

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 25D1019516	(X3) Date Survey Completed 12/03/2020
Name of Provider or Supplier Internal Medicine & Pediatric Clinic Of New Albany	Street Address, City, State 118 Fairfield Dr, New Albany, MS	
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
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on review of the Centers of Medicare and Medicaid Services (CMS) database proficiency testing report and confirmation by testing personnel at 1:30 pm on 12/3/20, the laboratory failed to enroll and participate in an HHS approved proficiency testing (PT) program for CKMB (Creatinine Kinase) performed on the Biosite Triage Meter. The laboratory must enroll and participate in an approved program for the specialties performed by the laboratory. Findings Include: 1. Based on review of the CMS data base proficiency report, the laboratory did not enroll in an approved program for CKMB. There were no scores for CKMB for the year 2020. The lab began testing patients in March 2020. 2. Interview with testing personnel at 1:30 pm on the day of survey (12/3/20) confirmed that the laboratory was not enrolled in proficiency for CKMB testing.</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:

A. Based on review of laboratory proficiency records, TOX drug screen records from installation of the Biosite Triage Meter (3/4/20) until the day of survey (12/3/20) and interview with testing personnel at 1:30 pm on the day of survey, the laboratory failed to verify the accuracy of myoglobin, troponin and the TOX drug screen (AMP, mAMP, Bar, Bzo, Coc, EDDP, Opi, TCA, THC) testing at least twice annually since the laboratory installed and began testing on the Biosite Triage Meter on 3/4/20. The laboratory must verify the accuracy of testing that is not included in subpart I of the CLIA regulations Findings Include: 1. Review of the cardiac marker (Troponin, Myoglobin) records on the Biosite Triage Meter from 3/4/20 until 12/3/20 revealed the cardiac markers had not been verified for accuracy twice a year. 2. Review of the Tox Drug Screen records (amphetamines, metamphetamines, barbiturates, benzodiazepines, cocaine, EDDP"methadone", opiates, TCA"tricyclic antidepressant", THC"tetrahydrocannabinol") performed on the Biosite Triage Meter from 3/4/20 until 12/3/20 revealed the Tox Drug screen had not been verified for accuracy twice a year. 3. Interview with staff at 1:30 pm on 12/3/20 confirmed that accuracy had not been verified on the cardiac panel (Troponin and Myoglobin) or the Tox drug screen since testing began. B. Based on review of the laboratory proficiency records, Alere Afinion procedure manual, microalbumin /Creatinine records from installation of the Alere Afinion (1/10/19) until the day of survey (12/3/10), and interview with staff at 2:00 pm on the day of survey, the laboratory failed to verify the accuracy of microalbumin /Creatinine testing at least twice annually since the laboratory began testing and installation of the Alere Afinion 1/10/19. The laboratory must verify the accuracy of testing that is not included in subpart I. Findings Include: 1. Microalbumin/Creatinine records from installation on the Alere Afinion (1/10/19) until the day of survey did not include any verification for accuracy. Review of proficiency records for 2019 and 2020 indicated not proficiency testing had been performed for microalbumin /Creatinine which would have verified accuracy. 2. Interview with testing personnel at 2:00 pm on 12/3/20 confirmed the accuracy had not been verified for Microalbumin /Creatinine on the Alere Afinion analyzer.

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:

A. Based on review of testing records for the Biosite Triage Meter Tox drug screen, Cardiac panel and lack of documentation of verification of performance specifications, and interview with testing personnel on 12/3/20 at 11:00 am, the laboratory failed to ensure that performance specifications were verified before reporting patient test results. The lab started using this analyzer on 3/4/20. Findings: 1. No documentation of verification of performance for the Tox Drug screen (AMP, mAMP, Bar, Bzo, Coc, EDDP, Opi, TCA, THC) was available for review on the day

of survey. 2. No documentation of verification of performance for the Cardiac (myoglobin, CKMB, troponin) panel was available for review on the day of survey. 2. Interview with testing personnel on 12/3/20 at 11:00 am revealed no verification of performance specifications was completed on cardiac or TOX drug screens before testing patients. B. Based on review of testing records for the Alere Afinion microalbumin, lack of the documentation of verification of performance specifications. and interview with testing personnel on 12/3/20 at 11:00 am, the laboratory failed to ensure that performance specifications were verified before reporting patient test results. The lab started testing on this analyzer 1/10/19. 1. No documentation of verification of performance for the Microalbumin on the Alere Afinion was available on the day of survey. 2. Interview with testing personnel on 12/3/20 at 11:00 am revealed no verification of performance specifications was completed on Microalbumin before testing patients. 3. The Abbott Afinion procedure verification procedure requires both precision and accuracy study be verified for the Microalbumin and Creatinine. It states the laboratory is responsible for verifying that reproducibility can be established during the verification process.

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 the Sysmex XN 330 hematology analyzer maintenance records from its installation on 1/21/20 until the day of survey (12/3/20) and interview with testing personnel at 2:30 pm on the day of survey, the laboratory failed to document as performed the weekly, monthly and quarterly maintenance on the Sysmex XN 330 analyzer as required by the manufacturer. Findings include: 1. Review of the Cell Dyn 1800 records revealed the following maintenance had only been documented as performed one time on the hematology analyzer since installation on 1/21/2020. Weekly (performed on 1/3/20) - Clean SRV tray Monthly (no documentation of performance) - a. Clean RBC and WBC transducer b. Clean waste chamber Quarterly (performed on 1/3/20) - Clean sample rotor valve 2. Interview with the testing personnel on the day of survey at 2:30 pm confirmed maintenance was not documented as performed on the Sysmex maintenance log provided by the manufacturer.

