Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1004466	08/03/2021
Name of Provider or Supplier	**Street Address, City, State**	
G Scot Johnson Md Pa	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.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	Laboratory representatives were present at the entrance conference. The survey process was discussed. An opportunity for questions and comments was given. The exit conference was held with the laboratory representatives. The laboratory was found to be in substantial compliance for the specialties/subspecialties for which it was surveyed. The standard level deficiencies cited were discussed. The process for submitting the corrections was explained. CMS form 2567 will be emailed from the Texas Health and Human Services Commission, Health Facility Compliance Arlington Group. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by:

	Based on review of laboratory policy, American Association of Bioanalysts (AAB) proficiency testing(PT) records, and confirmed in interview, the laboratory failed to retain a copy of all hematology PT records for 1 of 3 events in 2020 (Event 2). Findings: 1. Review of the laboratory's PT policy revealed: "D. Testing All lab personnel will perform proficiency testing. PT samples will be handled in the same manner patient samples are tested. There will be no communication with other laboratories about PT results until after the deadline for submission of data to the PT agency. The lab cannot send PT samples to other labs for testing. E. Reporting All results will be documented on result logs along with date and initials of the tech performing the testing. Results will be submitted via internet to AAB. The attestation sheet may be signed by Lab Consultant or Lab Director. A copy will be printed of submitted results." 2. Review of AAB PT records revealed the laboratory failed to retain a copy of the following records for hematology event 2 in 2020: Test records 3. During an interview on 08/03/2021 at 10:50 am, the Technical Consultant confirmed the above findings.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on direct observation, review of laboratory policy, Mindray quality control records, Hematology QC Action Log, and confirmed in interview, the laboratory failed to retain all quality control records for at least two years for 4 of 21 QC runs in 2021 (May). Findings: 1. Review of the laboratory's policy "QUALITY CONTROL" revealed: "Controls will be run daily with 3 levels of controls, high, normal and low, once every 24 hours. In the event that a control material does not fall within the acceptable parameters, the control will be rejected and repeated. If the repeated control does not fall into acceptable parameters follow manufacturer's instructions, or dispose of control and open a new set of controls. A control run can be accepted with 2 out of 3 controls in range. If controls are still not acceptable, report to laboratory director and no patient testing or reporting can be done until the problem is resolved." 2. Review of Mindray hematology analyzer QC results and Hematology QC Action Log revealed: High control lot# B0521H; expiration date: 08/05/2021 05/03/2021 8: 44 am QC failed for RBC, HCT Review of corrective action comment was documented "re-ran not passed", however the QC data did not have more one QC run. 05/04/2021 8:53 am QC failed for RBC, HCT Review of corrective action comment was documented "re-ran not passed", however the QC data did not have more one QC run. 05/06/2021 8:55 am QC failed for RBC, HCT, HGB Review of corrective action comment was documented "re-ran not passed", however the QC data did not have more one QC run. 05/10/2021 8:57 am QC passed Review of corrective action comment was documented "re-ran passed", however the QC data did not have any runs with QC failures. 3. During an interview on 08/03/2021 at 12:05 pm, Testing Person-1 (TP-1) was asked to provide documentation of the QC runs that were repeated. She stated that she could not provide the documentation because she had deleted the QC file; confirming the above findings. Word Key: RBC- red blood cell HCT - hematocrit HGB - hemoglobin
