

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D1000384	(X3) Date Survey Completed 09/17/2019
Name of Provider or Supplier Houma Health Clinic	Street Address, City, State 827 Bayou Gardens Blvd, Houma, LA	
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	An Initial survey was performed at Houma Health Clinic, CLIA ID # 19D1000384, on September 17, 2019. Houma Health Clinic was found not in compliance with the following CONDITION LEVEL DEFICIENCIES: 42 CFR 493.1250 CONDITION: Analytic systems 42 CFR 493.1403 CONDITION: Laboratories Performing Moderate Complexity Testing, Laboratory Director 42 CFR 493.1421 CONDITION: Laboratories Performing Moderate Complexity Testing, Testing Personnel 42 CFR 493.1441 CONDITION: Laboratories Performing High Complexity Testing, Laboratory Director 42 CFR 493.1447 CONDITION: Laboratories Performing High Complexity Testing, Technical Supervisor 42 CFR 493.1487 CONDITION: Laboratories Performing High Complexity Testing, Testing Personnel
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to establish written policies and procedures to assess competency assessment policies for testing personnel. Findings: 1. Review of the laboratory's records revealed the laboratory did not have a written policy for assessing the competency of personnel performing laboratory testing that includes the following six (6) procedures as a minimal requirement: a) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. b) Monitoring the recording and reporting of test results. c) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventative maintenance records. d) Direct observation of performance of instrument maintenance and function checks. e) Assessment of test performance</p>

through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. f) Assessment of problem solving skills. 2. In interview on September 17, 2019 at 11:15 am, the office practice manager stated the laboratory did not have a policy and procedure manual.

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 with personnel, the laboratory failed to verify the accuracy of all non-regulated analytes at least twice annually. Findings: 1. Review of the laboratory's records revealed the laboratory did not have a written policy and procedure for twice a year verification of accuracy for Toxicology testing. 2. Further review of the laboratory's records revealed the laboratory did not verify the accuracy of the following tests: Amphetamine, Barbiturate, Benzodiazepine, Buprenorphine, Cannabinoid (THC), Cocaine, Ethyl Alcohol, Methadone, Opiate, Oxycodone, Phencyclidine (PCP), and Urine Creatinine. 3. In interview on September 17, 2019 at 10:51 am, the Testing Personnel stated he was unfamiliar with proficiency testing and twice a year verification. The Testing Personnel confirmed the laboratory did not perform a verification of the accuracy of Toxicology testing since the start of patient testing in February 2019. 4. In interview on September 17, 2019 at 11:15 am, the office practice manager stated the laboratory did not have a policy and procedure manual.

D5400

ANALYTIC SYSTEMS
CFR(s): 493.1250

Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, 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 analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.

This CONDITION is not met as evidenced by:
Based on observation, record review, and interview with personnel, the laboratory failed to ensure the quality of testing within the analytic systems. Findings: 1. The laboratory failed to establish a complete policy and procedure manual. Refer to D5401. 2. The laboratory failed to establish a policy and procedure manual. Refer to D5403. 3. The laboratory failed to monitor the room temperature and humidity of the laboratory where the instrument and supplies are stored per manufacturer requirements. Refer to D5413 I. 4. The laboratory failed to monitor the temperature of the two (2) refrigerators where laboratory reagents are stored. Refer to D5413 II. 5. The laboratory failed to store reagents per manufacturer requirements. Refer to D5413 III. 6. The laboratory failed to ensure supplies did not exceed their expiration date. Refer to D5417. 7. The laboratory failed to have complete performance verification studies. Refer to D5421. 8. The laboratory failed to establish performance specifications for urine creatinine testing on the Thermo Scientific Indiko Plus

analyzer. Refer to D5423. 9. The laboratory failed to establish their own means and ranges for quality control (QC) material utilized for Urine Drug Screen (UDS) testing. Refer to D5469. 10. The laboratory failed to take corrective action when quality control samples were unacceptable for Urine Drug Screen (UDS) testing. Refer to D5783. 11. The laboratory failed to establish procedures to monitor, assess, and correct problems, identified with the analytic system. Refer to D5791.

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 record review and interview with personnel, the laboratory failed to establish a complete policy and procedure manual. Findings: 1. Review of the laboratory's documents and records revealed the laboratory did not have written policies and procedures that included: a) Corrective action: to address failures that may occur in the preanalytic, analytic, and post analytic systems b) Maintenance: how often to perform, required function checks and frequency c) Retention requirements d) Twice a year verification for accuracy of Toxicology testing to include frequency, acceptability criteria, and corrective action plan e) Performance specification: detailed procedures for performing accuracy and precision (day-to-day, run-to-run, and within-run, as well as, operator variance), reportable and reference range studies, specificity and sensitivity, acceptability criteria for studies, and actions to take when data from the studies fail to meet acceptability criteria f) Complaint Investigations g) Communication 2. In interview on September 17, 2019 at 10:40 am, the Testing Personnel stated he did not know if the laboratory had a policy and procedure manual. 3. In interview on September 17, 2019 at 11:15 am, the office practice manager stated the laboratory did not have a policy and procedure manual.

D5403

PROCEDURE MANUAL
CFR(s): 493.1251(b)

The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values.

(14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:

Based on record review and interview with personnel, the laboratory failed to establish a policy and procedure manual. Findings: 1. In interview on September 17, 2019 at 10:40 am, the Testing Personnel stated he did not know if the laboratory had a policy and procedure manual. 2. In interview on September 17, 2019 at 11:15 am, the office practice manager stated the laboratory did not have a policy and procedure manual. 3. Review of the laboratory's records revealed the laboratory did not have a policy and procedure manual to include the following: a) Detailed policies and procedures for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. Including handling of turbid urine. b) Step-by-step performance of the procedure, including test calculations c) Calibration and calibration verification procedures d) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing e) Quality Control to include, but not limited to: The establishing of means and ranges, how to establish ranges for quality control material and/or verification of quality control material; who is to monitor and how changes are to be made to the ranges of quality control material; and that the correct means and ranges are available to testing personnel. Also to include what quality control is required for each instrument and the acceptability criteria for each., corrective action for unacceptable results and flags. f) Reportable range for test results for the test system as established or verified g) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability h) Limitations in the test methodology; including interfering substances i) Reference intervals (normal values) j) Imminently life-threatening test results, or panic or alert values k) Pertinent literature references l) Laboratory's system for entering results in the patient record and reporting patient test results m) Course of action if test system becomes inoperable

