

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D2159994	(X3) Date Survey Completed 07/17/2019
Name of Provider or Supplier Ross Bridge Medical Practice Llc	Street Address, City, State 3635 Market Street Suite A, Hoover, 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
D0000	Initial Certification Surveys were conducted simultaneously for CLIA identification numbers (#) 01D2160654 and 01D2159994 on 7/17/2019. The surveys were conducted by two State Agency surveyors, accompanied by two Regional Office representatives (Atlanta), who conducted FMS (Federal Monitoring Surveys) of the State Agency surveyors. The two laboratories occupy the same space and utilize the same equipment. However, based on observations, record reviews (including personnel and training, quality control, temperature/humidity, manufacturer's requirements, installation and validation records) and interviews, the surveyors determined the laboratories' hours of operation overlapped; and the laboratories failed to operate as two distinctly different entities. Both laboratories began patient testing on 2/11/2019. The State Agency surveyors reviewed the records simultaneously and observed the documentation, including installation and validations records for the Horiba ABx Micros 60 Hematology analyzer, environmental logs, and Hematology Quality Control records were photocopied and placed in binders for the individual laboratories.
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on observations made during the initial tour of the laboratory on 7/17/2019, a review of temperature logs and manufacturer requirements for the Horiba Micro 60</p>

and quality control material, and an interview with the office manager (also Testing Personnel #3), the surveyor determined the laboratory failed to monitor the room temperature, humidity and refrigerator from February 11 - June, 2019, independently from a second laboratory which occupies the same space and equipment [CLIA # 01D2160654]. The laboratory presented temperature/humidity logs identical (photocopied) to those presented for the laboratory (CLIA identification #01D2160654), sharing the space and equipment. Each CLIA laboratory should operate independently of each other. It is indeterminable which laboratory should be credited with temperature and humidity monitoring. The laboratory further failed to define acceptable refrigerator temperatures for the Hematology quality control material to ensure the material was stored as per manufacturer's requirements. This affected sixty days in 2019. The findings include: 1. During the initial laboratory tour on 7/17/2019 at 9:30 AM, the surveyor observed one Horiba Micros 60, Hematology analyzer. Additionally, the surveyor observed one refrigerator/freezer unit, one thermometer and monitor for room temperature/humidity. 2. A review of the temperature logs revealed duplicated (photocopied) documents, shared with laboratory, CLIA identification #01D2160654. 3. A review of the Horiba ABx Micros 60 Hematology analyzer's Operator Manual revealed QC should be stored at 4-8 degrees Centigrade (39-46 degrees F [Fahrenheit]). 4. A review of the 2019 temperature logs revealed the acceptable range for the refrigerator in which the QC was stored was 36-46 degrees F. The surveyor noted temperatures were less than 39 degrees F (colder than the storage requirements specified by the manufacturer) sixty days from February 11 through June 2019: six days in February, thirteen days in March and April, sixteen days in May and twelve days in June. 5. During an interview on 7/17/2019 at approximately 2:15 PM, Testing Personnel #3 reviewed with the surveyor the environmental logs and manufacturer's QC storage requirements, and confirmed the above noted findings. .

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 observations made during initial tour on 7/17/19, a review of the installation and validation records for the Horiba Micros 60 Hematology analyzer, and an interview with the office manager [also Testing Personnel (TP) #3], the surveyor determined the laboratory failed to perform the performance specification verifications, independently of another laboratory, sharing the same space and equipment. The laboratory with CLIA identification number (#) 01D2159994 provided to the surveyor accuracy, precision and reportable range studies, performed on 2/11/2019; however were identical to the documents for laboratory with CLIA # 01D2160654 (the two laboratories share the same space and equipment). Each CLIA laboratory should operate independently of each other. It is indeterminable which laboratory should be credited with the studies performed. The findings include: 1. During the initial tour of the laboratory on 7/17/19 at 9:30 AM, the surveyor observed