D5401	PROCEDURE MANUAL

	CFR(s): 493.1251(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 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 laboratory policy, quality control (QC) records, and confirmed in interview, the laboratory failed to follow their own written policy for corrective action for unacceptable QC for 10 of 77 QC runs in 2021 (May-July). Findings: 1. Review of the laboratory's policy "QUALITY CONTROL" revealed: "Controls will be run daily with 3 levels of controls, high, normal and low, once every 24 hours. In the event that a control material does not fall within the acceptable parameters, the control will be rejected and repeated. If the repeated control does not fall into acceptable parameters follow manufacturer's instructions, or dispose of control and open a new set of controls. A control run can be accepted with 2 out of 3 controls in range. If controls are still not acceptable, report to laboratory director and no patient testing or reporting can be done until the problem is resolved." 2. Review of Mindray QC records revealed the laboratory failed to follow their own written policy for troubleshooting unacceptable QC on the following dates for the following analytes in 2021: QC normal level control lot #B0521N; expiration date: 08/05/2021 QC high level control lot #B0521H; expiration date: 08/05/2021 05/14/2021 High control 8:44 am - QC failed for RBC and was not repeated 05/17/2021 High control 8:47 am - QC failed for RBC, HCT and was not repeated 05/18/2021 High control 9:03 am - QC failed for RBC, HCT and was not repeated 05/24/2021 High control 10:12 am - QC failed for RBC and was not repeated 07/05/2021 High control 9:08 am - QC failed for HCT and was not repeated 07/12/2021 High control 5:20 pm - QC failed for RBC, HCT and was not repeated 07/13/2021 High control 9:04 am - QC failed for RBC, HCT and was not repeated 07/15/2021 Normal control 9:31 am - QC failed for RBC and was not repeated 07/20/2021 High control 8:52 am - QC failed for RBC and was not repeated 07/22/2021 Normal control 9:30 am - QC failed for RBC, HGB, HCT and was repeated 10:59 am and 11:00, 11:03 am, 11:05 am, 11:08 am, 3:02 pm, 3:08 pm, 3:10 pm, 3:13 pm - QC was repeated and failed for RBC, HGB 3:17 pm - QC was repeated and failed for RBC, HGB, HCT 3:18 pm - QC was repeated and failed for all CBC parameters 3:19 pm- QC was repeated and failed for RBC, HGB 3:37 pm - QC was repeated and failed for WBC, Lymph#, Gran#, Lymph%, Gran%, HGB, PLT 4: 40 pm, 4:44 pm - QC was repeated and failed for RBC, HGB 4:47 pm, 4:49 pm, 4:50 pm- QC was repeated and failed for RBC, HGB, HCT High control 9:31 am - QC failed for RBC, HCT and was repeated 11:02 am and 11:04 - QC was repeated and failed for RBC, HGB 11:07 am, 3:06 pm, 3:09 pm, 3:11 pm, 3:15 pm, 3:16 pm, 4:42 pm, 4:46 pm, 4:48 pm - QC was repeated and failed for RBC, HGB, HCT Note corrective action log stated: "toward end of vial". The laboratory failed to follow their own written policy for repeating unacceptable QC runs, following manufacturer's instructions, and disposing of control material and using a new vial of QC. 3. During an interview on 07/26/2021 at 10:47 am, the Technical Consultant confirmed the above findings. Word Key: RBC - red blood cell HGB - hemoglobin HCT - hematocrit WBC - white blood cell PLT - platelet Lymph - lymphocyte Gran- granulocyte
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)

	Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on direct observation and confirmed in interview, the laboratory failed to ensure culture swabs did not exceed their expiration date. Findings: 1. During a tour of the laboratory on 08/03/2021 at 12:50 pm, the surveyor observed 11 expired BBL Culture Swabs lot #200453900, expiration date 07/31/2021 in a drawer on the laboratory counter. 2. During an interview on 08/03/21 at 12:50 pm, Testing Person-1 and the Technical Consultant confirmed the above findings.
