

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D2057418	(X3) Date Survey Completed 07/13/2023
Name of Provider or Supplier Family Medicine & Rehabilitation Center, Pc	Street Address, City, State 2902 Central Heights Road, Goldsboro, NC	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5022	<p>TOXICOLOGY CFR(s): 493.1213</p> <p>If the laboratory provides services in the subspecialty of Toxicology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, and 493.1281 through 493.1299.</p> <p>This CONDITION is not met as evidenced by: Based on surveyor observations, review of laboratory policies and procedures, review of laboratory accession logs, review of Pictus 700 analyzer maintenance and quality control (QC) records, review of liquid chromatography mass spectrometry (LC/MS) analyzer maintenance records and interviews with laboratory director (LD) and technical supervisor (TS) 7/13/23, the laboratory failed to monitor and evaluate the overall quality of toxicology testing, identify problems and implement corrections. Findings: 1. The laboratory failed to ensure reagents for the Pictus 700 analyzer and LC/MS analyzer had not exceeded expiration dates (see D5417). 2. The laboratory failed to ensure required maintenance of the Pictus 700 analyzer was documented (see D5429). 3. The laboratory failed to ensure annual preventive maintenance was performed on the LC/MS analyzer (see D5433). 4. The laboratory failed to perform and/or document the performance of QC on the Pictus 700 analyzer (see D5445). 5. The laboratory failed to prepare LC/MS QC and calibration reagents from different standard stock solutions (see D5467).</p>
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>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.</p>

This STANDARD is not met as evidenced by:
Based on review of 2021, 2022 and 2023 laboratory records and interview with the TS 7/13/2023, the laboratory failed to perform a twice annual verification of accuracy of the LC/MS urine toxicology testing in 2021, 2022 and 2023, approximately 30 months in which a verification of accuracy was not performed. Findings: Review of 2021, 2022 and 2023 laboratory records for the verification of accuracy of LC/MS urine toxicology testing revealed no documentation. Interview with the TS at approximately 10:05 a.m. confirmed there was no documentation of a verification of accuracy for 2021, 2022 and 2023. The TS stated she did not think this had been done.

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 surveyors observations, review of laboratory accession logs and interviews with LD 7/13/23, the laboratory failed to ensure calibration reagents for the Pictus 700 urine drug screen analyzer had not exceeded their expiration dates before patient testing was performed, approximately 68 patients were tested. The laboratory also failed to discard reagents for the LC/MS that had exceeded expiration dates. Findings:
1. At approximately 9:45 a.m. a surveyor observed 2 bottles of calibration reagent, DRI Multi-Drug Urine Calibrator 4 - Lot # 74636309 and DRI Multi-Drug Urine Calibrator 2 - Lot # 74636302, in the door of laboratory refrigerator #2 on a shelf labeled Pictus 700 calibrators. The 2 bottles of calibration reagent had a written expiration date of 5/31/23. Review of laboratory accession logs revealed urine drug screens were performed on specimens received from 6/1/23 thru 6/11/23, approximately 68 patients were tested. Interview with LD at approximately 9:45 a.m. and 1:00 p.m. confirmed the 2 bottles of calibration reagent had exceeded their expiration dates of 5/31/23. He also confirmed urine drug screens were performed on specimens received 6/1/23 thru 6/11/23. The LD disposed of the expired reagents at time of survey. 2. At approximately 9:45 a.m. a surveyor observed 1 bottle of "Rapid Hydrolysis Buffer" - Lot # RHB-1001 with an expiration date of 10/22 and 1 bottle of "IMC5Zyme" reagent - Lot # E21-11002B with an expiration date of 2/20/23, in the door of laboratory refrigerator #2 on a shelf labeled LC/MS reagents. Interview with LD at approximately 9:45 a.m. confirmed the 2 bottles of reagent had exceeded their expiration dates. The LD disposed of the expired reagents at time of survey. 3. At approximately 9:45 a.m. a surveyor observed the following supplies in use on the LCMS instrument: a. 0.1 Formic Acid in H2O, expiration 2/23/23. b. Organic Solvent, expiration 2/19/23. c. LCMS Water, lot # DR401-D-45, expiration 7/1/21. d. Acetonitrile, lot # 58124, expiration 7/2/21. 4. At approximately 11:45 a.m. a surveyor observed the following supplies in the Flammables cabinet in the hallway outside the laboratory, available for use: a. 1 bottle of EKI Hydrochloric Acid Solution 0.100 Normal (lot #1733902, expiration date 12/8/19). b. 1 bottle of Birch Biotech LC-MS Grade Methanol (no lot #) with a handwritten in-use date of 12/5/22 and a handwritten expiration date of 6/5/23. c. 1 bottle of 2-Propanol HPLC Grade (lot #174182, expiration date 7/31/22.