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:

I. Based on observation, record review, and interview with personnel, the laboratory failed to monitor the room temperature and humidity of the laboratory where the instrument and supplies are stored per manufacturer requirements. Findings: 1. Observation by surveyor during the laboratory tour on September 17, 2019 revealed the laboratory did not monitor the temperature of the room where the following instrument and supplies were located: a) Thermo Scientific Indiko Plus instrument b) BD Vacutainer K2EDTA blood collection tubes, Lot # 9004667, Quantity: 228 tubes c) BD Vacutainer SST blood collection tubes, Lot # 8345977, Quantity: 100 tubes d) BD Vacutainer SST blood collection tubes, Lot # 966902, Quantity: 99 tubes e) BD

K2EDTA blood collection tubes, Lot # 8215722, Quantity: 100 tubes 2. Review of the instrument installation manual and manufacturer requirements revealed the following: a) Thermo Scientific Indiko Plus: ambient temperature 18-30 degrees Celsius, relative humidity 40-80 % non-condensing b) BD Vacutainer blood collection tubes: storage requirement 4-25 degrees Celsius 3. In interview on September 17, 2019 at 9:35 am, the office practice manager stated there is not a thermometer in the laboratory. II. Based on observation, record review, and interview with personnel, the laboratory failed to monitor the temperature of the two (2) refrigerators where laboratory reagents are stored. Findings: 1. Observation by surveyor during the laboratory tour on September 17, 2019 revealed the laboratory utilizes two refrigerators, one (1) Magic Chef and one (1) Frigidaire, for storage of reagents. 2. Further observation by surveyor during the laboratory tour on September 17, 2019 revealed the laboratory did not monitor the temperature of the identified refrigerators. 3. In interview on September 17, 2019 at 10:00 am, the Testing Personnel confirmed the laboratory did not have a thermometer in the Magic Chef refrigerator. The Testing Personnel stated he was unaware there was a thermometer in the Frigidaire refrigerator. The Testing Personnel further stated he does not record the temperature and unsure if someone else did. 4. Observation by surveyor during the laboratory tour on September 17, 2019 revealed the following reagents stored without temperature monitoring: Magic Chef refrigerator: a) Dri Creatinine, Detect 23.0 mg/dL control kit, Lot # 73376691, storage requirement: 2-8 degrees Celsius b) Dri Creatinine, Detect 7.5 mg/dL control kit, Lot # 73528415, storage requirement: 2-8 degrees Celsius c) DAU Urine Control Level 1, Lot # C1492, storage requirement: 2-8 degrees Celsius d) DAU Urine Control Level 2, Lot # C1493, storage requirement: 2-8 degrees Celsius e) Thermo Scientific Washing Solution 4.5%, Lot R343, storage requirement: 2-8 degrees Celsius Frigidaire refrigerator: a) UTak DAU Controls, Lot # C1492-93, storage requirements: 2-8 degrees Celsius b) Thermo Scientific Tubing Maintenance Solution, Lot # P607, storage requirement: 2-25 degrees Celsius c) Thermo Scientific Reagent Vessel, Ref # 981456, storage requirement: 2-30 degrees Celsius d) Dri Cannabinoid Assay, Lot # 73379265, storage requirement: 2-8 degrees Celsius e) Dri Phencyclidine, Lot # 73457005, storage requirement: 2-8 degrees Celsius f) Dri Ethyl Alcohol, Lot # 73460094, storage requirement: 2-8 degrees Celsius g) Dri Benzodiazepine, Lot # 73497013, storage requirement: 2-8 degrees Celsius h) Dri Barbiturates, Lot # 3496863, storage requirement: 2-8 degrees Celsius i) Dri Opiates, Lot # 73413058, storage requirement: 2-8 degrees Celsius j) Dri Amphetamines, Lot # 73449997, storage requirement: 2-8 degrees Celsius k) Dri Creatinine Calibrator Kit, Lot # 73528285, storage requirement: 2-8 degrees Celsius l) Dri Neg. Alcohol Calibrator, Lot # 73295901, storage requirement: 2-8 degrees Celsius m) Dri Multi Drug Calibrator, Lot # 72994402, storage requirement: 2-8 degrees Celsius n) Dri Amphetamine Assay, Lot # 73372164, storage requirement: 2-8 degrees Celsius o) Dri Barbiturates Assay, Lot # 73349630, storage requirement: 2-8 degrees Celsius p) Dri Cocaine Assay, Lot # 7337527, storage requirement: 2-8 degrees Celsius q) Cedia Buprenorphine Assay, Lot # 73376800, storage requirements: 2-8 degrees Celsius III. Based on observation, record review, and interview with personnel, the laboratory failed to store reagents per manufacturer requirements. Findings: 1. Observation by surveyor during laboratory tour on September 17, 2019 revealed the laboratory had the following reagent stored in the Frigidaire refrigerator: Thermo Scientific Dri Creatinine Detect Test, Lot # 73393580, Quantity: one (1) box, storage requirement: 15-30 degrees Celsius 2. In interview on September 17, 2019, the Testing Personnel stated he was told everything should be stored in the refrigerator.

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, record review, and interview with personnel, the laboratory failed to ensure supplies did not exceed their expiration date. Findings: 1. Observation by surveyor during laboratory tour on September 17, 2019 revealed the following expired items: a) e-swab collection and preservation of aerobic, anaerobic and fastidious bacteria, Lot # 180701100, Expiration date: 2019-07, Quantity: 51 swabs b) e-swab collection and preservation of aerobic, anaerobic and fastidious bacteria, Lot # 181161800, Expiration date: 2019-08, Quantity: 2 swabs c) BD Vacutainer Sodium Heparin blood collection tubes, Lot # 8011518, Expiration date: 05-31-2019, Quantity: 49 tubes d) BD Vacutainer K2EDTA blood collection tubes, Lot # 7305646, Expiration date: 03-31-2019, Quantity: 2 tubes e) BD Vacutainer Serum blood collection tubes, Lot # 6210581, Expiration date: 07-31-2018, Quantity: 100 tubes f) Copan Fecal Swab Collection, Transport, and Preservation of Enteric Bacteria, Lot # 180547500, Expiration date: 2019-06, Quantity: 9 swabs g) BD Universal Viral Transport for Viruses, Chlamydiae, Mycoplasmas, and Urea plasma, Lot # 172257700, Expiration date: 2019-05, Quantity: 14 swabs h) Remel Bactiswab, Lot # 017346, Expiration date: 2019-06-12, Quantity: 2 swabs i) Thermo Scientific Washing Solution 4.5 %, Lot P723, Expiration date: 2019-06-30, Quantity: 4 vials 2. In interview on September 17, 2019, the office practice manager and testing personnel confirmed the identified items were expired.