only one Horiba Micros 60, Hematology analyzer. 2. A review of the validation studies (accuracy, precision and reportable range), and calibration reports, revealed the laboratory staff presented duplicated (photocopied) documentation, including raw data (performed on 2/11/19) for the Horiba Micros 60, installed 2/11/19, as they presented for laboratory with CLIA #01D2160654. The two laboratories share the same space and Hematology analyzer; however failed to perform the studies independently. a) Precision was performed on 2/11 at 9:37-9:54 AM. b) The raw data for the reportable range study (linearity and accuracy) was dated 2/11/19 at 10:18 AM - 2:12 PM. 3. In the exit interview at 2:43 - 3:00 PM on 7/17/2019, TP #3 (also the office manager) confirmed the documents for the validation studies had been copied /duplicated, and not performed separately for the laboratories. .

D6000

MODERATE COMPLEXITY LABORATORY DIRECTOR
CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:

Based on a review of personnel and training records, a review of the installation and validation records for the Horiba Micros 60 Hematology analyzer, a review of quality control records, a review of temperature and humidity logs and manufacturer's requirements for storage of Hematology quality control (QC), and an interview with the office manager (also Testing Personnel #3), the surveyor determined the Laboratory Director failed to: 1. Ensure Testing Personnel (TP) #1 presented with the appropriate educational credentials, prior to testing patient specimens 2. Ensure TP #2 was trained to perform testing on the Micros 60, Hematology analyzer, prior to allowing the employee to test patient CBC (Complete Blood Count) specimens, and report the results. 3. Ensure the specification verifications were performed, as per the guidance of CLIA. The laboratory with CLIA identification number (#) 01D2159994 provided to the surveyor accuracy, precision and reportable range studies, performed on 2/11/2019; however were identical to the documents for laboratory with CLIA # 01D2160654 (the two laboratories share the same space and equipment). 4. Ensure the laboratory staff established acceptable refrigerator temperature ranges and ensured QC was stored as per manufacturer's requirements for 60 days in 2019. 5. Ensure the laboratory monitored environmental parameters (room temperature, humidity, and refrigerator temperatures) and documented independently from a second laboratory which occupies the same address and space [CLIA # 01D2160654]. Duplicate (photocopied) environmental records were observed for each laboratory by the two surveyors conducting simultaneous reviews. The surveyors were unable to determine which laboratory should be credited with temperature and humidity monitoring from February thru July 2019. 6. Ensure two laboratories, sharing the same space and Hematology analyzer, maintained different hours of operation, and tested quality control material independently of each other. The laboratory presented duplicated (photocopied) QC records for each laboratory. The findings include: 1. Refer to D6029. 2. Refer to D6029. 3. Refer to D6013. 4. Refer to D6010. 5. Refer to D6010. 6. Refer to D6020.

D6010

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(2)

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)(2) Ensure that the physical plant and environmental conditions of the laboratory are appropriate for the testing performed.

This STANDARD is not met as evidenced by:

Based on observations during the initial tour of the laboratory, a review of the temperature and humidity logs, a review of Hematology Quality Control (QC) storage requirements, and an interview with Testing Personnel #3 (also the office manager), the surveyor determined the Laboratory Director failed to ensure: 1) The laboratory established acceptable refrigerator temperature ranges and ensured QC was stored as per manufacturer's requirements for 60 days in 2019. 2) The laboratory ensured environmental parameters (room temperature, humidity, and refrigerator temperatures) were monitored and documented independently from a second laboratory which occupies the same address and space [CLIA # 01D2160654]. Duplicate (photocopied) environmental records were observed for each laboratory by the two surveyors conducting simultaneous reviews. The surveyors were unable to determine which laboratory should be credited with temperature and humidity monitoring from February thru July 2019. The findings include: 1. Refer to D5413. .

D6013

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(3)(ii)

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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method;

This STANDARD is not met as evidenced by:

Based on a review of the installation and validation records for the Horiba Micros 60, Hematology analyzer and an interview with the office manager, the surveyor determined the Laboratory Director failed to ensure the specification verifications were performed, as per the guidance of CLIA. The laboratory with CLIA identification number (#) 01D2159994 provided to the surveyor accuracy, precision and reportable range studies, performed on 2/11/2019; however were identical to the documents for laboratory with CLIA # 01D2160654 (the two laboratories share the same space and equipment). Each CLIA laboratory should operate independently of each other. It is indeterminable which laboratory should be credited with the studies performed. The findings include: 1. Refer to D5421. .

