

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  01D2124641	<b>(X3) Date Survey Completed</b>  08/18/2021
<b>Name of Provider or Supplier</b>  Birmingham Internal Medicine Associates Llc	<b>Street Address, City, State</b>  480 Walker Drive, Springville, AL	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D2009</b>	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on a review of Proficiency Testing records and an interview with Testing Personnel #1, the Laboratory Director failed to sign the attestation statement provided by American Proficiency Institute (API). This was noted on four out of seven 2019 - 2021 Hematology Proficiency Testing Events. The findings include: 1. A review of Proficiency Testing records revealed the Hematology Event #1 2019, Event #2 2019, Event #3 2019, and Event #2 2020 attestation statements were not signed by the Laboratory Director/delegate. 2. During an interview on 08/18/2021 at 12:00 PM, Testing Personnel #1 confirmed the above attestations were not signed by the Laboratory Director/delegate.</p>
<b>D2010</b>	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2)</p> <p>The laboratory must test samples the same number of times that it routinely tests patient samples.</p> <p>This STANDARD is not met as evidenced by: Based on a review of Proficiency Testing (PT) records, the Proficiency Testing Procedure, and an interview with Testing Personnel #1, the Laboratory failed to test proficiency samples the same number of times that it routinely tests patient samples. This was noted on four out of seven 2019 - 2021 Hematology Proficiency Testing</p>

Events. The findings include: 1. A review of Proficiency Testing records revealed the following: a) 2019 Hematology 1st Event - Samples 2, 3, and 5 had no critical values and were run twice. b) 2019 Hematology 2nd Event - Samples 6 and 7 had no critical values and were run twice. c) 2019 Hematology 3rd Event - Samples 11-15 were run 4 times over the span of 3 different days. d) 2020 Hematology 2nd Event - Sample 10 had no critical values and was run twice. 2. A review of the Proficiency Testing Procedure revealed the following, "...Do not test PT samples more than once unless it is regular documented laboratory procedure for testing patient samples. For example, if patient samples with abnormal results are retested, retest PT samples with abnormal results..." 3. During an interview on 08/18/2021 at 12:00 PM, Testing Personnel #1 confirmed the above PT samples were tested more than a routine patient sample.

**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 a review of the Hematology maintenance records, a review of the Sysmex XP-300 User Manual, and an interview with Testing Personnel #1, the laboratory failed to retain documentation of daily, weekly, monthly, and quarterly maintenance. This was noted on 23 months out of 28 months reviewed by the surveyor. Also, the laboratory failed to documented weekly maintenance each week of patient testing on three out of five months reviewed. The findings include: 1. A review of the Hematology maintenance records revealed September to December 2020 (maintenance logs from April 2019 to August 2020 could not be located) and July 2021 (maintenance logs from January 2021 to June 2021 could not be located) maintenance log completed. For October 2020 three out of four weekly maintenance documented, November 2020 two out of four weekly maintenance documented, and December 2020 three out of four weekly maintenance documented. 2. A review of the Sysmex XP-300 User Manual revealed daily weekly, monthly and quarterly maintenance is required on this analyzer. 3. During an interview on 08/18/2021 at 1:40 PM, Testing Personnel #1 confirmed the documentation above could not be located during the onsite survey and the weekly maintenance was not documented weekly for 3 out of 5 months reviewed. Also, an email from Testing Personnel #1 on 08/19/2021 stated the maintenance logs were unable to be located.

**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 Hematology quality control (QC) records for the Sysmex XP-300 and an interview with Testing Personnel #1, the laboratory failed to ensure at

least two levels of quality control were run and acceptable. This was noted nine days out of 10 months reviewed from April 2019 to July 2021 by the surveyor. The findings include: 1. A review of the QC records for the Sysmex XP-300 Hematology analyzer revealed the following: a) 09/16/2019 - No quality control run documented or documentation if patients were performed on this day. b) 04/17/2020 - No quality control run documented or documentation if patients were performed on this day. c) 04/29/2020 - No quality control run documented or documentation if patients were performed on this day. d) 07/29/2020 - No quality control run documented or documentation if patients were performed on this day. e) 10/09/2020 - No quality control run documented or documentation if patients were performed on this day. f) 10/28/2020 - No quality control run documented or documentation if patients were performed on this day. g) 04/05/2021 - No quality control run documented or documentation if patients were performed on this day. 2. During an interview on 08/18/2021 at 1:20 PM, Testing Personnel #1 confirmed the documentation above could not be located during the onsite survey. Also, an email from Testing Personnel #1 on 08/19/2021 stated the quality control for these days were unable to be located.

