

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D0987260	(X3) Date Survey Completed 01/30/2025
Name of Provider or Supplier Birmingham Internal Medicine Associates	Street Address, City, State 70 Plaza Drive, Pell City, 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
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>(a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the Urgent Care Hematology maintenance records, the Sysmex XP-300 user manual, and an interview with the Technical Consultant (TC), the Urgent Care Laboratory failed to document weekly maintenance on the Sysmex XP-300 Hematology analyzer as per the manufacturer's requirements for twelve of twelve months in 2023. The findings include: 1. A review of the Sysmex XP-300 Hematology analyzer records revealed no documentation of weekly maintenance for the year of 2023. 2. A further review of the Sysmex XP-300 Hematology user manual revealed, "Weekly: Clean the SRV tray." 3. During an interview on 1/30/2025, at 1: 10 PM, the TC confirmed the above findings.</p>
D5437	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a)</p> <p>(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (a)(1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (a)(2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (a)(2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (a)(2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (a)(3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration</p>

verification.

This STANDARD is not met as evidenced by:

Based on a review of the Hematology records, the Quality Assurance (QA) plan, and an interview with the Technical Consultant (TC), the Laboratory failed to perform calibrations on the Sysmex XP-300 Hematology analyzer every six months as per the QA policy. The laboratory failed to perform one of two calibrations due in 2024. The findings include: 1. A review of the Hematology calibration records revealed the Sysmex XP-300 was last verified on 4/3/2024. There was no evidence of documentation for a calibration the second half of 2024. 2. A further review of the QA plan revealed on page 3 "Calibrations are done according to manufacturer's recommendations and at least every six months." 3. During an interview on 1/30/2025, at 2:15 PM, TC confirmed the calibration due in the second half of 2024 was not performed.

D5445

CONTROL PROCEDURES

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

(d) 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. (d)(3) At least once each day patient specimens are assayed or examined perform the following for:

This STANDARD is not met as evidenced by:

Based on a review of the Urgent Care Cardiac and D-dimer Triage QC (Quality Control) records, the Triage IQCP (Individualized Quality Control Plan), and an interview with the Technical Consultant, the Laboratory failed to ensure testing personnel performed the Triage QC every 30 days as per the IQCP. The surveyor noted 2 out of 12 months in 2023 when QC was not performed as required by the IQCP. The findings include: 1. A review of the Urgent Care Triage records for #83311 and #83646 revealed the laboratory exceeded the 30-day requirements for external Cardiac and D-dimer QC for November and December 2023. 2. A review of the Triage IQCP revealed, "Assay a high and low QC material.... every 30 days." 3. During an interview on 1/30/25 at 1:10 PM, the Technical Consultant confirmed the above findings.

D5781

CORRECTIVE ACTIONS

CFR(s): 493.1282(b)(1)

(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.

This STANDARD is not met as evidenced by:
Based on a review of the Urgent Care refrigerator temperature records, a review of the Hematology QC (Quality Control) package insert, and an interview with the TC (Technical Consultant), the Laboratory failed to document corrective actions when the refrigerator temperature was outside the manufacturer's acceptable ranges for items stored therein. The surveyor noted refrigerator temperatures were below acceptable ranges for 30 days of the 6 months reviewed in 2023. The findings include: 1. A review of the temperature records for the refrigerator where Hematology QC was stored revealed no documentation of corrective action for days when temperatures were below the acceptable ranges specified on the log (2 - 8 Celsius), as follows: a) May 2023: 8 days b) August 2023: 4 days c) September 2023: 3 days d) October 2023: 5 days e) November 2023: 6 days f) December 2023: 4 days 2. A review of the Hematology Eightcheck-3WP QC package insert revealed storage at 2 - 8 Celsius. 3. During an interview on 1/30/2025, at 2:15 PM, TC confirmed the above findings.

D6053

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(9)

(b)(9) 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 a review of the personnel records and an interview with the Technical Consultant (TC), the TC failed to evaluate semi-annual competencies for Testing Personnel (TP) performing moderate complexity testing. This was noted for 6 of 13 new TP, for Urgent Care, listed on the CMS-209 (Laboratory Personnel Report). The findings include: 1. A review of the personnel records revealed no evidence of semi-annual competency evaluation by the Technical Consultant for TP#6 - TP#11. 2. During an interview on 1/30/2025, at 2:15 PM, TC confirmed the above findings.

D6054

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(9)

(b)(9) Thereafter, evaluations must be performed at least annually

This STANDARD is not met as evidenced by:
Based on a review of the personnel records and an interview with the Technical Consultant (TC), the TC failed to evaluate annual competencies for Testing Personnel (TP) performing moderate complexity testing. This was noted for 5 of 13 TP listed on the CMS-209 (Laboratory Personnel Report), for Urgent Care, since the date of the last survey (1/5/2023) to the date of the current survey (1/30/2025). The findings include: 1. A review of the personnel records revealed no evidence of annual competency evaluation by the Technical Consultant for the following TP: 2023: TP#2 and TP#6 2024: TP#3, TP#7, and TP#10 2. During an interview on 1/30/2025, at 2:15 PM, TC confirmed the above findings.