| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 01D2124642 | 01/27/2022 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Birmingham Internal Medicine Associates Llc | 7201 Happy Hollow Road, Suite 101, Trussville, 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 |
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| **D2007** | TESTING OF PROFICIENCY TESTING SAMPLES<br>CFR(s): 493.801(b)(1)<br><br>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of API (American Proficiency Institute) proficiency testing (PT) records, and an interview with Testing Personnel #3, the surveyor determined the laboratory failed to ensure proficiency testing samples were rotated between all personnel who performed patient testing. This was noted on three out of three Hematology surveys reviewed for 2020. The findings include: 1. A review of API attestation statements revealed Testing Personnel #3 had performed all three events in 2020 for Hematology - Complete Blood Count. 2. During an interview on 01/27/2022 at 10:05 AM, Testing Personnel #3 stated she performed PT because testing personnel were so new and couldn't do PT. The surveyor asked if the testing personnel could perform patient testing, and Testing Personnel #3 confirmed yes they could performed patient testing. |
| **D5429** | MAINTENANCE AND FUNCTION CHECKS<br>CFR(s): 493.1254(a)(1)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of the Hematology Sysmex XP-300 maintenance records, a review |

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| | of the Sysmex XP-300 Instructions For Use, and an interview with the Laboratory Consultant, the laboratory failed to document quarterly maintenance. This was noted from 2020 -2021. The findings include: 1. A review of the Hematology maintenance records revealed a place to document quarterly (every 3 months) maintenance on the Sysmex XP-300 Maintenance Log and it was documented the following times: May 2020, July 2020, December 2020, February 2021, September 2021, and October 2021. No documentation of quarterly maintenance during these gaps Jan 2020 - March 2020, August 2020 - November 2020, and March 2021 - August 2021. 2. A review of the Sysmex XP-300 Instructions For Use revealed in section 12 page 12-12 under Clean SRV "When the main power switch is turned ON, and if either the counter value exceeds 4,500, or if 3 months have passed since the last maintenance, a message will appear prompting the operator to perform periodic maintenance (SRV cleaning)..." 3. During an interview on 01/27/2022 at 3:25 PM, the Laboratory Consultant confirmed the above findings and agreed quarterly maintenance was not documented at least every 3 months. |
| **D5445** | CONTROL PROCEDURES<br>CFR(s): 493.1256(d)(1)(2)(g)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of the IQCP (Individualized Quality Control Plan), the Quality Control (QC) records for the Triage meter (Troponin I), the patient logs, and an interview with the Laboratory Consultant, the laboratory failed to ensure two levels of quality control (QC) were performed and documented every 30 days of patient testing as per the IQCP. This was noted for two month from January 2020 to December 2021. The findings include: 1. A review of the IQCP for the Triage meter (Troponin I) revealed a QC Plan which specified two levels of QC should be performed and documented every 30 days of patient testing, and with each new lot number. 2. A review of the January 2020 to December 2021 Triage meter QC data log revealed QC had been performed most months (except July 2021 and August 2021), however the QC testing exceeded the 30 day frequency specified in the IQCP during those months. QC was performed on 06/09/2021, and the next QC run was on 09/15/2021; during this period, 13 patient tests were performed. 3. During an interview on 01/27/2022 at 2:50 PM, the Laboratory Consultant confirmed the laboratory failed to follow the IQCP between 07/09/2021 to 09/15/2021 and 13 patient tests were performed during this time period. |
| **D5481** | CONTROL PROCEDURES<br>CFR(s): 493.1256(f)(g)<br><br>(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. |

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| | This STANDARD is not met as evidenced by:<br>Based on a review of the Hematology quality control (QC) reports, patient logs, and an interview with the Laboratory Consultant , the laboratory failed to ensure at least two levels of quality control was performed and acceptable prior to performing patient testing. This was noted one day out of 8 months reviewed by the surveyor. This is a repeat citation. The findings include: 1. A review of the Levey-Jennings for the Sysmex XP-300 revealed only the Low QC was performed on 4/20/2021; there was no documentation of the Normal and High QC on this date. 2. A review of the patient logs revealed 3 patient Complete Blood Counts (CBCs) were run on 04/20/2021. 3. During an interview on 01/27/2022 at 2:50 PM, the Laboratory Consultant confirmed only one level of QC was run on 04/20/2021 and three patients were performed on this day. |
| **D5781** | CORRECTIVE ACTIONS<br>CFR(s): 493.1282(b)(1)<br><br>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of temperature logs, the Quidel Triage Total 5 Control Product Insert, and an interview with the Laboratory Consultant, the laboratory failed to document corrective action when temperatures were not within acceptable limits. This was noted in 14 out of 24 months reviewed by the surveyor. The findings include: 1. A review of temperature logs revealed Freezer temperatures were warmer than the manufacturer's requirements of -20 degrees C or colder for the items therein, as follows: a) January 2020 - 4 days b) February 2020 - 13 days c) March 2020 - 21 days d) April 2020 - 19 days e) July 2020 - 1 days f) August 2020 - 2 days g) March 2021 - 16 days h) April 2021 - 21 days i) May 2021 - 19 days j) June 2021 - 22 days k) July 2021 - 21 days l) August 2021 - 21 days m) September 2021 - 21 days n) October 2021 - 21 days 2. A review of Quidel Triage Total 5 Control Product Insert stated "Store frozen at -20 degree C or colder in a non-defrosting freezer." 3. During an interview on 01/27/2022 at 3:00 PM, the Laboratory Consultant confirmed Freezer temperatures should have been below -20 degrees Celsius and no corrective action was documented for the days listed above. |