D5421

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE
CFR(s): 493.1253(b)(1)

Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

Based on observation, record review, and interview with personnel, the laboratory failed to have complete performance verification studies. Findings: 1. Observation by surveyor during laboratory tour on September 17, 2019 revealed the laboratory utilizes the Thermo Scientific Indiko Plus analyzer for urine drug screen (UDS) testing of the following: Amphetamine, Barbiturate, Benzodiazepine, Buprenorphine, Cannabinoid (THC), Cocaine, Ethyl Alcohol, Methadone, Opiate, Oxycodone, Phencyclidine (PCP), and Urine Creatinine. 2. Review of the United States Food and Drug Administration (FDA) database for laboratory test complexity revealed the following analytes for the Thermo Scientific Indiko Plus are categorized as moderate: Amphetamine, Barbiturate, Benzodiazepine, Buprenorphine, Cannabinoid (THC), Cocaine, Ethyl Alcohol, Methadone, Opiate, Oxycodone, and Phencyclidine (PCP). 3. Review of the laboratory's records revealed the laboratory did not have a written policy and procedure for performance specification studies. 4. In interview on

September 17, 2019, the Testing Personnel stated the laboratory began patient testing on February 14, 2019. 5. Review of the laboratory's validation binder revealed documentation of performance of accuracy, simple precision, and linearity studies. 6. Further review of the laboratory's validation records revealed the following items were not included: a) Laboratory Director's review/approval of validation studies b) Acceptability Criteria c) Precision, to include day-to day d) Reference Range 7. In interview on September 17, 2019 at 10:55 am, the Testing Personnel stated he was unsure what was done for the validation. The Testing Personnel further stated the company came and installed the instrument; he received training and assisted in running some samples. The Testing Personnel further stated the company said the instrument was good to go and the instrument was put into use by the laboratory. 8. Review of the laboratory's test menu revealed the laboratory performs 39,600 UDS tests annually.

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 observation, record review, and interview with personnel, the laboratory failed to establish performance specifications for urine creatinine testing on the Thermo Scientific Indiko Plus analyzer. Findings: 1. Observation by surveyor during the laboratory tour on September 17, 2019 revealed the laboratory utilizes the Thermo Scientific Indiko Plus for urine drug screening and urine creatinine testing. 2. Review of the United States Food and Drug Administration (FDA) database for laboratory tests complexity revealed urine creatinine was not approved or categorized.; therefore, considered a lab developed high complexity test. 3. In interview on September 17, 2019 at 9:21 am, the office practice manager stated the laboratory performs only moderate complexity tests. 4. Review of random selection of patient final reports revealed the laboratory reports urine creatinine to providers. 5. Review of the laboratory's records revealed the laboratory did not have a written policy and procedure for performance specification studies. 6. Review of the laboratory's validation binder for the Thermo Scientific Indiko Plus analyzer revealed the laboratory had documentation of performance of accuracy, simple precision, and linearity studies for urine creatinine. 7. Further review of the laboratory's validation records revealed the laboratory did not include the following: a) Laboratory Director's review/approval of validation studies b) Acceptability Criteria c) Precision, to include day-to day d) Reference Range d) analytical sensitivity e) analytical specificity (to include interfering substances). 8. In further interview on September 17, 2019, the office practice manager stated she was unaware urine creatinine was not moderately complex. 9. In interview on September 17, 2019 at 10:55 am, the Testing Personnel stated he was unsure what was done for the validation. The Testing Personnel further

stated the company came and installed the instrument, he received training and assisted in running some samples. The Testing Personnel further stated the company said the instrument was good to go and the instrument was put into use by the laboratory. 10. During the exit conference on September 17, 2019, the Laboratory Director (via telephone) stated he thought the urine creatinine was not reported. 11. Review of the laboratory's test menu revealed the laboratory performs 3,600 urine creatinine tests annually.

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 observation, record review, and interview with personnel, the laboratory failed to establish their own means and ranges for quality control (QC) material utilized for Urine Drug Screen (UDS) testing. Findings: 1. Observation by surveyor during the laboratory tour on September 17, 2019 revealed the laboratory utilized the Thermo Scientific Indiko Plus with UTAK DAU Level 1 and 2 controls for UDS testing. 2. Review of the UTAK package insert under "Expected Values" revealed "It is suggested that each laboratory establish means and ranges necessary." 3. Review of the laboratory's records revealed the laboratory did not have a written policy and procedure for quality control. 4. In interview on September 17, 2019 at 11:15 am, the office practice manager stated the laboratory did not have a policy and procedure manual. 5. Review of the laboratory's records revealed the laboratory did not have documentation the identified quality control means and ranges were established. 6. In interview on September 17, 2019 at 12:00 pm, the Testing Personnel stated the installation rep. set up the quality control in the instrument, 2 SD from the mean. 7. Review of the laboratory's test menu revealed the laboratory performs 39,600 UDS tests annually.

D5783

CORRECTIVE ACTIONS
CFR(s): 493.1282(b)(2)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.

This STANDARD is not met as evidenced by:

Based on observation, record review, and interview with personnel, the laboratory failed to take corrective action when quality control samples were unacceptable for Urine Drug Screen (UDS) testing. Findings: 1. Observation by surveyor during the laboratory tour on September 17, 2019 revealed the laboratory utilizes the Thermo Scientific Indiko Plus analyzer for urine drug screen (UDS) testing of the following: Amphetamine, Barbiturate, Benzodiazepine, Buprenorphine, Cannabinoid (THC), Cocaine, Ethyl Alcohol, Methadone, Opiate, Oxycodone, Phencyclidine (PCP), and Urine Creatinine. 2. Review of the laboratory's records revealed the laboratory did not have a written policy or procedure for quality control (QC) or actions to take for unacceptable results. 3. In interview on September 17, 2019 at 11:15 am, the office practice manager stated the laboratory did not have a policy and procedure manual. 4. In interview on September 17, 2019 at 11:20 am, the Testing Personnel stated the instrument alerts him if a control is out. The Testing Personnel stated if a control is out he calibrates the instrument and reruns QC. 5. In interview on September 17, 2019 at 12:00 pm, the Testing Personnel stated the installation rep. set up the quality control in the instrument. After contacting the service rep., the Testing Personnel stated the quality control is 2 SD from the mean in the instrument. 6. Review of the laboratory's QC records for February 2019, May 2019, and September 2019, manufacturer's package insert, and instrument QC values revealed the following QC results not within the laboratory's range: a) February 22, 2019: Opiates Level 2: 502 (acceptable range 310-490) Creatinine 7.5: 4.9 (acceptable range 6.5-8.5), Flag: "Viol. 2" Creatinine 23: 15.3 (acceptable range 20-26, Flag: "Viol. 2" Barbiturates Level 1: 200 (acceptable range 130-190) b) May 29, 2019: Creatinine 7.5: -69.6 (acceptable range 5.5-9.5) c) May 30, 2019: Creatinine 7.5: 3.8 (acceptable range 5.5-9.5) d) September 4, 2019: ETOH Level 1: 2.5 (acceptable range 10-90) reported at 9:33 am ETOH Level 2: 83.3 (acceptable range 110-190) reported at 4:22 pm 7. In interview on September 17, 2019, the Testing Personnel stated the instrument did not alert him of the identified unacceptable QC. 8. Review of the patient logs for the identified dates revealed the following patients were reported without corrective action: February 22, 2019: eleven (11) patients May 29, 2019: twenty one (21) patients May 30, 2019: three (3) patients September 4, 2019: six (6) patients

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 observation, record review, and interview with personnel, the laboratory failed to establish procedures to monitor, assess, and correct problems, identified with the analytic system. Findings: 1. The laboratory failed to establish a complete policy and procedure manual. Refer to D5401. 2. The laboratory failed to establish a policy and procedure manual. Refer to D5403. 3. The laboratory failed to monitor the room temperature and humidity of the laboratory where the instrument and supplies are stored per manufacturer requirements. Refer to D5413 I. 4. The laboratory failed to monitor the temperature of the two (2) refrigerators where laboratory reagents are

stored. Refer to D5413 II. 5. The laboratory failed to store reagents per manufacturer requirements. Refer to D5413 III. 6. The laboratory failed to ensure supplies did not exceed their expiration date. Refer to D5417. 7. The laboratory failed to have complete performance verification studies. Refer to D5421. 8. The laboratory failed to establish performance specifications for urine creatinine testing on the Thermo Scientific Indiko Plus analyzer. Refer to D5423. 9. The laboratory failed to establish their own means and ranges for quality control (QC) material utilized for Urine Drug Screen (UDS) testing. Refer to D5469. 10. The laboratory failed to take corrective action when quality control samples were unacceptable for Urine Drug Screen (UDS) testing. Refer to D5783.

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:

I. Based on record review and interview with personnel, the laboratory failed to ensure patient final reports included a second unique patient identifier. Findings: 1. Review of random selection of patient final reports revealed the laboratory did not include a second unique patient identifier. 2. In interview on September 17, 2019, the office practice manager stated the laboratory uses the patient's name and date of birth on the final reports as identifiers. 3. Review of the laboratory's test menu revealed the laboratory performs 39,600 Urine Drug Screen and 3,600 urine creatinine tests annually. II. Based on observation, record review, and interview with personnel, the laboratory failed to report Urine Drug Screen (UDS) results as required by the manufacturer. Findings: 1. Observation by surveyor during the laboratory tour on September 17, 2019 revealed the laboratory utilizes the Thermo Scientific Indiko Plus for UDS and urine creatinine testing. 2. Review of the Thermo Scientific CEDIA and DRI assay package inserts under "Intended Use" section revealed "This assay provides only a preliminary analytical test results. A more specific alternative chemical method must be used to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgement should be applied to any drug of abuse test result particularly when preliminary positive results are used." 3. Review of UDS final report for Patient 1 (Test date: September 4, 2019) revealed the laboratory did not include the indicated preliminary comment. 4. In interview on September 17, 2019, the office practice manager confirmed the laboratory did not report UDS results as stated in the manufacturer's package inserts. 5. Review of the laboratory's test menu revealed the laboratory performs 39,600 Urine Drug Screens annually. III. Based on observation, record review, and interview with personnel, the laboratory failed to include on the reports for urine creatinine a disclaimer stating "The performance characteristics for this test were determined by Houma Health Clinic. It has not been cleared or approved by the U.S. Food and Drug Administration." Findings: 1. Observation by surveyor during the laboratory tour on September 17, 2019 revealed

the laboratory utilizes the Thermo Scientific Indiko Plus for UDS and urine creatinine testing. 2. Review of the United States Food and Drug Administration (FDA) database for laboratory tests complexity revealed urine creatinine was not approved or categorized.; therefore, considered a lab developed high complexity test. 3. In interview on September 17, 2019, the office practice manager stated she was unaware urine creatinine was not moderately complex. 4. Review of random selection of patient test reports revealed the above disclaimer was not included on patient final reports for the non-FDA approved urine creatinine. 5. Review of the laboratory's test menu revealed the laboratory performs 3,600 urine creatinine tests annually

D5807

TEST REPORT
CFR(s): 493.1291(d)

Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.

This STANDARD is not met as evidenced by:
Based on record review and interview with personnel, the laboratory failed to ensure reference values were included on patient final test reports for Urine Drug Screens. Findings: 1. Review of final test report for Patient 1 (Test date September 4, 2019) revealed the laboratory reported a qualitative with measurement value. 2. Further review of the final test report revealed the laboratory included the following invalid reference ranges: Amphetamine "Ref. range *-999.0" Barbiturates "Ref. range *-199.0" Benzodiazepines "Ref. range *-199.0" Burprenorphine "Ref. range *-9.90" Cocaine "Ref. Ref. range *-299.0" Ethanol "Ref. range *-99.90" Methadone " Ref. range *-299.0" Opiates "Ref. range *-299.0" Oxycodone "Ref. range *-99.90" Phencyclidine "Ref. range *-24.90" THC "Ref. range "*-49.90" 3. In interview on September 17, 2019, the office manager confirmed the laboratory did not include valid reference ranges. 4. Review of the laboratory's test menu revealed the laboratory performs 39,600 Urine Drug Screens annually.

D5891

POSTANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1299(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 postanalytic systems specified in 493.1291.