**D6047**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(8)(i)

The procedures for evaluation of the competency of the staff must include, but are not limited to direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing.

This STANDARD is not met as evidenced by:  
Based on a review of personnel evaluation records and an interview with Testing Personnel #1, the Technical Consultant failed to include direct observations of routine patient testing in the evaluation of competency at least semiannually and annually during the first year of performing CBC's (Complete Blood Counts). This was noted on one of three Testing Personnel (two of the three testing personnel performed initial training in June 2021 and August 2021). The findings include: 1. A review of personnel evaluation records revealed Testing Personnel #1 had a form on file that stated at the top "Tests qualified and trained to perform:" for Sysmex 300 it had the following dates listed Initial Training Date 04/30/20, 6 Month Competency Date 10/13/20, and Annual Competency Date 04/12/20/21. There was supporting documentation for this form for other test performed at a different location, but no supporting documentation for the Sysmex XP-300 located at Birmingham Internal Medicine DBA STV at Springville. 2. During an interview on 08/18/2021 at 10:20 AM, Testing Personnel #1 confirmed there was no supporting documentation for the Sysmex XP-300 for this location and competencies were performed at a different location.

**D6048**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(8)(ii)

The procedures for evaluation of the competency of the staff must include, but are not limited to monitoring the recording and reporting of test results.

This STANDARD is not met as evidenced by:  
Based on a review of personnel evaluation records and an interview with Testing Personnel #1, the Technical Consultant failed to include monitoring the recording and reporting of test results in the evaluation of competency at least semiannually and

annually during the first year of performing CBC's (Complete Blood Counts). This was noted on one of three Testing Personnel (two of the three testing personnel performed initial training in June 2021 and August 2021). The findings include: 1. A review of personnel evaluation records revealed Testing Personnel #1 had a form on file that stated at the top "Tests qualified and trained to perform:" for Sysmex 300 it had the following dates listed Initial Training Date 04/30/20, 6 Month Competency Date 10/13/20, and Annual Competency Date 04/12/20/21. There was supporting documentation for this form for other test performed at a different location, but no supporting documentation for the Sysmex XP-300 located at Birmingham Internal Medicine DBA STV at Springville. 2. During an interview on 08/18/2021 at 10:20 AM, Testing Personnel #1 confirmed there was no supporting documentation for the Sysmex XP-300 for this location and competencies were performed at a different location.

**D6049**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(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 a review of personnel evaluation records and an interview with Testing Personnel #1, the Technical Consultant failed to include review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records in the evaluation of competency at least semiannually and annually during the first year of performing CBC's (Complete Blood Counts). This was noted on one of three Testing Personnel (two of the three testing personnel performed initial training in June 2021 and August 2021). The findings include: 1. A review of personnel evaluation records revealed Testing Personnel #1 had a form on file that stated at the top "Tests qualified and trained to perform:" for Sysmex 300 it had the following dates listed Initial Training Date 04/30/20, 6 Month Competency Date 10/13/20, and Annual Competency Date 04/12/20/21. There was supporting documentation for this form for other test performed at a different location, but no supporting documentation for the Sysmex XP-300 located at Birmingham Internal Medicine DBA STV at Springville. 2. During an interview on 08/18/2021 at 10:20 AM, Testing Personnel #1 confirmed there was no supporting documentation for the Sysmex XP-300 for this location and competencies were performed at a different location.

**D6050**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(8)(iv)

The procedures for evaluation of the competency of the staff must include, but are not limited to direct observation of performance of instrument maintenance and function checks.

This STANDARD is not met as evidenced by:  
Based on a review of personnel evaluation records and an interview with Testing Personnel #1, the Technical Consultant failed to include direct observation of performance of instrument maintenance and function checks in the evaluation of

competency at least semiannually and annually during the first year of performing CBC's (Complete Blood Counts). This was noted on one of three Testing Personnel (two of the three testing personnel performed initial training in June 2021 and August 2021). The findings include: 1. A review of personnel evaluation records revealed Testing Personnel #1 had a form on file that stated at the top "Tests qualified and trained to perform:" for Sysmex 300 it had the following dates listed Initial Training Date 04/30/20, 6 Month Competency Date 10/13/20, and Annual Competency Date 04/12/20/21. There was supporting documentation for this form for other test performed at a different location, but no supporting documentation for the Sysmex XP-300 located at Birmingham Internal Medicine DBA STV at Springville. 2. During an interview on 08/18/2021 at 10:20 AM, Testing Personnel #1 confirmed there was no supporting documentation for the Sysmex XP-300 for this location and competencies were performed at a different location.

