3. Review of the quality control records revealed the laboratory used MGC Primary DAU Control Set for Benzodiazepine (Benz) toxicology testing on the Microgenics MGC-240 analyzer. 4. Review of the quality control records revealed the laboratory used Lin-Zhi Norbuprenorphine (Bup) DAU (Drugs of abuse) control for Buprernorphine toxicology testing on the Microgenics MGC-240 analyzer. 5. Review of the quality control records revealed the laboratory used MAS UrichemTRAK Urine chemistry liquid assayed Urine Control for urine Creatinine testing on the Microgenics MGC-240 analyzer. 6. Review of the laboratory qualtiy control records from December 2018 to May 2019 revealed the laboratory used the following acceptable ranges for the following quality control: UDT Multi Control lot K1804, exp 12/31/19 Barb level 1 acceptable range 75 - 225 ng/mL Barb Level 2 acceptable range 150 - 300 ng/mL THC 50 Level 1: acceptable range 8 - 68 ng/mL THC 50 Level 2: acceptable 49.6 - 74.4 ng/mL Amph level 1 acceptable range 300 - 1200 ng/mL Amph level 2 acceptable range 400 - 1600 ng/mL Cocaine level 1 acceptable range 150-300 ng/mL Cocaine level 2 acceptable range 300 - 450 ng/mL Opi level 1: acceptable range 150 - 300 ng/mL Opi level 2: acceptable range 300 - 450 ng/mL MGC Primary DAU low Control Set lot 73037557, exp 11/01/19 Benz LO level: acceptable range 75 - 225 ng/mL MGC Primary DAU high Control Set lot

	73037561, exp 11/01/19 Benz HI level: acceptable range 150 - 300 ng/mL Lin-Zhi Norbuprenorphine (Bup) DAU (Drugs of abuse) control Negative lot 1803044, exp 9 /19/19 Bup Negative: acceptable range 0 - 6.0 ng/ml Lin-Zhi Norbuprenorphine (Bup) DAU (Drugs of abuse) control Positive lot 1811024, exp 10/31/19 Bup Positive: acceptable range 1 - 25 ng/mL MAS UrichemTRAK Urine chemistry liquid assayed Urine Control level 1 lot UC19031A, exp 3/31/19 Urine Creatinine level 1: acceptable result 2 - 152 mg/dL level 2 lot UC19032A, exp 3/31/19 Urine Creatinine level 1: acceptable result 113 - 263 mg/dL 7. Review of the laboratory qualtiy control records from Apirl - June 2019 Levey Jennings chart revealed the laboratory used the following acceptable ranges for the following quality control: UDT Multi Control lot K1804, exp 12/31/19 Barb level 1 acceptable range 120 - 180 ng/mL Barb Level 2 acceptable range 200 - 300 ng/mL THC 50 Level 1: acceptable range 30.4 - 45.6 ng /mL THC 50 Level 2: acceptable 49.6 - 74.4 ng/mL Amph level 1 acceptable range 600 - 900 ng/mL Amph level 2 acceptable range 1000 - 1500 ng/mL Cocaine level 1 acceptable range 180-270 ng/mL Cocaine level 2 acceptable range 300 - 450 ng/mL Opi level 1: acceptable range 180 - 270 ng/mL Opi level 2: acceptable range 300 - 450 ng/mL MGC Primary DAU low Control Set lot 73037557, exp 11/01/19 Benz LO level: acceptable range 120 - 180 ng/mL MGC Primary DAU high Control Set lot 73037561, exp 11/01/19 Benz HI level: acceptable range 200 - 300 ng/mL Lin-Zhi Norbuprenorphine (Bup) DAU (Drugs of abuse) control Negative lot 1803044, exp 9 /19/19 Bup Negative: acceptable range 12 - 18 ng/ml Lin-Zhi Norbuprenorphine (Bup) DAU (Drugs of abuse) control Positive lot 1811024, exp 10/31/19 Bup Positive: acceptable range 20 - 30 ng/mL MAS UrichemTRAK Urine chemistry liquid assayed Urine Control level 1 lot UC19031A, exp 3/31/19 Urine Creatinine level 1: acceptable result 62.16 - 93.24 mg/dL level 2 lot UC19032A, exp 3/31/19 Urine Creatinine level 1: acceptable result 8 - 12 mg/dL 8. Review of the laboratory quality control records revealed no documentation of the laboratory establishing the above acceptable ranges. 