This STANDARD is not met as evidenced by:
Based on record review and interview with personnel, the laboratory failed to establish procedures to monitor, assess, and correct problems, identified with the postanalytic system. Findings: 1. The laboratory failed to ensure patient final reports included a second unique patient identifier. Refer to D5805 I. 2. The laboratory failed to report Urine Drug Screen (UDS) results as required by the manufacturer. Refer to D5805 II. 3. The laboratory failed to include on the reports for urine creatinine a disclaimer stating "The performance characteristics for this test were determined by Houma Health Clinic. It has not been cleared or approved by the U.S. Food and Drug Administration." Refer to D5805 III. 4. The laboratory failed to ensure reference values were included on patient final test reports for Urine Drug Screens. Refer to D5807.

D6000

MODERATE COMPLEXITY LABORATORY DIRECTOR
CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:

Based on observation, record review, and interview with personnel, the Laboratory Director failed to provide overall management and direction for the laboratory. Findings: 1. The Laboratory Director failed to ensure that complete verification procedures were performed. Refer to D6013. 2. The Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Refer to D6014. 3. The Laboratory Director failed to ensure that a quality control program was established and maintained to assure quality laboratory services were provided. Refer to D6020. 4. The Laboratory Director failed to ensure that a quality assessment (QA) program was maintained to assure the quality of laboratory services provided. Refer to D6021. 5. The Laboratory Director failed to ensure corrective actions were taken and documented when deviations from laboratory's quality control limits occurred. Refer to D6024. 6. The Laboratory Director failed to ensure final reports for Urine Drug Screens and urine creatinine included required pertinent information. Refer to D6026. 7. The Laboratory Director failed to ensure Testing Personnel had appropriate training documentation and met licensure requirements. Refer to D6029. 8. The Laboratory Director failed to ensure policies and procedures for assessing personnel competency were established and maintained. Refer to D6030. 9. The Laboratory Director failed to ensure that an approved procedure manual was available to all personnel responsible for any aspect of the testing process. Refer to D6031. 10. The Laboratory Director failed to provide written job descriptions for all laboratory personnel. Refer to D6032.

D6013

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(3)(ii)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method;

This STANDARD is not met as evidenced by:

Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure that complete verification procedures were performed. Refer to D5421.

D6014

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(3)(iii)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently

and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results.

This STANDARD is not met as evidenced by:

Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Findings: 1. The laboratory failed to verify the accuracy of all non-regulated analytes at least twice annually. Refer to D5217. 2. The laboratory failed to monitor the room temperature and humidity of the laboratory where the instrument and supplies are stored per manufacturer requirements. Refer to D5413 I. 3. The laboratory failed to monitor the temperature of the two (2) refrigerators where laboratory reagents are stored. Refer to D5413 II. 4. The laboratory failed to store reagents per manufacturer requirements. Refer to D5413 III. 5. The laboratory failed to ensure supplies did not exceed their expiration date. Refer to D5417.

D6020

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(5)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure that a quality control program was established and maintained to assure quality laboratory services were provided. Refer to D5469.

D6021

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(5)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure that a quality assessment (QA) program was maintained to assure the quality of laboratory services provided. Findings: 1. The laboratory failed to establish procedures to monitor, assess, and correct problems, identified with the analytic system. Refer to D5791. 2. The laboratory failed to establish procedures to monitor, assess, and correct problems, identified with the postanalytic system. Refer to D5891.

D6024

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(7)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified,

This STANDARD is not met as evidenced by:

Based on observation, record review and interview with personnel, the Laboratory Director failed to ensure corrective actions were taken and documented when deviations from laboratory's quality control limits occurred. Refer to D5783.

D6026

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(8)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(8) Ensure that reports of test results include pertinent information required for interpretation.

This STANDARD is not met as evidenced by:

Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure final reports for Urine Drug Screens and urine creatinine included required pertinent information. Findings: 1. The laboratory failed to ensure patient final reports included a second unique patient identifier. Refer to D5805 I. 2. The laboratory failed to report Urine Drug Screen (UDS) results as required by the manufacturer. Refer to D5805 II. 3. The laboratory failed to include on the reports for urine creatinine a disclaimer stating "The performance characteristics for this test were determined by Houma Health Clinic. It has not been cleared or approved by the U.S. Food and Drug Administration." Refer to D5805 III. 4. The laboratory failed to ensure reference values were included on patient final test reports for Urine Drug Screens. Refer to D5807.

D6029

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(11)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) 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 record review and interview with personnel, the Laboratory Director failed to ensure Testing Personnel had appropriate training documentation and met licensure requirements. Findings: 1. In interview on September 17, 2019, the Testing Personnel stated he received instrument training from the service installation rep. The Testing Personnel further stated the Laboratory Director sat in on some of the training. 2. Review of the laboratory's records revealed the laboratory did not have documentation of the Testing Personnel's initial laboratory orientation or Laboratory Director's approval/signature for patient testing. 3. The laboratory failed to ensure testing personnel met the state of Louisiana licensure requirement. Refer to D6064.

D6030

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(12)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

This STANDARD is not met as evidenced by:
Based on record review and interview with personnel, the Laboratory Director failed to ensure policies and procedures for assessing personnel competency were established and maintained. Findings: 1. The laboratory failed to establish written policies and procedures to assess competency assessment policies for testing personnel. Refer to D5209. 2. The Technical Consultant failed to perform a competency assessment at least semi-annually during the first year for the testing personnel. Refer to D6053.

D6031

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(13)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process;

This STANDARD is not met as evidenced by:
Based on record review and interview with laboratory personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel responsible for any aspect of the testing process. Findings: 1. The

laboratory failed to establish a complete policy and procedure manual. Refer to D5401. 2. The laboratory failed to establish a policy and procedure manual. Refer to D5403.

D6032

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(14)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:

Based on record review and interview with personnel, the Laboratory Director failed to provide written job descriptions for all laboratory personnel. Findings: 1. Review of the laboratory's documents and personnel records revealed the laboratory did not have written job descriptions for the following personnel: Laboratory Director (who also serves as the Technical Consultant and Clinical Consultant) Testing Personnel 2. In interview on September 17, 2019 at 11:15 am, the office practice manager stated the laboratory did not have a policy and procedure manual.

