

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 45D1004466	<b>(X3) Date Survey Completed</b> 01/22/2025
<b>Name of Provider or Supplier</b> G Scot Johnson Md Pa	<b>Street Address, City, State</b> 5110 North 10th Street Suite E, Mcallen, TX	
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>D0000</b>	The laboratory was found NOT to be in compliance with the CLIA regulations found at 42 CFR 493 CLIA requirements. The condition not met was: D6063 - 42 C.F.R. 493.1421 Condition: Laboratories performing moderate complexity testing; testing personnel
<b>D2009</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> CFR(s): 493.801(b)(1)</p> <p>(b)(1) 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 review of the laboratory's American Association of Bioanalysts/Medical Laboratory Evaluation (AAB/MLE) proficiency testing records from 2023 and 2025, and staff interview, the laboratory failed to have documentation of testing personnel signing 6 of 6 attestation statements. The findings included: 1. A review of the laboratory's American Association of Bioanalysts/Medical Laboratory Evaluation Non-Chemistry proficiency testing records from 2023 (M1, M2 and M3) and 2024 (M1, M2 and M3) determined the laboratory failed to have documentation of testing personnel signing 6 of 6 attestation statements. They were: 2023 Non-Chemistry M1 2023 Non-Chemistry M2 2023 Non-Chemistry M3 2024 Non-Chemistry M1 2024 Non-Chemistry M2 2024 Non-Chemistry M3 2. The technical consultant confirmed the findings in an interview conducted on 01/22/205 at 1244 hours in the break room.</p>
<b>D5401</b>	<p><b>PROCEDURE MANUAL</b> CFR(s): 493.1251(a)</p> <p>(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks</p>

may supplement but not replace the laboratory's written procedures for testing or examining specimens.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's procedures, review of the laboratory's hematology quality control records from 2024, and staff interview, the laboratory failed to have documentation of following its policy for the verification of new lots of quality control material for 4 of 4 lots. The findings included: 1. A review of the laboratory's procedure titled "Hematology CBC Quality Control" stated the laboratory required testing new lots of quality control material a minimum of 10 times prior to placing the lot into use to verify the control. 2. A review of Mindray BC-3D hematology quality control records from 2024 identified 4 of 4 new lots which were placed into use without documentation of the minimum of 10 runs. They were: Lot: B0224 expiration: 5-5-2024 tested one time Lot: B0524 expiration: 8-5-2024 tested one time Lot: B0824 expiration: 11-5-2024 tested one time Lot: B1124 expiration: 2-5-2025 tested one time 3. The technical consultant confirmed the findings in an interview conducted on 01/22/2025 at 1244 hours in the break room.

**D5791**

**ANALYTIC SYSTEMS QUALITY ASSESSMENT**

CFR(s): 493.1289(a)(c)

(a) 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 analytic systems specified in 493.1251 through 493.1283.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's calibration records for the Mindray 3600 hematology analyzer from 2023 and 2024, and staff interview, the laboratory's quality assurance plan failed to identify that calibration factors were changed without documentation of calibrations being performed for 3 of 3 calibrations. The findings included: 1. A review of the laboratory's calibration records for the Mindray 3600 hematology analyzer from 2023 and 2024 revealed the instrument documented the calibration factors in use prior to the calibration and the new calibration factors determined as a result of the calibration. Thus, the new calibration values should be the same as the old calibration values documented at the next calibration. 2. Further review of the calibration records showed: a) Calibration: 2/6/2023 New Calibration Factors: WBC: 101.09 RBC: 100.60 HGB: 104.07 MCV: 94.75 PLT: 98.45 b) Calibration: 7/26/2023 Old Calibration Factors: WBC: 101.57 (changed) RBC: 100.58 (changed) HGB: 103.90 (changed) MCV: 94.84 (changed) PLT: 100.09 (changed) New Calibration Factors: WBC: 102.22 RBC: 102.39 HGB: 105.13 MCV: 95.24 PLT: 101.68 c) Calibration: 01/22/2024 Old Calibration Factors: WBC: 101.09 (changed) RBC: 100.60 (changed) HGB: 104.07 (changed) MCV: 94.75 (changed) PLT: 98.45 (changed) New Calibration Factors: WBC: 99.02 RBC: 99.67 HGB: 98.32 MCV: 98.83 PLT: 96.09 d) Old Calibration Factors: WBC: 102.22 (changed) RBC: 102.39 (changed) HGB: 105.13 (changed) MCV: 95.24 (changed) PLT: 101.68 (changed) 3. The laboratory did not have documentation of calibrations being performed to support the change of calibration factors. 4. The technical consultant reviewed the records and confirmed the findings in an interview conducted on 01/22/2024 at 1300 hours in the break room.

**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 review of the laboratory's submitted Form CMS 209, review of the laboratory's personnel records, and staff interview, the laboratory failed to have documentation of the technical consultant performing a competency assessment twice within the first year for 1 of 1 testing personnel. The findings included: 1. A review of the laboratory's submitted Form CMS 209 determined the laboratory identified 1 testing personnel. 2. A review of the laboratory's personnel records for testing personnel number 1 identified she started performing moderate complexity testing on the Mindray 3600 hematology analyzer in January 2024. The file contained a single competency assessment performed in January 2025. 3. The technical consultant confirmed the findings in an interview conducted on 01/22/2025 at 12:44 hours in the break room. She reviewed the entire personnel record and did not see documentation of two competency assessments being performed.

**D6063**

LABORATORY TESTING PERSONNEL

CFR(s): 493.1421

The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.

This CONDITION is not met as evidenced by:

Based on review of the laboratory's submitted Form CMS 209, review of the laboratory's personnel records, and staff interview, the laboratory failed to have documentation of training to qualify 1 of 1 testing personnel to perform moderate complexity testing (refer to D6066).

**D6066**

TESTING PERSONNEL QUALIFICATIONS

CFR(s): 493.1423(b)(4)(ii)

(b)(6)(ii) Have documentation of laboratory training appropriate for the testing performed prior to analyzing patient specimens. Such training must ensure that the individual has-

- (b)(6)(ii)(A) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation, and storage of specimens;
- (b)(6)(ii)(B) The skills required for implementing all standard laboratory procedures;
- (b)(6)(ii)(C) The skills required for performing each test method and for proper instrument use;
- (b)(6)(ii)(D) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed;
- (b)(6)(ii)(E) A working knowledge of reagent stability and storage;
- (b)(6)(ii)(F) The skills required to implement the quality control policies and procedures of the laboratory;
- (b)(6)(ii)(G) An awareness of the factors that influence test results; and
- (b)(6)(ii)(H) The skills required to assess and verify the validity of patient test results through the evaluation of quality control sample values prior to reporting patient test results.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's submitted Form CMS 209, review of the laboratory's personnel records, and staff interview, the laboratory failed to have documentation of training to qualify 1 of 1 testing personnel to perform moderate complexity testing. The findings included: 1. A review of the laboratory's submitted Form CMS 209 determined the laboratory identified 1 testing personnel. 2. A review of the laboratory's personnel records for testing personnel number 1 identified she started performing moderate complexity testing on the Mindray 3600 hematology analyzer in January 2024. The laboratory failed to have documentation of testing personnel number 1 being trained on the Mindray 3600 analyzer. 3. The technical consultant confirmed the findings in an interview conducted on 01/22/2025 at 12:44 hours in the break room. She reviewed the entire personnel record and did not see documentation of training on the Mindray 3600 hematology analyzer.