9. Review of the laboratory records revealed the laboratory performed ? toxicology analytes annually. 10. An interview with the laboratory consultant on 7/25/19 at 1440 hours via phone confirmed the above findings.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions, laboratory quality control records, patient test records and confirmed in interview, the laboratory failed to document corrective actions to resolve instrument errors. Findings were: 1. Review of the Microgenics MGC-240 operator's manual (10008776-0; 2004-9) revealed the following errors: C - cell blank error. Absorbance rate of main wavelength which canceled cell blank value is lower than [absorbance limit low] at all the measuring points or the first measuring point. R1 - shortage of 1st reagent. 2. Random review of

the quality control records and patient test records from December 2018 to May 2019 revealed 4 of 10 days with quality control and patient testing with 1 or more of the above error codes with no documentation of the corrective action to resolve the error code. UDT Multi Control lot K1804, exp 12/31/19 1/11/19 Barbiturate level 1: lab result 205 (cell blank error) THC50 level 1: lab result 30 (cell blank error) Barb level 2: lab result 263 (cell blank error) THC 50 level 2: lab result 82 (cell blank error) Amph level 1: lab result 1138 (cell blank error) Cocaine level 1: lab result 352 (cell blank error) Opi level 1: lab result 237 (cell blank error) Amph level 2: lab result 1323 (cell blank error) Cocaine level 2: lab result 454 (cell blank error) Opi level 2: lab result 399 (cell blank error) 1/04/19 Urine Creatinine level 1: lab result 0 (R1 error) Urine Creatinine level 2: lab result 0 (R1 error) Patient ID 2613 1/4/19 Barb: lab result 129 ng/mL (C - cell blank error) Patient ID 001 11/30/18 THC50: lab result 0 (C - cell blank error) Patient ID 2347 11/30/18 Benz: lab result 18462 (C - cell blank error) Patient ID 1268 11/30/18 Benz: lab result 16652 (C - cell blank error) 3. An interview with the laboratory consultant on 7/25/19 at 1440 hours via phone confirmed the above findings. B. Based on review of the laboratory quality control records from December 2018 to May 2019 revealed the laboratory failed to document corrective actions for quality control outside of the acceptable range. Findings were: 1. Review of the quality control records revealed the laboratory used UDT Multi Control for Barbiturate, Amphetamine, Cannabinoid (THC50), Cocaine, and Opiate toxicology testing on the Microgenics MGC-240 analyzer. 2. Review of the quality control records revealed the laboratory used MGC Primary DAU Control Set for Benzodiazepine (Benz) toxicology testing on the Microgenics MGC-240 analyzer. 3. Review of the quality control records revealed the laboratory used Lin-Zhi Norbuprenorphine (Bup) DAU (Drugs of abuse) control for Buprernorphine toxicology testing on the Microgenics MGC-240 analyzer. 4. Review of the quality control records revealed the laboratory used MAS UrichemTRAK Urine chemistry liquid assayed Urine Control for urine Creatinine testing on the Microgenics MGC-240 analyzer. 