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 review of laboratory policies, quality control (QC) records, patient records, and confirmed in interview, the laboratory failed to perform two levels of control each day of patient testing on the Mindray hematology analyzer for 8 of 77 days in 2021 (May-July). Findings: 1. Review of the laboratory's policy "QUALITY CONTROL" revealed: "Controls will be run daily with 3 levels of controls, high, normal and low, once every 24 hours. In the event that a control material does not fall within the acceptable parameters, the control will be rejected and repeated. If the repeated control does not fall into acceptable parameters follow manufacturer's instructions, or dispose of control and open a new set of controls. A control run can be accepted with 2 out of 3 controls in range. If controls are still not acceptable, report to laboratory director and no patient testing or reporting can be done until the problem is resolved." 2. A review of QC and patient records from May 2021 through July 2021, revealed the following dates QC was not performed and patients were tested on the Mindray hematology analyzer: 06/08/2021- Patient Sample ID: 3; analysis time 10:04 am QC high control was performed at 9:50 am and failed. It was repeated at 6:28 pm and passed. QC low control was performed at 6:17 pm and the normal control was performed at 6:20 pm but it failed. The normal control was repeated at 6:23 pm and it passed. QC was performed AFTER patient specimens were analyzed and reported. 06 /14/2021- Patient Sample ID: 4; analysis time 9:31 am QC low control was performed at 4:42 pm, normal control was performed at 4:46 pm, high control was performed at 4:48 pm. QC was performed AFTER patient specimens were analyzed and reported. 06/15/2021- Patient Sample ID: 3; analysis time 10:13 am QC low control was performed at 3:57 pm, normal control was performed at 3:58 pm, high control was performed at 4:01 pm. QC was performed AFTER patient specimens were analyzed and reported. 06/16/2021- Patient Sample ID: 3; analysis time 1:33 pm QC low control was performed at 5:09 pm, normal control was performed at 5:11 pm, high control was performed at 5:12 pm. QC was performed AFTER patient specimens were analyzed and reported. 06/21/2021- Patient Sample ID: 6; analysis time 10:24

	am QC low control was performed at 5:33 pm, normal control was performed at 5:38 pm, high control was performed at 5:40 pm. QC was performed AFTER patient specimens were analyzed and reported. 07/12/2021- Patient Sample ID: 2; analysis time 9:23 am QC low control was performed at 5:16 pm, normal control was performed at 5:20 pm, high control was performed at 5:18 pm. QC was performed AFTER patient specimens were analyzed and reported. 07/14/2021- Patient Sample ID: 8; analysis time 2:42 pm QC low control was performed at 4:51 pm. Normal control was performed at 4:53 pm, 4:55 pm, 5:13 pm, 5:16 pm, 5:19 pm, and 5:28 pm 5:31 pm all runs resulted in failures. QC normal control passed at 5:34 pm. High control was performed at 4:57 pm, 5:18 pm, and 5:29 pm all runs resulted in failures. QC high control passed at 5:32 pm. QC was performed AFTER patient specimens were analyzed and reported. 07/21/2021- Patient Sample ID: 5; analysis time 10:54 am QC low control was performed at 5:05 pm. Normal control was performed at 5:19 pm and 5:32 pm both runs resulted in failures. QC normal control passed at 5:33 pm. High control was performed at 5:06 pm and 5:29 pm both runs resulted in failures. QC high control passed at 5:31 pm. QC was performed AFTER patient specimens were analyzed and reported. 3. During an interview on 08/03/2021 at 12:05 pm, Testing Person-1 (TP-1) stated that she performed QC every morning and Testing Person-2 performed QC in the afternoons as part of her training and lot roll overs. TP-1 was asked to provide documentation of the morning QC runs. She stated that she could not provide the documentation because she had deleted the QC file. This confirmed the above findings.