**D6051**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(8)(v)

The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples.

This STANDARD is not met as evidenced by:  
Based on a review of personnel evaluation records and an interview with Testing Personnel #1, the Technical Consultant failed to include assessment of test performance through testing previously analyzed specimens, internal blind testing samples, or external proficiency testing samples in the evaluation of competency at least semiannually and annually during the first year of performing CBC's (Complete Blood Counts). This was noted on one of three Testing Personnel (two of the three testing personnel performed initial training in June 2021 and August 2021). The findings include: 1. A review of personnel evaluation records revealed Testing Personnel #1 had a form on file that stated at the top "Tests qualified and trained to perform:" for Sysmex 300 it had the following dates listed Initial Training Date 04/30/20, 6 Month Competency Date 10/13/20, and Annual Competency Date 04/12/20/21. There was supporting documentation for this form for other test performed at a different location, but no supporting documentation for the Sysmex XP-300 located at Birmingham Internal Medicine DBA STV at Springville. 2. During an interview on 08/18/2021 at 10:20 AM, Testing Personnel #1 confirmed there was no supporting documentation for the Sysmex XP-300 for this location and competencies were performed at a different location.

**D6052**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(8)(vi)

The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of problem solving skills.

This STANDARD is not met as evidenced by:  
Based on a review of personnel evaluation records and an interview with Testing Personnel #1, the Technical Consultant failed to include assessment of problem solving skills in the evaluation of competency at least semiannually and annually during the first year of performing CBC's (Complete Blood Counts). This was noted

on one of three Testing Personnel (two of the three testing personnel performed initial training in June 2021 and August 2021). The findings include: 1. A review of personnel evaluation records revealed Testing Personnel #1 had a form on file that stated at the top "Tests qualified and trained to perform:" for Sysmex 300 it had the following dates listed Initial Training Date 04/30/20, 6 Month Competency Date 10/13/20, and Annual Competency Date 04/12/20/21. There was supporting documentation for this form for other test performed at a different location, but no supporting documentation for the Sysmex XP-300 located at Birmingham Internal Medicine DBA STV at Springville. 2. During an interview on 08/18/2021 at 10:20 AM, Testing Personnel #1 confirmed there was no supporting documentation for the Sysmex XP-300 for this location and competencies were performed at a different location.

**D6053**

**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 semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

Based on a review of personnel evaluation records and an interview with Testing Personnel #1, the Technical Consultant failed to evaluate the performance of personnel at least semiannually during the first year of performing CBC's (Complete Blood Counts). This was noted on one of three Testing Personnel (two of the three testing personnel performed initial training in June 2021 and August 2021). The findings include: 1. A review of personnel evaluation records revealed Testing Personnel #1 had a form on file that stated at the top "Tests qualified and trained to perform:" for Sysmex 300 it had the following dates listed Initial Training Date 04/30/20, 6 Month Competency Date 10/13/20, and Annual Competency Date 04/12/20/21. There was supporting documentation for this form for other test performed at a different location, but no supporting documentation for the Sysmex XP-300 located at Birmingham Internal Medicine DBA STV at Springville. 2. During an interview on 08/18/2021 at 10:20 AM, Testing Personnel #1 confirmed there was no supporting documentation for the Sysmex XP-300 for this location and competencies were performed at a different location on different instrumentation.

**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 a review of personnel evaluation records and an interview with Testing Personnel #1, the Technical Consultant failed to evaluate the performance of personnel at least annually after the first year of performing CBC's (Complete Blood Counts). This was noted on one of three Testing Personnel (two of the three testing personnel performed initial training in June 2021 and August 2021). The findings include: 1. A review of personnel evaluation records revealed Testing Personnel #1 had a form on file that stated at the top "Tests qualified and trained to perform:" for

Sysmex 300 it had the following dates listed Initial Training Date 04/30/20, 6 Month Competency Date 10/13/20, and Annual Competency Date 04/12/20/21. There was supporting documentation for this form for other test performed at a different location, but no supporting documentation for the Sysmex XP-300 located at Birmingham Internal Medicine DBA STV at Springville. 2. During an interview on 08/18/2021 at 10:20 AM, Testing Personnel #1 confirmed there was no supporting documentation for the Sysmex XP-300 for this location and competencies were performed at a different location on different instrumentation.