D5429

MAINTENANCE AND FUNCTION CHECKS
CFR(s): 493.1254(a)(1)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:

Based on review of 2021, 2022 and 2023 Pictus 700 analyzer maintenance logs and interview with LD 7/13/23, the laboratory failed to ensure required maintenance of the Pictus 700 analyzer was documented for 6 of 36 months reviewed. Findings: Review of 2021, 2022 and 2023 maintenance logs for the Pictus 700 revealed the maintenance logs were blank for the months of January 2022 through June 2022, 6 months in which maintenance was not documented. Interview with LD at approximately 12:00 p. m. confirmed the laboratory had no documentation for the maintenance of the Pictus 700 analyzer from January 2022 through June 2022.

D5433

MAINTENANCE AND FUNCTION CHECKS
CFR(s): 493.1254(b)(1)

For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.

This STANDARD is not met as evidenced by:

Based on review of laboratory policy, review of 2021, 2022 and 2023 LC/MS analyzer maintenance records and interview with the TS 7/13/2023, the laboratory failed to ensure annual preventive maintenance was performed on the LC/MS analyzer for a period of approximately 30 months. Findings: Review of the laboratory policy revealed in section "N. Function Checks, Instrument Maintenance...Annual Preventive Maintenance of the LC/MS/MS instrument system is performed by a certified manufacturer service engineer.". The review of 2021, 2022 and 2023 LC/MS maintenance records revealed no documentation of the performance of annual preventive maintenance. Interview with the TS at 9:50 a.m. confirmed annual preventive maintenance of the LC/MS analyzer was not performed in 2021, 2022 and 2023.

D5445

CONTROL PROCEDURES
CFR(s): 493.1256(d)(1)(2)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--
(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on review of 2021, 2022 and 2023 quality control (QC) records for the Pictus 700 analyzer and interview with LD 7/13/23, the laboratory failed to perform and/or document the performance of QC on the Pictus 700 analyzer 19 of 36 months reviewed. Findings: Review of 2021, 2022 and 2023 QC records for the Pictus 700 analyzer revealed no documentation QC was performed for the following time periods. 1. January and February of 2021 2. April, May, June, July, August, September. October, November, and December of 2021. 3. January and February of 2022. 4. April, May, June, July, August and September of 2022. Interview with LD at approximately 1:00 p.m. confirmed the laboratory was unable to locate all QC records for the Pictus 700 analyzer. He stated that testing personnel had quit unexpectedly without advising new testing personnel of the location of QC records and also the Pictus 700 was unable to retain QC records beyond September of 2022.

D5467

CONTROL PROCEDURES
CFR(s): 493.1256(d)(9)(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--
When using calibration material as a control material, use calibration material from a different lot number than that used to establish a cut-off value or to calibrate the test system. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on interview with the TS 7/13/23, the laboratory failed to prepare LC/MS QC and calibration reagents from different standard stock solutions. Findings: During interview with the TS at approximately 9:50 a.m., the TS stated that both QC and calibration reagents are prepared from the same standard stock solution.

D6076

LABORATORY DIRECTOR
CFR(s): 493.1441

The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.

This CONDITION is not met as evidenced by:
Based on review of laboratory policies and procedures, review of LC/MS verification of accuracy and QC records, review of personnel records and interviews with LD and TS 7/13/23, the LD failed to provide overall management and direction for the laboratory services provided. Findings: 1. The LD failed to ensure a verification of accuracy of the LC/MS urine toxicology testing was performed twice annually (see D6086). 2. The LD failed to ensure the maintenance of the quality assessment program to identify and correct problems and prevent their recurrence (see D6094). 3. The LD failed to ensure 1 of 1 testing personnel (TP) received appropriate training and could perform all testing operations reliably prior to testing patient specimens (see D6102). 4. The LD failed to evaluate and document the competency of the TS during 2021, 2022, and 2023 (see D6103). 5. The LD failed to ensure the procedures for the performance of QC and calibration on the Pictus 700 analyzer included the levels and /or type of QC and calibration reagents used by the laboratory (see D6106).