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (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. This STANDARD is not met as evidenced by: Based on review of laboratory policy, Mindray 2 hematology quality control (QC) records, patient test records, and confirmed in interview, the laboratory failed to ensure QC was within established acceptability before reporting patient test results for 1 of 1 day in 2021 (July). Findings: 1. Review of the laboratory's policy "QUALITY CONTROL" revealed: "Controls will be run daily with 3 levels of controls, high, normal and low, once every 24 hours. In the event that a control material does not fall within the acceptable parameters, the control will be rejected and repeated. If the repeated control does not fall into acceptable parameters follow manufacturer's instructions, or dispose of control and open a new set of controls. A control run can be accepted with 2 out of 3 controls in range. If controls are still not acceptable, report to laboratory director and no patient testing or reporting can be done until the problem is resolved." 2. Review of Mindray hematology quality control (QC) records and staff interview revealed QC was not within acceptable range before reporting patient test results for the following day in July 2021: QC normal level lot #B0251, expiration date 08/05/2021 QC high level lot #B0521H, expiration date 08/05/2021 Complete Blood Count (CBC) acceptable ranges: Normal level: RBC: 4.34-4.82*10^6/uL HGB: 13.2-14.4 g/dL HCT: 37.6-41.6% WBC: 6.8-8.8*10^3/uL Lymph#: 1.8-3.2*10^3/uL Gran#: 4.1-5.5*10^3/uL Lymph%: 23.5-39.5% Gran%: 53.5-69.5% PLT: 208-288*10^3/uL High level: RBC: 5.40-6.0*10^6/uL HGB: 18.4-20.0 g/dL HCT: 51.8-56.6% 07/22/2021 Normal level QC 9:30 am RBC: 4.20*10^6/uL, HGB: 13.1 g/dL, HCT: 37.4% 10:59 am (repeat) RBC: 4.26*10^6/uL, HGB: 13.0 g/dL 11:00 am

	(repeat) RBC: 4.27*10^6/uL, HGB: 13.0 g/dL 11:03 am (repeat) RBC: 4.27*10^6/uL, HGB: 13.1 g/dL 11:05 am (repeat) RBC: 4.24*10^6/uL, HGB: 12.9 g/dL 11:08 am (repeat) RBC: 4.31*10^6/uL, HGB: 13.1 g/dL 1:02 pm (repeat) RBC: 4.27*10^6/uL, HGB: 13.1 g/dL 1:08 pm (repeat) RBC: 4.24*10^6/uL, HGB: 13.1 g/dL 1:10 pm (repeat) RBC: 4.25*10^6/uL, HGB: 13.1 g/dL 1:13 pm (repeat) RBC: 4.24*10^6/uL, HGB: 13.1 g/dL 1:17 pm (repeat) RBC: 4.23*10^6/uL, HGB: 13.0 g/dL, HCT: 37.5% 1:18 pm (repeat) WBC: 0.0*10^3/uL, Lymph#: *****, Mid#: *****, Gran#: *****, Lymph%: *****, Mid%: *****, Gran%: *****, RBC: 0.00*10^6/uL, HGB: 0.00 g /dL, HCT: 0.00%, MCV: *****, MCH:*****, MCHC: *****, RDW: *****, PLT: 1*10^3/uL, MPV: ***** 1:19 pm (repeat) (repeat) RBC: 4.33*10^6/uL, HGB: 13.1 g /dL 1:37 pm (repeat) WBC: 9.8*10^3/uL, Lymph#: 0.7*10^3/uL, Gran#: 8.4*10^3 /uL, Lymph%: 7.5%, Gran%: 85.8%, HGB: 12.9 g/dL, PLT: 176*10^3/uL 4:40 pm (repeat) RBC: 4.24*10^6/uL, HGB: 12.9 g/dL 4:44 pm (repeat) RBC: 4.25*10^6/uL, HGB: 12.9 g/dL 4:47 pm (repeat) RBC: 4.22*10^6/uL, HGB: 13.0 g/dL, HCT: 37.3% 4:49 pm (repeat) RBC: 4.21*10^6/uL, HGB: 13.0 g/dL, HCT: 37.3% 4:50 pm (repeat) RBC: 4.22*10^6/uL, HGB: 13.0 g/dL, HCT: 37.4% High level QC 9:31 am RBC: 5.25 *10^6/uL, HCT: 51.6% 11:02 am (repeat) RBC: 5.35*10^6/uL, HGB: 18.2 g/dL 11: 04 am (repeat) RBC: 5.31*10^6/uL, HGB: 18.2 g/dL 11:07 am (repeat) RBC: 5.28 *10^6/uL, HGB: 18.1 g/dl, HCT: 51.7% 1:06 pm (repeat) RBC: 5.25*10^6/uL, HGB: 18.1 g/dL, HCT: 51.5% 1:09 pm (repeat) RBC: 5.30*10^6/uL, HGB: 18.3 g/dL, HCT: 51.7% 1:11 pm (repeat) RBC: 5.19*10^6/uL, HGB: 18.1 g/dL, HCT: 50.7% 1:16 pm (repeat) RBC: 5.20*10^6/uL, HGB: 18.1 g/dL, HCT: 50.8% 4:42 pm (repeat) RBC: 5.29*10^6/uL, HGB: 18.3 g/dL, HCT: 51.7% 4:46 pm (repeat) RBC: 5.22*10^6/uL, HGB: 18.2 g/dL, HCT: 51.7% 4:48 pm (repeat) RBC: 5.28*10^6/uL, HGB: 18.2 g /dL, HCT: 51.6% The results for RBC, HGB, and HCT for both the normal and high level of control were not within acceptable range and 1 patient was tested and reported: Sample ID: 1 3. During the exit interview on 08/03/2021 at 1:30 pm, the Technical Consultant and Testing Person-1 confirmed the above findings. Word key: RBC- red blood cell HGB- hemoglobin HCT- hematocrit WBC- white blood cell Lymph- lymphocyte Gran-granulocyte PLT- platelet MID- Minimum Inhibitory Dilution MCV- mean corpuscular volume MCH- mean corpuscular hemoglobin MCHC- mean corpuscular hemoglobin concentration RDW- red cell distribution width
