Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D0960987	12/18/2018
Name of Provider or Supplier	**Street Address, City, State**	
Apg Medical Laboratory	916 Talon Dr, Ste 102, O Fallon, IL	

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
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 laboratory records and interview with laboratory testing personnel (TP) #1; the laboratory failed to meet the toxicology subspecialty requirements specified in 493.1230 through 493.1256. Findings Include: 1. The laboratory failed to ensure 6 month calibration verifications were performed for urine toxicology analytes on the Mindray BS-200 in 2018. See D5439. 2. The laboratory failed to ensure Cannabinoid quality controls were within the manufacturer's acceptable range prior to reporting patient test results for 6 of 13 dates reviewed in 2018 on the Mindray BS-200 analyzer. See D5481.
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 review of laboratory records and interview with laboratory testing personnel (TP) #1; the laboratory failed to conduct six month calibration verifications as required for the Mindray BS-200 for drugs of abuse testing in 2018. Findings include: 1. Review of the laboratory's policy and procedure manual identified the procedure, "Calibration Verification", which stated the following on page 3 through 4: "For analyzers and analytes that are not calibrated with a minimum of three calibrators verifying the low, midpoint and high end of the reportable range, a calibration verification must be performed to substantiate the continued accuracy of the monitors throughout the reportable range, after initial validation studies are performed with the setup of the analyzer. Calibration verification is performed every six months, as stated in current CLIA regulations." 2. Review of the calibration records for the Mindray BS-200 found two point calibrations are performed for the following analytes: Amphetamine, Barbiturate, Benzodiazepine, Cannabinoid (THC), Cocaine Metabolite, Methadone, Opiates, Phencyclidine, and Propoxyphene. 3. Interview on 12-18-2018, at 10:12 am, with laboratory TP#1 confirmed that all calibrations performed on the Mindray BS-200 are two point calibrations and no six month calibration verifications had been performed since the instrument was put into use for patient testing on March 1st, 2018. 4. Review of patient test records found 3,564 toxicology tests had been performed on the Mindray BS-200 in September of 2018 through November of 2018 when no six month calibration verification had been performed.
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 review of laboratory records and interview with testing personnel (TP) #1; the laboratory failed to ensure two levels of quality control (QC) materials were acceptable prior to reporting patient test results for cannabinoid (THC) testing on the Mindray BS-200 analyzer for 6 of 13 dates reviewed. Findings Include: 1. Review of the laboratory policy and procedure manual identified the policy, "Quality Control Acceptancy Policy", which states, "No control value will be accepted at APG Medical Center unless it is within the established limits set forth by the manufacturer of that control for the particular control lot number in use. This applies for each of the controls used to monitor Drug testing normal and abnormal. Controls which do not fall within the acceptable limits will be tested a maximum of two times before

	performing some type of corrective actions." 2. Review of quality control records for THC testing on the Mindray BS-200 found THC quality control testing results were outside the manufacturer's acceptable range for 6 of 13 dates reviewed when patient testing was performed. Date Control Range Result 05-21-2018 50.20-69.80 ng/ml 71.1 ng/ml 05-22-2018 50.20-69.80 ng/ml 74.6 ng/ml 05-23-2018 50.20-69.80 ng/ml 74.7 ng/ml 05-24-2018 50.20-69.80 ng/ml 70.9 ng/ml 11-16-2018 24.00-40.00 ng/ml 23.3 ng/ml 11-21-2018 24.00-40.00 ng/ml 23.4 ng/ml 3. Review of patient test records for the above mentioned dates found 51 patients were tested for THC when quality control values were outside the manufacturer's acceptable range and the laboratory's quality control acceptance procedure was not followed. 4. Interview with TP#1 on 12-18-2018, at 2:55 pm, confirmed quality control results were outside the acceptable range for THC quality control testing for the above mentioned dates when patient testing was still reported for THC on the Mindray BS-200.
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 review of the laboratory records and interview with testing personnel (TP) #1; the laboratory failed to have 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. Findings Include: 1. The laboratory failed to ensure 1 of 1 TP were qualified for high complexity urine toxicology testing. See 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 laboratory records and interview with testing personnel (TP) #1; the laboratory failed to ensure 1 of 1 testing personnel were qualified for high complexity urine toxicology testing on the Mindray BS-200. Findings Include: 1. Review of educational documentation for 1 of 1 testing personnel identified on the CMS-209 failed to meet the educational requirements for high complexity testing. a. TP#1 - Associate of Applied Science in Human Services 2. On survey date 12-18-2018, at 2:55 pm, the above findings were confirmed by TP#1.