5. Review of the laboratory qualtiy control records from December 2018 to May 2019 revealed 9 of 9 days reviewed with 1 or more quality control failures with no documentation of corrective actions. UDT Multi Control lot K1804, exp 12/31/19 12/14/18 Barb level 1: lab result 182 (acceptable range 120 - 180 ng /mL) THC 50 Level 2: lab result 113 (acceptable 49.6 - 74.4 ng/mL) Amph level 1: lab result 974 (acceptable range 600 - 900 ng/mL) Cocaine level 1: lab result 283 (acceptable range 180-270 ng/mL) Opi level 1: lab result 439 (acceptable range 180 - 270 ng/mL) 12/21/18 Barb level 1: lab result 282 (acceptable range 120 - 180 ng/mL) THC50 level 1: lab result 23 (acceptable range 30.4 - 45.6 ng/mL) Amph level 1: lab result 1113 (acceptable range 600 - 900 ng/mL) Cocaine level 1: lab result 0 (acceptable range 180-270 ng/mL) Opi level 1: lab result 332 (acceptable range 180 - 270 ng/mL) Amph level 2: lab result 872 (acceptable range 1000 - 1500 ng/mL) Cocaine level 2: lab result 0 (acceptable range 300-450 ng/mL) Opi level 2: lab result 634 (acceptable range 300 - 450 ng/mL) 12/28/18 Barb level 1: lab result 354 (acceptable range 120 - 180 ng/mL) THC 50 Level 1: lab result 64 (acceptable range 30.4 - 45.6 ng/mL) THC 50 Level 2: lab result 87 (acceptable range 49.6 - 74.4 ng /mL) Cocaine level 1: lab result 691 (acceptable range 180-270 ng/mL Opi level 1: lab result 668 (acceptable range 180 - 270 ng/mL) Cocaine level 2: lab result 267 (acceptable range 300-450 ng/mL) 1/4/19 Barb level 1: lab result 284 (acceptable range 120 - 180 ng/mL) THC 50 Level 2: lab result 84 (acceptable 49.6 - 74.4 ng/mL) Amph level 1: lab result 1203 (acceptable range 600 - 900 ng/mL) Cocaine level 1: lab result 314 (acceptable range 180-270 ng/mL) Opi level 1: lab result 336 (acceptable range 180 - 270 ng/mL) Amph level 2: lab result 686 (acceptable range 1000 - 1500 ng/mL) Cocaine level 2: lab result 205 (acceptable range 300-450 ng/mL) Opi level 2: lab result 641 (acceptable range 300 - 450 ng/mL) 4/4/19 Amph level 1:

lab result 993 (acceptable range 600 - 900 ng/mL) Cocaine level 1: lab result 282 (acceptable range 180-270 ng/mL) 4/12/19 Amph level 1: lab result 1114 (acceptable range 600 - 900 ng/mL) Opi level 1: lab result 315 (acceptable range 180 - 270 ng /mL) Opi level 2: lab result 471 (acceptable range 300 - 450 ng/mL) 4/19/19 Barb level 1: lab result 231 (acceptable range 120 - 180 ng/mL) THC 50 Level 2: lab result 85 (acceptable 49.6 - 74.4 ng/mL) Amph level 1: lab result 1019 (acceptable range 600 - 900 ng/mL) Cocaine level 1: lab result 286 (acceptable range 180-270 ng/mL) 4 /25/19 Barb level 1: lab result 191 (acceptable range 120 - 180 ng/mL) THC50 level 1: lab result 16 (acceptable range 30.4 - 45.6 ng/mL) Barb level 2: lab result 195 (acceptable range 200 - 300 ng/mL) Cocaine level 1: lab result 297 (acceptable range 180-270 ng/mL) Opi level 1: lab result 312 (acceptable range 180 - 270 ng/mL) Opi level 2: lab result 451 (acceptable range 300 - 450 ng/mL) 5/2/19 Barb level 1: lab result 326 (acceptable range 120 - 180 ng/mL) THC50 level 1: lab result 24 (acceptable range 30.4 - 45.6 ng/mL) Amph level 1: lab result 1223 (acceptable range 600 - 900 ng/mL) Cocaine level 1: lab result 342 (acceptable range 180-270 ng/mL) Opi level 1: lab result 332 (acceptable range 180 - 270 ng/mL) Amph level 2: lab result 681 (acceptable range 1000 - 1500 ng/mL) Cocaine level 2: lab result 218 (acceptable range 300-450 ng/mL) Opi level 2: lab result 573 (acceptable range 300 - 450 ng/mL) MGC Primary DAU Low Control Set lot 73037557, exp 11/01/19 12/21 /18 Benz LO level: lab result 204 (acceptable range 120 - 180 ng/mL) 12/14/18 Benz LO level: lab result 192 (acceptable range 120 - 180 ng/mL) 4/4/19 Benz LO level: lab result 226 (acceptable range 120 - 180 ng/mL) 4/25/19 Benz LO level: lab result 186 (acceptable range 120 - 180 ng/mL) Lin-Zhi Norbuprenorphine (Bup) DAU (Drugs of abuse) control