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on review of laboratory policy, quality control (QC) records, corrective action logs, patient reports, and confirmed in interview, the laboratory failed to evaluate all patient test results after performing test system adjustments for QC failures and since the last acceptable test run to ensure accurate and reliable test results 1 of 1 patient in 2021 (July) on the Mindray hematology analyzer. Findings: 1. Review of the laboratory's policy "QUALITY CONTROL" revealed: "Controls will be run daily

	with 3 levels of controls, high, normal and low, once every 24 hours. In the event that a control material does not fall within the acceptable parameters, the control will be rejected and repeated. If the repeated control does not fall into acceptable parameters follow manufacturer's instructions, or dispose of control and open a new set of controls. A control run can be accepted with 2 out of 3 controls in range. If controls are still not acceptable, report to laboratory director and no patient testing or reporting can be done until the problem is resolved." The policy did not include evaluation of patients when test systems adjustments were performed for QC failures since the last acceptable QC run. 2. Review of Mindray hematology quality control (QC) records revealed test system adjustments performed for the following sampling of QC test events in 2021: 07/23/2021 High control lot #B0821H; expiration date 11/05/2021 1: 15 pm QC failed for RBC, HGB, HCT 1:53 pm QC was repeated and failed for RBC, HGB, HCT 8:47 pm QC was repeated and passed The corrective action log stated, "analyzer calibration performed QC accepted". The following patients were not evaluated to ensure accurate and reliable test results since the last acceptable QC run with test system adjustments performed (07/21/2021). (Note two levels of QC failed on 07/22/2021): Patient Sample ID: 5 3. During an interview on 08/03/2021 at 12:05 pm, the Technical Consultant confirmed the laboratory failed to evaluate all patient test results after performing test system adjustments for QC failures and since the last acceptable test run to ensure accurate and reliable test results.
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 review of Centers for Medicaid and Medicare Services (CMS) 209 form, laboratory policy, personnel records, and confirmed in interview the technical consultant (TC) failed to evaluate and document the performance for 1 of 2 Testing Persons (TP-1) responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. Findings: 1. Review of the CMS 209 form revealed the laboratory identified two testing persons who performed moderate complexity testing. 2. Review of the laboratory's personnel policy titled "Competency Assessment" revealed: "POLICY: Initial and annual competency assessments will be performed on all laboratory personnel by the Laboratory Consultant. This [sic] actions will be documented on a competency log sheet." The policy failed to indicate the frequency of competency assessments at least semiannually during the first year an individual responsible for moderate complexity tests patient specimens. 2. Review of personnel records for TP-1 revealed an initial training assessment was performed on 03/27/2019 on the hematology analyzer and an annual competency assessment 02/21/2020. There was no documentation of a semiannual performance for hematology. The laboratory was asked to provide the semiannual performance assessment, none was provided. 3. During an interview on 08 /03/2021 at 9:42 hours, the Technical Consultant confirmed the above findings.