D6053

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

Based on record review and interview with personnel, the Technical Consultant failed to perform a competency assessment at least semi-annually during the first year for the testing personnel. Findings: 1. Review of the laboratory's CMS 209 (Laboratory Personnel Report) revealed the laboratory has one (1) testing personnel. 2. In interview on September 17, 2019 at 9:50 am, the Testing Personnel stated he received training from the service rep. who did the installation of the instrument in February. The Testing Personnel further stated he began patient testing on February 14, 2019. 3. Review of personnel records revealed the Testing Personnel did not have documentation of a semi-annual competency assessment due August 2019. 4. In interview on September 17, 2019 at 11:07 am, the Testing Personnel confirmed the Laboratory Director did not perform a competency assessment for him.

D6063

LABORATORY TESTING PERSONNEL
CFR(s): 493.1421

The laboratory must have a sufficient number of individuals who meet the

	<p>qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.</p> <p>This CONDITION is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to provide documentation to ensure testing personnel met licensure requirements. Refer to D6064.</p>
D6064	<p>TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(a)</p> <p>Each individual performing moderate complexity testing must possess a current license issued by the State in which the laboratory is located, if such licensing is required.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to ensure testing personnel met the state of Louisiana licensure requirement. Findings: 1. Review of the laboratory's CMS 209 (Laboratory Personnel Report) revealed the laboratory had one (1) testing personnel. 2. Review of personnel records for the testing personnel revealed no documentation of a Louisiana State Board of Medical Examiners (LSBME) license for laboratory testing. 3. In interview on September 17, 2019 at 11:07 am, the Testing Personnel stated he did not have a LSBME license.</p>
D6076	<p>LABORATORY DIRECTOR CFR(s): 493.1441</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on observation, record review and interview with personnel, the Laboratory Director failed to provide overall management and direction. Findings: 1. The Laboratory Director failed to establish complete performance characteristics for urine creatinine. Refer to D6086. 2. The Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Refer to D6087. 3. The Laboratory Director failed to ensure that a quality assessment (QA) program was maintained to assure the quality of laboratory services provided. Refer to D6094. 4. The Laboratory Director failed to ensure final reports for urine creatinine included required pertinent information. Refer to D6098. 5. The Laboratory Director failed to ensure all personnel had the appropriate education, licensure, training, and experience for performing high complexity testing. Refer to D6102. 6. The Laboratory Director failed to ensure policies and procedures for assessing personnel competency were established and maintained. Refer to D6103. 7. The Laboratory Director failed to ensure that an approved procedure manual was available to all personnel responsible for any aspect of the testing process. Refer to D6106. 8. The Laboratory Director failed to provide written job descriptions for all laboratory personnel. Refer to D6107.</p>
D6086	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii)</p>

The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method.

This STANDARD is not met as evidenced by:
Based on observation, record review, and interview with personnel, the Laboratory Director failed to establish complete performance characteristics for urine creatinine. Refer to D5423.

D6087

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(3)(iii)

The laboratory director must ensure that laboratory personnel are performing the test methods as required for accurate and reliable results.

This STANDARD is not met as evidenced by:
Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Findings: 1. The laboratory failed to verify the accuracy of all non-regulated analytes at least twice annually. Refer to D5217. 2. The laboratory failed to monitor the room temperature and humidity of the laboratory where the instrument and supplies are stored per manufacturer requirements. Refer to D5413 I. 3. The laboratory failed to monitor the temperature of the two (2) refrigerators where laboratory reagents are stored. Refer to D5413 II. 4. The laboratory failed to store reagents per manufacturer requirements. Refer to D5413 III.

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 observation, record review, and interview with personnel, the Laboratory Director failed to ensure that a quality assessment (QA) program was maintained to assure the quality of laboratory services provided. Findings: 1. The laboratory failed to establish procedures to monitor, assess, and correct problems, identified with the analytic system. Refer to D5791. 2. The laboratory failed to establish procedures to monitor, assess, and correct problems, identified with the postanalytic system. Refer to D5891.

D6098

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(8)

The laboratory director must ensure that reports of test results include pertinent information required for interpretation.

This STANDARD is not met as evidenced by:
Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure final reports for urine creatinine included required pertinent information. Findings: 1. The laboratory failed to ensure patient final reports included a second unique patient identifier. Refer to D5805 I. 2. The laboratory failed to include on the reports for urine creatinine a disclaimer stating "The performance characteristics for this test were determined by Houma Health Clinic. It has not been cleared or approved by the U.S. Food and Drug Administration." Refer to D5805 III.

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 observation, record review, and interview with personnel, the Laboratory Director failed to ensure all personnel had the appropriate education, licensure, training, and experience for performing high complexity testing. Findings: 1. In interview on September 17, 2019, the Testing Personnel stated he received instrument training from the service installation rep. The Testing Personnel further stated the Laboratory Director sat in on some of the training. 2. Review of the laboratory's records revealed the laboratory did not have documentation of the Testing Personnel's initial laboratory orientation or Laboratory Director's approval/signature for patient testing. 3. The Technical Supervisor failed to meet the experience qualification. Refer to D6111. 4. The laboratory failed to ensure testing personnel met the state of Louisiana licensure requirement to perform high complexity testing. Refer to D6170. 5. The laboratory failed to provide documentation that testing personnel met the educational qualifications for performing high complexity testing. Refer to D6171.

D6103

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(13)

The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills.

This STANDARD is not met as evidenced by:
Based on record review and interview with personnel, the Laboratory Director failed to ensure policies and procedures for assessing personnel competency were established and maintained. Findings: 1. The laboratory failed to establish written policies and procedures to assess competency assessment policies for testing

	<p>personnel. Refer to D5209. 2. The Technical Supervisor failed to perform a competency assessment at least semi-annually during the first year for the testing personnel. Refer to D6120.</p>
<p>D6106</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14)</p> <p>The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with laboratory personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel responsible for any aspect of the testing process. Findings: 1. The laboratory failed to establish a complete policy and procedure manual. Refer to D5401. 2. The laboratory failed to establish a policy and procedure manual. Refer to D5403.</p>
<p>D6107</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15)</p> <p>The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to provide written job descriptions for all laboratory personnel. Findings: 1. Review of the laboratory's documents and personnel records revealed the laboratory did not have written job descriptions for the following personnel: Laboratory Director (who was listed as Clinical Consultant, Technical Supervisor, and General Supervisor) Testing Personnel 2. In interview on September 17, 2019 at 11:15 am, the office practice manager stated the laboratory did not have a policy and procedure manual.</p>
<p>D6108</p>	<p>LABORATORY TECHNICAL SUPERVISOR CFR(s): 493.1447</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on observation, record review, and interview with personnel, the Technical Supervisor failed to provide technical oversight for high complexity testing. Findings:</p>

1. The Technical Supervisor failed to meet the experience qualification. Refer to D6111. 2. The Technical Supervisor failed to perform a competency assessment at least semi-annually during the first year for the testing personnel. Refer to D6120.