Negative lot 1803044, exp 9/19/19 Positive lot 1811024, exp 10/31/19 12/14/18 Bup Negative: lab result 8.3 (acceptable range 0 - 6.0 ng/ml) Bup Positive: lab result 10.7 (acceptable range 1 - 25 ng/mL) 4/4/19 Bup Positive: lab result 48.0 (acceptable range 1 - 25 ng/mL) 4/25/19 Bup Negative: lab result 12.0 (acceptable range 0 - 6.0 ng/ml) 5/2/19 Bup Negative: lab result 7.8 (acceptable range 0 - 6.0 ng/ml) MAS UrichemTRAK Urine chemistry liquid assayed Urine Control level 1 lot UC19031A, exp 3/31/19 level 2 lot UC19032A, exp 3/31/19 12/14/18 Urine Creatinine level 1: lab result 58 (acceptable result 62.16 - 93.24 mg/dL) Urine Creatinine level 2: lab result 241 (acceptable result 151 - 226 mg/dL) 12/21/18 Urine Creatinine level 1: lab result 54 (acceptable result 62.16 - 93.24 mg/dL) 1/04/19 Urine Creatinine level 1: lab result 0 (acceptable result 62.16 - 93.24 mg/dL) Urine Creatinine level 2: lab result 0 (acceptable result 151 - 226 mg/dL) 1/11/19 Urine Creatinine level 1: lab result 57 (acceptable result 62.16 - 93.24 mg/dL) 4/4/19 Urine Creatinine level 2: lab result 276 (acceptable result 151 - 226 mg/dL) 4/25/19 Urine Creatinine level 2: lab result 253 (acceptable result 151 - 226 mg/dL) 5/2/19 Urine Creatinine level 1: lab result 98 (acceptable result 62.16 - 93.24 mg/dL) Urine Creatinine level 2: lab result 263 (acceptable result 151 - 226 mg/dL) 6. An interview with the laboratory consultant on 7/25/19 at 1440 hours via phone confirmed the above findings. 41687 C. Based on the laboratory's establishment studies for the Microgenics MGC-240, patient's test reports from June 7- July 5, 2019, and staff interview, it was revealed the laboratory reported patient test values that are outside of the laboratory's established reportable ranges for analytes run on the Mircrogenics MGC-240 toxicology analyzer. Findings include: 1. A review of the laboratory's establishment studies for the Microgenics MGC-240 toxicology analyzer (accepted by the laboratory director on 11/1/2018) revealed the following analytes and the established reportable ranges: Amphetamine (AMPH) 0-1437 ng/mL Barbiturate (BARB) 22-412 ng/mL Benzodiazepine (BENZ) 2.6-457 ng/mL Buprenorphine (BUP) 0-12.2 ng/mL Cocaine (COCM) 0-653 ng/mL Opiate (OP300) 2.2-620 ng/mL Tetrahydrocannabinol (THC50) 0-89 ng/mL Creatinine (UCRE) 0-213 ng/mL 2. A random review of patient test reports from June 7- July 5, 2019 revealed the following

	analytes were reported outside of the laboratory's reportable range: Patient ID: 3 Run Date: 6/7/19 BARB: 0 ng/mL BENZ: 0 ng/mL BUP: 13.9 ng/mL OP300: 0 ng/mL Patient ID:4 Run Date: 6/7/19 BARB: 14 ng/mL BENZ: 482 ng/mL BUP: 24.0 ng/mL THC50: 111 ng/mL Patient ID: 7 Run Date: 6/7/19 BARB: 0 ng/mL BENZ: 0 ng/mL BUP: 12.4 ng/mL Patient ID: 8 Run Date: 6/7/19 BENZ: 567 ng/mL BUP: 30.5 ng /mL THC50: 294 ng/mL Patient ID: 9 Run Date: 6/7/19 BARB: 445 ng/mL BUP: 40.7 ng/mL OP300: 0 ng/mL Patient ID: 2139 Run Date: 6/17/19 BARB: 0 ng/mL BENZ: 0 ng/mL OPI: 0 ng/mL Patient ID: 380 Run Date: 6/17/19 BARB: 0 ng/mL BENZ: 0 ng/mL BUP: 56.5 ng/mL UCRE: 239 mg/dL Patient ID: 2 Run Date: 6/17 /19 BARB: 0 ng/mL BENZ: 0 ng/mL BUP: 65.1 ng/mL OP300: 0 ng/mL Patient ID: 1 Run Date: 7/5/19 BUP: 42.2 ng/mL THC50: 331 ng/mL Patient ID: 1524 Run Date: 7/5/19 BUP: 91.9 ng/mL OP300: 0 ng/mL UCRE: 254 mg/dL 3. An interview with the certified medical assistant on 7/25/19 at 11:00 in the nurse's station confirmed that the "page with the quantitative results is considered the patient report and it is scanned into the patient's chart."