<p>D6086</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii)</p> <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.</p> <p>This STANDARD is not met as evidenced by: Based on review of 2021, 2022 and 2023 laboratory records and interview with the TS 7/13/2023, the LD failed to ensure a verification of accuracy of the LC/MS urine toxicology testing was performed twice annually. Findings: Review of 2021, 2022 and 2023 laboratory records revealed no documentation of a twice annual verification of accuracy for the LC/MS urine toxicology testing (see D5217).</p>
<p>D6094</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory quality assessment plan 7/13/23 and deficiencies cited at D6086, D6102, D6103, D6106, and D6123, the LD failed to ensure the maintenance of the quality assessment program to identify and correct problems and prevent their recurrence. Findings: The laboratory's "Quality Assessment Plan" states "... Responsibility The lab service is under the jurisdiction of the Lab Director. It is the responsibility of the Technical Consultant to implement the plan. The Laboratory Director and Technical Consultant will be responsible either directly or by delegation for the following: ... Periodic review of a problem log and action logs which are kept by testing personnel, and resolution of any problem not immediately addressed by the personnel. ... Implementation of policies and procedures as well as evaluation of their effectiveness. Assuring the prompt, accurate, and reliable reporting of test results. Assuring the adequacy and competency of staff. Maintaining required enrollment in Proficiency Testing programs, with appropriate review and actions. Overseeing the Quality Control program. ..." The laboratory's quality assessment program failed to identify problems in the following areas identified during the survey: 1. Enrollment in proficiency testing or verification of accuracy for LCMS testing (see D6086). 2. Training and competency of personnel (see D6102, D6103). 3. Procedure manual (see D6106). 4. Quality control review (see D6123).</p>
<p>D6102</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12)</p> <p>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.</p>

This STANDARD is not met as evidenced by:
 Based on review laboratory policies and procedures, review of personnel records, and interview with the TS 7/13/23, the LD failed to ensure 1 of 1 testing personnel (TP) received appropriate training and could perform all testing operations reliably prior to testing patient specimens. Findings: Review of the laboratory's policies and procedures revealed the "EMPLOYEE ORIENTATION/CONTINUING EDUCATION" policy states "ORIENTATION OF NEW EMPLOYEES A general orientation/training which includes all facets of testing within the lab is done to train the employee. Orientation of a new employee may be done by existing testing personnel. Validation of competency of the employee shall be done by the Technical Consultant in accordance with CLIA regulations. The employee should be required to read and sign/initial all manuals as well. The orientation and competencies shall be documented. The employee will sign competency evaluations. ...". Review of personnel records revealed TP #1 was hired 5/8/23. Personnel records included "LC /MS Sample Preparation Training" that was performed 5/10/23 by the TS. Records also included an initial competency assessment for "SAMPLE PREP" performed 5/8 /23 by the TS. During interview at approximately 11:40 a.m., the TS stated that TP #1 had received approximately 2 days of training on the Pictus 700 from the laboratory's former TP, but they were unable to locate any documentation of the training. The TS stated that she trained TP #1 on sample prep for LC/MS, but not on analysis and interpretation of LC/MS chromatograms for patient test results. The TS stated she was not trained on analysis and interpretation of LC/MS chromatograms.

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 review of personnel records and interview with the TS 7/13/23, the LD failed to evaluate and document the competency of the TS during 2021, 2022, and 2023. Findings: Review of personnel records revealed the TS was hired in December 2020. The only competency evaluation available for the TS was dated 10/13/20. All criteria listed on the form were marked with a check mark and "Competency has been satisfactorily demonstrated" was checked "Yes". The evaluation was not signed by the LD, and it was unclear who completed the evaluation form. During interview at approximately 12:05 p.m., the TS stated she thought a former LD had evaluated her competency, but she was unable to locate any documentation.