D5439

CALIBRATION AND CALIBRATION VERIFICATION
CFR(s): 493.1255(b)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless

the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:
Based on review of Biosite Triage Meter records from installation on 3/20/20 through the day of this survey on 12/3/20 and confirmation with testing personnel at 3:00 pm on 12/3/20, the laboratory failed to perform calibration verification on the Biosite Triage Meter chemistry analyzer every 6 months for the cardiac panel and Tox drug screen. Findings include: 1. Review of the laboratory Biosite Triage Meter Tox Drug screen records for: AMP, mAMP, Bar, Bzo, Coc, EDDP, Opi, TCA, THC from 3/20/20 until the day of survey revealed no calibration verification had been performed on the Tox Drug screen tests every 6 months as required by the manufacturer. 2. Review of the laboratory Biosite Triage Meter Cardiac panel records for: CKMB, troponin, myoglobin from installation on 3/20/20 revealed that a calibration verification was not performed on the cardiac panel every 6 months as required by the manufacturer. 3. Interview with testing personnel at 3:00 pm on the day of survey confirmed that calibration verification was not performed for Tox Drug screen tests or the Cardiac Panel every 6 months as required by the manufacturer.

D5447

CONTROL PROCEDURES
CFR(s): 493.1256(d)(3)(i)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on review of quality control (QC) and patient records for the Alere Afinion Microalbumin/Creatinine from 9/22/20 through 12/3/20, lack of documentation of an IQCP (Individualized Quality Control Plan), and an interview with the laboratory general supervisor (GS) at 3:30 on the day of survey, the laboratory failed to include a positive and negative control on each day of patient testing for Microalbumin /Creatinine. Findings Include: 1. Interview with the laboratory GS on the day of survey (12/3/20) at 3:30 pm confirmed that laboratory testing personnel were not performing QC each day of Microalbumin/Creatinine testing on the Alere Afinion but per lot number change. 2. Review of the QC and patient Microalbumin/Creatinine log from 9/22/20 through 12/3/20 revealed a total of 13 patient specimens were tested and results reported with no documentation of the performance of 2 levels of controls each day of testing. The following days patients were tested but no QC documented as performed: 10/27/20 - 2 patients tested 11/5/20 - 1 patient tested 11/12/20 - 2 patients tested 11/20/20 - 3 patients tested 11/24/20 - 1 patient tested 11/25/20- 1 patient tested 11/27/20 - 2 patients tested 12/2/20 - 1 patient tested

D6015

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(4)

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)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed.

This STANDARD is not met as evidenced by:

Based on review of the laboratory proficiency testing records, Centers of Medicare and Medicaid Services (CMS) database proficiency testing report and confirmation with testing personnel at 3:30 pm on 12/3/20, the laboratory director failed to ensure the laboratory was enrolled and participated in an HHS approved proficiency testing (PT) program for CKMB performed on the Biosite Triage Meter for the year 2020. Findings include: 1. Observation of the CMS database proficiency testing report revealed no scores for 2020. 2. Review of laboratory records since installation of the Triage Meter on 3/4/20 through the day of survey, 12/3/20, revealed no evidence of proficiency testing participation prior to survey. 3. Interview with testing personnel at 3:30 pm on day of survey revealed the laboratory did not enroll in proficiency for the year 2020 for CKMB on the Biosite Triage meter.

D6040

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(2)

The technical consultant is responsible for-- (b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system.

This STANDARD is not met as evidenced by:

Based on laboratory and installation records for the Biosite Triage Meter and the Alere Afinion and interview with Testing Personnel at 2:00 pm on the day of the survey (12/3/20), the technical consultant (TC) did not ensure that test performance was established and verified for the Microalbumin/Creatinine, cardiac panel and drug screen test procedures. Findings Include.: 1. Review of installation records for the Biosite Triage Meter did not reveal verification or test performance was established for the Tox Drug Screen: AMP, mAMP, Bar, Bzo, Coc, EDDP, Opi, TCA, THC 2. Review of installation records for the Biosite Triage Meter did not reveal verification or test performance was established for the Cardiac Panel: Myoglobin, CKMB, Troponin 3. Review of the installation records for the Alere Afinion did not reveal verification or test performance was established for the Microalbumin/Creatinine. 4. Interview with testing personnel at 2:00 pm confirmed no verification of performance was performed for the Microalbumin/Creatinine, drug screens or cardiac panel and ensured by the TC.

D6054

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

annually, after the first year.

This STANDARD is not met as evidenced by:

Based on review of laboratory personnel records from the last survey on 6/6/18 through the day of survey on 12/3/20, the Centers of Medicare and Medicaid Services (CMS) 209 personnel form, and lack of documentation for review, the technical consultant (TC) failed to evaluate annually and document the performance of laboratory testing personnel (TP) #3 and #16 responsible for laboratory testing. An annual evaluation/competency must be performed each year of employment by the technical consultant. Findings include: 1. Review of TP #3 personnel records since the last survey revealed the initial training/competency was performed on 10/22/19 by the TC. The 6 month or biannual evaluation/competency was performed on 4/22/20 by the TC. There was no annual evaluation documented for 2020. 2. Review of TP #16 personnel records since the last survey revealed the initial training/competency was performed on 10/21/18 by the TC. The 6 month or biannual evaluation/competency was performed on 4/21/19 by the TC. There was no annual evaluation documented for 2020.