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of the laboratory's quality assurance records from 2018 and 2019, it was revealed the laboratory's quality assurance plan failed to identify and correct problems with analytic systems. 1. The laboratory failed to have documentation of a completed establish the performance specifications for the analytes run on the Microgenics MGC-240 toxicology analyzer before reporting patient test results (refer to D5423). 2. The laboratory failed to have documentation of performing calibration verifications on the Microgenics MGC-240 toxicology analyzer (refer to D5439). 3. The laboratory reported patient test values that are outside of the laboratory's established reportable ranges for analytes run on the Mircrogenics MGC-240 toxicology analyzer (refer to D5781).
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies, patient's test records from June 7- July 5, 2019, and staff interview, it was revealed the laboratory failed to report out

	creatinine results according to its policy. Findings include: 1. A review of the laboratory's policy titled, 'Specimen Handling' states the following under section 6.0 Specimen Rejection Criteria: 6.7 Acceptable Creatinine level: 80-200 mg/mL. Report as Dilute if Creatinine level is less than 20 mg/dL. Report as "Substituted; not consistent with human urine" if Creatinine level is less than 5 mg/dL. Report as "adulterated" if Creatinine level is > 200 mg/dL. 2. A random review of patient's test results from June 7- July 5, 2019 revealed the above criteria is not being followed. The following patient's lab results were reported as: Patient ID: 9 Urine Creatinine Result (UCRE): 14 mg/dL Reported on: 6/7/19 Patient ID: 10 Urine Creatinine Result (UCRE): 226 mg/dL Reported on: 6/7/19 Patient ID: 2139 Urine Creatinine Result (UCRE): 0 mg/dL Reported on: 6/17/19 Patient ID: 380 Urine Creatinine Result (UCRE): 239 mg/dL Reported on: 6/17/19 Patient ID: 4 Urine Creatinine Result (UCRE): 257 mg/dL Reported on: 7/5/19 3. An interview with the certified medical assistant on 7/25/19 at 1:20 pm in the laboratory revealed, when asked what the laboratory does with the creatinine results when the value is above 200 mg/dL, less than 5 mg/dL or less than 20 mg/dL, she responded, "we don't do anything." This confirmed the above findings.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on review of laboratory's records and staff interview, it was revealed the laboratory director failed to provide overall management and direction for high complexity testing. The findings were: 1. The laboratory director failed to ensure establishment studies were complete (refer to D6082). 2. The laboratory director failed to ensure a quality control program was established and followed (refer to D6093). 3. The laboratory director failed to ensure a quality assessment plan could identify and correct problems (refer to D6094). 4. The laboratory director failed to ensure that 2 of 3 testing personnel had appropriate education for high complexity testing. (refer to D6102)
D6082	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1) The laboratory director must ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing. This STANDARD is not met as evidenced by: Based on review of the laboratory's establishment studies for its non FDA-approved assays, and staff interview, it was revealed the laboratory director failed to ensure the studies were complete prior to patient testing (refer to D5423).