D6106

LABORATORY DIRECTOR RESPONSIBILITIES
 CFR(s): 493.1445(e)(14)

The laboratory director must 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 review of laboratory procedure manual, and review of manufacturer package inserts 7/13/23, the LD failed to ensure the procedures for the performance of QC and calibration on the Pictus 700 analyzer included the levels and/or type of QC and calibration reagents used by the laboratory. Findings: ... Review of laboratory procedure manual for the Pictus 700 analyzer revealed the laboratory utilizes the manufacturer package inserts for the performance of QC and calibration. Review of manufacturer package inserts revealed the package inserts fail to define the specific level and type of QC reagents utilized by the laboratory for the performance of QC on the Pictus 700 analyzer. For example: a. Package insert "DRI Cannabinoid Assay" revealed "Quality Control and Calibration...Use controls near the cutoff calibrator to validate the calibration.". b. Package insert "DRI Oxycodone Assay" revealed "Quality Control and Calibration...Qualitative analysis...For qualitative analysis of samples, use either the Oxycodone 100 Calibrator, or the Oxycodone 300 calibrator, as a cutoff level.". c. Package insert "DRI Opiate Assay" revealed "Quality Control and Calibration...Qualitative analysis...For qualitative analysis of samples, use the 300 ng/mL or 2000 ng/mL calibrator as a cutoff level for distinguishing "positive" for "negative" samples.". Review of manufacturer package inserts revealed the package inserts fail to define the specific level and type of calibration reagents utilized by the laboratory for the performance of calibration of the Pictus 700 analyzer. For example: a. Package insert "DRI Cocaine Metabolite Assay" revealed "Quality Control and Calibration...For qualitative analysis of samples, use the DRI-Multi Drug Urine Calibrator 1, ..., or DRI-Multi Drug Calibrator 2, ...". b. Package insert "DRI Opiate Assay" revealed "Quality Control and Calibration...For qualitative analysis of samples, use the 300 ng/mL or 2000 ng/mL calibrator as a cutoff level for distinguishing "positive" from "negative" samples.".

D6123

TECHNICAL SUPERVISOR RESPONSIBILITIES
CFR(s): 493.1451(b)(8)(iii)

The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.

This STANDARD is not met as evidenced by:
Based on review of laboratory policy, review of LC/MS QC data and interview with TS and LD 7/13/2023, the TS failed to provide LC/MS QC data to the LD on a monthly basis in 2020, 2021, 2022 and January through June 2023, approximately 42 months in which LC/MS QC data was not provided to the LD for review. Findings: Review of laboratory policy revealed "L5. Quality Control Procedures...The procedures below describe the steps to (2) accept/reject the Quality Control data within a batch and complete the official record (performed by the Technical Supervisor or Lab Director)..." The laboratory policy also states in "2.6 At the end of the month provide the Lab Director with the official record for the month...". The review of LC/MS QC data revealed no documentation to confirm the monthly review of LC/MS QC by the LD. Interviews with TS at approximately 11:55 a.m. and current LD at approximately 1:25 p.m. revealed the LD has not been provided LC/MS QC data to review in 2020, 2021, 2022 and January through June 2023.

D6175

TESTING PERSONNEL RESPONSIBILITIES
CFR(s): 493.1495(b)(1)

Each individual performing high complexity testing must follow the laboratory's

procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results.

This STANDARD is not met as evidenced by:

Based on observation, review of the laboratory policies and procedures, and interview with LD 7/13/23, testing personnel failed to follow the laboratory's procedure for the retention of urine drug screen samples. Findings: During a tour of the facility at approximately 12:30 p.m., surveyors observed approximately 1400 aliquoted patient specimens in capped tubes stored in the refrigerator in the hallway outside the laboratory. Collection dates on the tubes indicated that the samples were collected January through June of 2023. Review of the laboratory's "Specimen Retention" procedure revealed "All urine specimens that are sent to the laboratory for a urine drug screen (UDS) will be retained for the following lengths of time: The test tube containing the aliquoted urine that is run on the Pictus700 will be capped and frozen. These frozen samples will be placed in a bag(s) together for easy identification and will be kept until the first day of the month following 30 days of retention....". During interview at approximately 12:45 p.m., the LD stated he was unsure why the samples were stored in the refrigerator instead of the freezer.