D6021

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(5)

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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

Based on observations made during the initial tour, reviews of Hematology Quality Control (QC) logs, a review of quality assurance records, and an interview with Testing Personnel (TP) #3 (also the office manager), the surveyor determined the Laboratory Director failed to ensure two laboratories, sharing the same space and Hematology analyzer, maintained different hours of operation, and tested quality control material independently of each other. The laboratory presented duplicated (photocopied) QC records for each laboratory, CLIA identification numbers #01D2159994 and 01D2160654. The findings include: 1. During the initial tour of the laboratory on 7/17/19 at 9:30 AM, the surveyor observed only one Horiba Micros 60 Hematology analyzer. 2. During the surveyors simultaneous reviews of the quality control records, the surveyors noted the quality control records for February 11 (the first day of patient testing for both laboratories) - March 2019, the quality control records were duplicated/photocopied and maintained for each laboratory. The laboratories failed to independently perform QC testing and document the findings. 3. In March of 2019, the Technical Consultant documented a quality assurance note, instructions to the laboratory staff, to separate QC testing for the two laboratories: The pediatric laboratory was to perform QC in the mornings and the internal medicine laboratory was to perform QC in the PM. However the laboratories still maintained overlapping hours of operation. The laboratory listed the operation hours on the CMS form #116 (application): for the pediatric laboratory as 8:00 AM - 5:00 PM, Monday through Friday; and 8:00 AM - 8:00 PM, Monday through Friday and 9:00 AM - 1:00 PM on Saturday and Sunday for the internal medicine laboratory, sharing the same space and equipment. 4. During the exit interview on 7/17/2019 at 2:43 - 3:00 PM, the above noted findings were discussed with TP #3 (also the office manager).

D6029

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(11)

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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:

Based on a review of the personnel and training records, and an interview with the office manager, the surveyor determined the Laboratory Director (LD) failed to ensure Testing Personnel (TP) #1 presented with the appropriate educational credentials, prior to testing patient specimens. The LD further failed to ensure TP #2 was trained to perform testing on the Micros 60, Hematology analyzer, prior to allowing the employee to test patient CBC (Complete Blood Count) specimens, and report the results. This affected two of three testing personnel, which the laboratory listed on the CLIA Laboratory Personnel Report. The findings include: 1. A review of the CLIA

Laboratory Personnel Report revealed the laboratory staff listed three testing personnel of moderate complexity testing (CBCs). 2. The personnel records failed to include the appropriate and acceptable educational credentials for TP#1, who has a date-of-hire, 2/11/2019. TP #1's personnel file included a transcript of medical assisting. At 10:21 AM, the office manager stated the MA (Medical Assistant) transcript was the only educational record she had for TP #1. 3. TP #2's date-of-hire was indicated as 3/28/2019. The Micros 60 training checklist was dated 6/01/2019. The file contained another laboratory training checklist; however the checklist was not dated. At 10:25 AM, the office manager stated the testing personnel began patient testing (CBCs) on April 1 (2019). 4. The surveyor discussed the above noted findings with the office manager in the exit interview on 7/17/2019 at 2:43 - 3:00 PM.

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 a review of the installation and validation records for the Horiba Micros 60, Hematology analyzer and an interview with the office manager, the surveyor determined the Technical Consultant failed to ensure the specification verifications were performed, as per the guidance of CLIA. The laboratory with CLIA identification number (#) 01D2159994 provided to the surveyor accuracy, precision and reportable range studies, performed on 2/11/2019; however were identical to the documents for laboratory with CLIA # 01D2160654 (the two laboratories share the same space and equipment). Each CLIA laboratory should operate independently of each other. It is indeterminable which laboratory should be credited with the studies performed. The findings include: 1. Refer to D5421.