D6111

TECHNICAL SUPERVISOR QUALIFICATIONS

CFR(s): 493.1449

(a) The technical supervisor must possess a current license issued by the State in which the laboratory is located, if such licensing is required; and (b) The laboratory may perform anatomic and clinical laboratory procedures and tests in all specialties and subspecialties of services except histocompatibility and clinical cytogenetics services provided the individual functioning as the technical supervisor-- (b)(1) Is a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(2) Is certified in both anatomic and clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or Possesses qualifications that are equivalent to those required for such certification. (c) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of bacteriology, the individual functioning as the technical supervisor must-- (c)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (c)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (c)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (c)(2)(ii) Have at least one year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of bacteriology; or (c)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (c)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of bacteriology; or (c)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (c)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of bacteriology; or (c)(5)(i) Have earned a bachelor's degree in a chemical, physical, or biological science or medical technology from an accredited institution; and (c)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of bacteriology. (d) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of mycobacteriology, the individual functioning as the technical supervisor must-- (d)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (d)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (d)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor or podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (d)(2)(ii) Have at least 1 year of laboratory training or

experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycobacteriology; or (d)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (d)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycobacteriology; or (d)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (d)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycobacteriology; or (d)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (d)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycobacteriology. (e) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of mycology, the individual functioning as the technical supervisor must-- (e)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (e)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (e)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (e)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycology; or (e)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (e)(3)(ii) Have at least 1 year of laboratory training or experience, or both in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycology; or (e)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (e)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycology; or (e)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (e)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycology. (f) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of parasitology, the individual functioning as the technical supervisor must-- (f)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (f)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (f)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (f)(2)(ii) Have at least one year of

laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of parasitology; (f)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (f)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of parasitology; or (f)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (f)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of parasitology; or (f)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (f)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of parasitology. (g) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of virology, the individual functioning as the technical supervisor must-- (g)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (g)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (g)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (g)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of virology; or (g)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (g)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of virology; or (g)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (g)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of virology; or (g)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (g)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of virology. (h) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of diagnostic immunology, the individual functioning as the technical supervisor must- (h)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (h)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (h)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (h)(2)(ii) Have at least 1 year of

laboratory training or experience, or both, in high complexity testing for the specialty of diagnostic immunology; or (h)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (h)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of diagnostic immunology; or (h)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (h)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing for the specialty of diagnostic immunology; or (h)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (h)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing for the specialty of diagnostic immunology. (i) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of chemistry, the individual functioning as the technical supervisor must-- (i)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (i)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (i)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (i)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing for the specialty of chemistry; or (i)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (i)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of chemistry; or (i)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (i)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing for the specialty of chemistry; or (i)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (i)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing for the specialty of chemistry. (j) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of hematology, the individual functioning as the technical supervisor must-- (j)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (j)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (j)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (j)(2)(ii) Have at least one year of laboratory training or experience, or both, in high complexity testing for the specialty of hematology (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or (j)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (j)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of hematology; or (j)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (j)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing for the specialty of hematology; or (j)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or

medical technology from an accredited institution; and (j)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing for the specialty of hematology. (k)(1) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of cytology, the individual functioning as the technical supervisor must-- (k)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (k)(1)(ii) Meet one of the following requirements-- (k)(1)(ii)(A) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (k)(1)(ii)(B) Be certified by the American Society of Cytology to practice cytopathology or possess qualifications that are equivalent to those required for such certification; (l) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of histopathology, the individual functioning as the technical supervisor must-- (l)(1) Meet one of the following requirements: (l)(1)(i)(A) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (l)(1)(i)(B) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; (l)(1)(ii) An individual qualified under 493.1449(b) or paragraph (l)(1) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraph (b) or (l)(1)(i)(B) of this section, the responsibility for examination and interpretation of histopathology specimens. (l)(2) For tests in dermatopathology, meet one of the following requirements: (l)(2)(i)(A) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located and-- (l)(2)(i)(B) Meet one of the following requirements: (l)(2)(i)(B)(1) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (l)(2)(i)(B)(2) Be certified in dermatopathology by the American Board of Dermatology and the American Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (l)(2)(i)(B)(3) Be certified in dermatology by the American Board of Dermatology or possess qualifications that are equivalent to those required for such certification; or (l)(2)(ii) An individual qualified under 493.1449(b) or paragraph (l)(2)(i) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraphs (b) or (l)(2)(i)(B) of this section, the responsibility for examination and interpretation of dermatopathology specimens. (l)(3) For tests in ophthalmic pathology, meet one of the following requirements: (l)(3)(i)(A) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located and-- (l)(3)(i)(B) Must meet one of the following requirements: (l)(3)(i)(B)(1) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (l)(3)(i)(B)(2) Be certified by the American Board of Ophthalmology or possess qualifications that are equivalent to those required for such certification and have successfully completed at least 1 year of formal post-residency fellowship training in ophthalmic pathology; or (l)(3)(ii) An individual qualified under 493.1449(b) or paragraph (l)(3)(i) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraphs (b) or (l)(3)(i)(B) of this section, the responsibility for examination and interpretation of ophthalmic specimens; or (m) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of oral pathology, the individual

functioning as the technical supervisor must meet one of the following requirements:

(m)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located and-- (m)(1)(ii) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (m)(2) Be certified in oral pathology by the American Board of Oral Pathology or possess qualifications for such certification; or (m)(3) An individual qualified under 493.1449(b) or paragraph (m)(1) or (2) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraphs (b) or (m)(1) or (2) of this section, the responsibility for examination and interpretation of oral pathology specimens. (n) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of radiobioassay, the individual functioning as the technical supervisor must-- (n)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (n)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (n)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (n)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing for the specialty of radiobioassay; or (n)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (n)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of radiobioassay; or (n)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (n)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing for the specialty of radiobioassay; or (n)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (n)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing for the specialty of radiobioassay. (o) If the laboratory performs tests in the specialty of histocompatibility, the individual functioning as the technical supervisor must either-- (o)(1)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (o)(1)(ii) Have training or experience that meets one of the following requirements: (o)(1)(ii)(A) Have 4 years of laboratory training or experience, or both, within the specialty of histocompatibility; or (o)(1)(ii)(B)(1) Have 2 years of laboratory training or experience, or both, in the specialty of general immunology; and (o)(1)(ii)(B)(2) Have 2 years of laboratory training or experience, or both, in the specialty of histocompatibility; or (o)(2)(i) Have an earned doctoral degree in a biological or clinical laboratory science from an accredited institution; and (o)(2)(ii) Have training or experience that meets one of the following requirements: (o)(2)(ii)(A) Have 4 years of laboratory training or experience, or both, within the specialty of histocompatibility; or (o)(2)(ii)(B)(1) Have 2 years of laboratory training or experience, or both, in the specialty of general immunology; and (o)(2)(ii)(B)(2) Have 2 years of laboratory training or experience, or both, in the specialty of histocompatibility. (p) If the laboratory performs tests in the specialty of clinical cytogenetics, the individual functioning as the technical supervisor must-- (p)(1)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (p)(1)(ii) Have 4 years of training or experience, or both, in genetics, 2 of

which have been in clinical cytogenetics; or (p)(2)(i) Hold an earned doctoral degree in a biological science, including biochemistry, or clinical laboratory science from an accredited institution; and (p)(2)(ii) Have 4 years of training or experience, or both, in genetics, 2 of which have been in clinical cytogenetics. (q) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of immunohematology, the individual functioning as the technical supervisor must-- (q)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (q)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (q)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (q)(2)(ii) Have at least one year of laboratory training or experience, or both, in high complexity testing for the specialty of immunohematology. Note: The technical supervisor requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service. For example, an individual, who has a doctoral degree in chemistry and additionally has documentation of 1 year of laboratory experience working concurrently in high complexity testing in the specialties of microbiology and chemistry and 6 months of that work experience included high complexity testing in bacteriology, mycology, and mycobacteriology, would qualify as the technical supervisor for the specialty of chemistry and the subspecialties of bacteriology, mycology, and mycobacteriology.

This STANDARD is not met as evidenced by:
 Based on observation, record review, and interview with personnel, the Technical Supervisor failed to meet the experience qualification. Findings: 1. Observation by surveyor during the laboratory tour on September 17, 2019 revealed the laboratory utilizes the Thermo Scientific Indiko Plus for urine drug screening and urine creatinine testing. 2. Review of the United States Food and Drug Administration (FDA) database for laboratory tests complexity revealed urine creatinine was not approved or categorized.; therefore, considered a lab developed high complexity test. 3. Review of the laboratory's CMS 209 (Laboratory Personnel Report) form revealed the Laboratory Director was listed as the Technical Supervisor. 4. Review of the Laboratory Director's resume revealed no documentation of at least one (1) year laboratory training or experience in high complexity testing for the specialty of Chemistry. 5. In interview on September 17, 2019 the office practice manager stated the Laboratory Director previously served as a Technical Consultant (moderate complexity) for the laboratory. 6. In further interview on September 17, 2019, the office practice manager stated she was unaware urine creatinine was not moderately complex. 7. During the exit conference on September 17, 2019, the Laboratory Director (via telephone) stated he thought the urine creatinine was not reported.

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 record review and interview with personnel, the Technical Supervisor failed to perform a competency assessment at least semi-annually during the first year for the testing personnel. Findings: 1. Review of the laboratory's CMS 209 (Laboratory Personnel Report) revealed the laboratory has one (1) testing personnel. 2. In interview on September 17, 2019 at 9:50 am, the Testing Personnel stated he received training from the service rep. who did the installation of the instrument in February. The Testing Personnel further stated he began patient testing on February 14, 2019. 3. Review of personnel records revealed the Testing Personnel did not have documentation of a semi-annual competency assessment due August 2019. 4. In interview on September 17, 2019 at 11:07 am, the Testing Personnel confirmed a competency assessment was not performed.

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 observation, record review, and interview with personnel, the laboratory failed to provide documentation to ensure testing personnel met educational and licensure requirements for performing high complexity testing. Findings: 1. The laboratory failed to ensure testing personnel met the state of Louisiana licensure requirement to perform high complexity testing. Refer to D6170. 2. The laboratory failed to provide documentation that testing personnel met the educational qualifications for performing high complexity testing. Refer to D6171.

D6170

TESTING PERSONNEL QUALIFICATIONS

CFR(s): 493.1489(a)

Each individual performing high complexity testing must possess a current license issued by the State in which the laboratory is located, if such licensing is required.

This STANDARD is not met as evidenced by:

Based on observation, record review, and interview with personnel, the laboratory failed to ensure testing personnel met the state of Louisiana licensure requirement to perform high complexity testing. Findings: 1. Observation by surveyor during the laboratory tour on September 17, 2019 revealed the laboratory utilizes the Thermo Scientific Indiko Plus for urine drug screening and urine creatinine testing. 2. Review of the United States Food and Drug Administration (FDA) database for laboratory tests complexity revealed urine creatinine was not approved or categorized.; therefore, considered a lab developed high complexity test. 3. Review of the laboratory's CMS 209 (Laboratory Personnel Report) revealed the laboratory had one (1) testing personnel. 4. Review of personnel records for the testing personnel revealed no

documentation of a Louisiana State Board of Medical Examiners (LSBME) license for laboratory testing. 5. In interview on September 17, 2019 at 11:07 am, the Testing Personnel stated he did not have a LSBME license.

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 observation, record review, and interview with personnel, the laboratory failed to provide documentation that testing personnel met the educational qualifications for performing high complexity testing. Findings: 1. Observation by surveyor during the laboratory tour on September 17, 2019 revealed the laboratory utilizes the Thermo Scientific Indiko Plus for urine drug screening and urine creatinine testing. 2. Review of the United States Food and Drug Administration (FDA) database for laboratory tests complexity revealed urine creatinine was not approved or categorized.; therefore, considered a lab developed high complexity test. 3. Review of the laboratory's CMS 209 (Laboratory Personnel Report) revealed the laboratory had one (1) testing personnel. 4. Review of personnel records for the testing personnel revealed the laboratory had documentation of a high school diploma and Bachelor's degree in Business Administration, not of the minimum qualifications for high complexity testing. 5. In interview on September 17, 2019, the office practice manager stated she was unaware urine creatinine was not moderately complex.