

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D1034255	(X3) Date Survey Completed 05/31/2022
Name of Provider or Supplier Birmingham Internal Medicine Associates, P C	Street Address, City, State 7191 Cahaba Valley Road, Suite 300, Birmingham, AL	
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
D5291	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the Quality Assessment (QA) records, the Policy and Procedure Manual, and an interview with the Technical Consultant, the laboratory failed to establish policies and procedures for an ongoing mechanism to monitor, assess, and correct problems identified. This was noted from the previous survey (03/11/2020) to the current survey (05/31/2022). The findings include: 1. A review of the Quality Assurance (QA) records from March 2020 to May 2022 revealed the only QA measure in place was a monthly patient chart review. 2. A review of the Policy and Procedure Manual under section "Quality Assurance Plan" revealed, "...The Quality Assurance Plan ensures that Personnel Standards are met; ensures that the pre-analytical phase, the testing phase, and the post-analytical phase are performed accurately and that systems are in place to detect and correct problems as they arise...". 3. During an interview on 05/31/2022 at 4:10 PM, the Technical Consultant confirmed QA included monthly chart reviews only. The Surveyor then asked what measures were in place to monitor Proficiency Testing, Personnel, Quality Control, and other indicators of quality; the Technical Consultant confirmed her understanding QA monitoring should include these additional areas of review.</p>
D5407	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p>

Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.

This STANDARD is not met as evidenced by:

Based on a review of the Policy and Procedure Manual and an interview with the Technical Consultant, the Laboratory Director failed to approve the Sysmex XN-530 Procedure as indicated by signature, prior to using this instrument for patient testing. This was noted from the time patient testing started in September 2021 to the date of the current survey (05/31/2022). The findings include: 1. A review of the Policy and Procedure Manual revealed a procedure for the Sysmex XN-350/XN-330 instruments only. On the day of the survey, Testing Personnel #1 printed the procedure for the Sysmex XN-530 instrument, in use since September 2021. 2. During an interview on 05/31/2022 at 12:35 PM, the Technical Consultant confirmed the Laboratory Director had not documented review/approval of the Sysmex XN-530 procedure before the instrument was used for patient testing.

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 a review of the verification of performance records for the Quidel Triage Meter and an interview with the Technical Consultant, the laboratory failed to document an evaluation of the raw data for precision, accuracy, and reportable range of the Cardiac Panel [CK-MB (Creatine Kinase-MB), Myoglobin I, and Troponin] and D-Dimer. This was noted from 12/07/2020 when patient testing started to the current survey (05/31/2022). The findings include: 1. A review of the verification of performance records for the Quidel Triage Meter revealed the following: a) Raw data for Troponin and D-Dimer for precision, however there was no evaluation of the data to verify the manufacturer's performance specifications. b) Raw data for Troponin and D-Dimer for the Calibration Verification, however there was no evaluation of the data to determine the instrument's reportable range. c) Raw data for Troponin and D-Dimer for Comparison, however there was no evaluation of the data to verify the manufacturer's performance specifications for accuracy. d) There was no data for CK-MB and Myoglobin I. 2. During an interview on 05/31/2022 at 1:50 PM, the Technical Consultant confirmed the laboratory could only provide the raw data for Troponin and D-Dimer, and there was no evaluation of the raw data to determine if the manufacturer's performance specifications were met.

D5439

CALIBRATION AND CALIBRATION VERIFICATION

CFR(s): 493.1255(b)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification

procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:
 Based on a review of the Vitros 5600 calibration verification records, a review of the Policy and Procedure Manual, and an interview with Testing Personnel #1, the laboratory failed to perform calibration verifications at least every six months, as per CLIA regulations. This was noted as missing opportunities for two out of four calibration verifications from March 2020 to May 2022. The findings include: 1. A review of the Vitros 5600 records revealed calibration verifications were performed on analytes (all with less than three calibrators), as follows: a) LDL Cholesterol: 06/30/2020 and 05/20/2021 b) Vitamin D: 06/30/2020 and 05/18/2021 c) Total Iron-Binding Capacity (TIBC): 06/30/2020 and 05/18/2021 d) Hemoglobin A1c: 07/02/2020 and 05/18/2021 e) Vitamin B12: 07/02/2020 and 05/18/2021 2. A review of the Policy and Procedure Manual under the section "Calibration Verification" revealed, "... Linear verification will be performed every six months on all analytes that use less than three calibrators in the calibrations...". 3. During an interview at 4:20 PM on 05/31/2022, Testing Personnel #1 confirmed the laboratory had not performed calibration verifications every six months as required, for the above listed analytes.

D5447

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

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

This STANDARD is not met as evidenced by:
 Based on a review of the Triage Meter Quality Control (QC) records and an interview with the Technical Consultant, the laboratory failed to run controls at least once each day patient specimens are performed or implement an Individualized Quality Control Plan (IQCP) for the Triage Meter. This was noted from December 2020 when patient testing started to May 2022. The findings include: 1. A review of the Triage Meter QC records revealed QC was being performed monthly from 11/17/2020 to 05/03/2022

for D-Dimer and the Cardiac Panel [Troponin, CK-MB (Creatine Kinase-MB), and Myoglobin]. 2. During an interview on 05/31/2022 at 1:30 PM, the Technical Consultant confirmed the IQCP for the Triage Meter could not be located. The Technical Consultant could only provide an IQCP for the Triage Meter for an affiliated location.

D5481

CONTROL PROCEDURES

CFR(s): 493.1256(f)(g)

(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on a review of the Vitros 5600 Quality Control (QC) records, the patient results log, the Procedure Manual, and an interview with Testing Personnel #1, the laboratory failed to ensure at least two levels of QC were run and acceptable, prior to analyzing patient specimens and reporting the results. This was noted on two days out of six months reviewed from May 2020 to May 2022 by the surveyor. The findings include:
1. A review of the QC records for the Vitros 5600 analyzer revealed the following: a) On 12/1/2020, one out of two levels of QC for Total Bilirubin (TBIL) was out of range. 38 patients were performed on this date. b) On 02/14/2022, one out of two levels of QC was out of range for Direct Bilirubin (DBIL). 50 patients were performed on this date. 2. A review of the Procedure Manual under section 2. Chemistry revealed, "...Two levels of controls will be run daily. Values should be within the performance range specified by the manufacturer of the assayed control. No patient results are reported for any assay for which the controls fall outside of this range. Patient specimens will be sent to Quest for completion if the problem is not resolved within 24 hours...". 3. During an interview on 05/31/2022 at 3:00 PM, Testing Personnel #1 confirmed the above findings.