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)

	The laboratory director must ensure that the quality control 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 laboratory's quality control records and staff interview, it was revealed the laboratory director failed to ensure a quality control plan was established and followed for high complexity testing. Refer to D5447, D5469
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 laboratory's records and staff interview, it was revealed the laboratory director failed to ensure the laboratory's quality assessment plan assured quality testing for high complexity testing. Refer to D5391, D5791
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 the laboratory's personnel records and staff interview, it was revealed the laboratory director failed to ensure that 2 of 3 testing personnel had appropriate education for high complexity testing. (testing person #1, 2) The findings were: 1. A review of the laboratory's personnel records revealed that 2 of 3 testing personnel (testing person #1, 2) had no documentation of their education to qualify them for high complexity testing. 2. An interview with the lab consultant on 7/25/19 at 1035 hour via phone confirmed the above findings. He stated that he had them "somewhere."
D6108	LABORATORY TECHNICAL SUPERVISOR CFR(s): 493.1447 The laboratory must have a technical supervisor who meets the qualification requirements of 493.1449 of this subpart and provides technical supervision in accordance with 493.1451 of this subpart. This CONDITION is not met as evidenced by:

	Based on direct observations, laboratory policies, quality control records, manufacturer's instructions, patient results, and confirmed in interview of facility personnel, the technical supervisor failed to provide overall management and direction of the laboratory services. (refer to D6115, D6117, D6120)
D6115	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(2) The technical supervisor is responsible for verification of the test procedures performed and establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system. This STANDARD is not met as evidenced by: Based on review of the laboratory's establishment studie and and confirmed in interview, the technical supervisor failed to ensure establishment studies for non-FDA approved testing on the Microgenics MGC-240 toxicology analyzer were complete prior to patient testing. (refer to D5423)
D6117	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(4) The technical supervisor is responsible for establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results. This STANDARD is not met as evidenced by: Based on review of the laboratory quality control records, laboratory patient records, and confirmed in interview, the technical supervisor failed to ensure the laboratory established and maintained a quality control program for the toxicology testing. Refer to D5469
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 review of the laboratory policy, review of the laboratory personnel files, and confirmed in interview, the technical supervisor failed to document competency, training and ensure appropriate education was documented for 2 of 3 testing personnel. Findings were: 1. Review of the laboratory policy Training, Competency Assessment of Technical Personnel (QM00019.02) revealed "upon completion of training and before reporting patient test results, and initial competency assessment of

	the employee must be performed." 2. Review of the laboratory personnel files revealed no documentation of the training nor the initial competency for testing person #1, 2. 3. An interview with the laboratory consultant on 7/25/19 at 1010 hours via phone confirmed the above findings.
D6168	TESTING PERSONNEL CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: Based on a review of the Laboratory Personnel Report, personnel records and staff interview, it was revealed that 2 of 3 testing personnel performing high complexity testing did not have the appropriate education credentials required to perform high complexity testing (refer to D6171).
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(1) 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; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for

	proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations. This STANDARD is not met as evidenced by: Based on review of the laboratory policy, laboratory personnel records, and confirmed in interview, the laboratory failed to ensure the all laboratory personnel had documentation of education to qualify them to perform high-complexity toxicology testing on the Microgenics MGC-240 analyzer. Findings were: 1. Review of the laboratory policy Personnel Qualifications and Responsibilities (QM0001.02) revealed "ensure that prior to testing patient specimens, all personnel have the appropriate education and experience, and receive the appropriate training for the type and complexity of services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate test results." 2. Review of the CMS209 revealed 3 testing personnel (TP). TP#1 TP#2 TP#3 3. Review of the laboratory personnel records revealed no education documentation for 2 of 3 testing person TP#1, TP#2. 4. An interview with testing person #3 on 7/25/19 at 1015 hours in the nurse's station revealed that she had a medical assistant certification and graduated high school. She also stated "I do testing with [TP#3] via facetime. I know I'm not qualified for that testing."