

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D1053583	(X3) Date Survey Completed 03/10/2026
Name of Provider or Supplier Verley Gordon Md Pa	Street Address, City, State 5711 N La Homa Rd Ste B, Mission, 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	The laboratory was found NOT to be in compliance with the CLIA regulations found at 42 CFR 493 CLIA requirements for laboratories as a result of an announced recertification survey completed on March 10, 2026. The condition not met was: D6063 - 42 C.F.R. 493.1421 Condition: Laboratories performing moderate complexity testing; testing personnel;
D5213	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1)</p> <p>(b) The laboratory must verify the accuracy of the following: (b)(1) Any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's American Proficiency Institute's proficiency testing records from 2025 and staff interview, the laboratory failed to have documentation of evaluating 2 of 2 results reported by the proficiency testing agency as 'ungraded'. The findings included: 1. A review of the laboratory's American Proficiency Institute's proficiency testing records from 2025 (events 1, 2 and 3) determined the proficiency agency returned two results marked as "ungraded". They were: a) Event 2 2025 Sample: HEM-09 Analyte: Hematocrit b) Event 2 2025 Sample: HEM-09 Analyte: Red Cell Count 2. The laboratory did not have documentation of evaluating the ungraded results. 3. The laboratory director confirmed the findings in an interview conducted on 03/10/2026 at 1230 hours in exam room 3.</p>
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>(d) Reagents, solutions, culture media, control materials, calibration materials, and</p>

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 review of the manufacturer's instructions for the CDS 3PD Hematology Controls, review of the laboratory's quality control records from September 2025 to March 2026, review of patient test records from September 2025 to March 2026, and staff interview, the laboratory failed to ensure controls materials were not used for 6 of 7 control changes. The findings included: 1. The manufacturer's instructions for the CDS 3PD Hematology Control (PN 202448C R06.05.18) stated: "Open Vial Stability: 14 days" 2. A review of the laboratory's quality control logs from September 2025 to March 2026 identified the laboratory changed controls on the following dates: Lot: 32508 opened: 9/11/2025 Lot: 32508 opened: 10/9/2025 elapsed time: 28 days Lot: 32508 opened: 11/4/2025 elapsed time: 25 days Lot: 32508 opened: 12/1/2025 elapsed time: 26 days Lot: 32511 opened: 12/18/2025 elapsed time: 17 days Lot: 32511 opened: 1/20/2026 elapsed time: 32 days Lot: 32511 opened: 2/16/2026 elapsed time: 26 days Lot: 32511 opened: 3/02/2026 elapsed time: 14 days 3. A review of patient test records identified the following patients tested on days when expired control materials were used: a) 9/16/2025 to 10/8/2025 45 patients tested (see patient alias list) b) 10/24/2025 to 11/3/2025 27 patients tested (see patient alias list) c) 11/19/2025 to 11/30/2026 22 patients tested (see patient alias list) d) 12/16/2026 to 12/17/2026 8 patients tested (see patient alias list) e) 01/02/2026 to 01/19/2026 47 patients tested (see patient alias list) f) 02/04/2026 to 02/15/2026 39 patients tested (see patient alias list) 4. The laboratory director confirmed the findings after his review of the records in an interview conducted on 03/10/2026 at 1230 hours in exam room 3.

D5437

CALIBRATION AND CALIBRATION VERIFICATION
CFR(s): 493.1255(a)

(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 verification.

This STANDARD is not met as evidenced by:

Based on a review of the hematology calibration records from 2024 and 2025, and staff interview, it was revealed that the laboratory adjusted calibration factors without documentation of performing a calibration. The findings included: 1 . The facility performed a calibration of the Coulter AcT diff 2 hematology analyzer on 10/31/2024. This calibration record showed calibration factors of: WBC (white blood cell count): 1.061 RBC (red blood cell count): 1.139 HGB (hemoglobin): 1.134 MCV (mean Corpuscular hemoglobin): 0.9247 PLT (platelets count): 1.166 MPV (mean platelet volume): 1.059 2. The facility performed the next calibration on 03/27/2025. The pre-

calibration records indicated the following calibration factors were in use prior to calibration: WBC: 1.061 RBC: 1.147 HGB: 1.137 MCV: 0.9247 PLT: 1.166 MPV: 1.059 There was no documentation to show where the RBC and HGB calibration factors were derived and when they were changed. There was no documentation of a calibration from 10/31/2024 to 03/27/2025. Calibration factors in use as a results of the calibration performed on 03/27/2025 were: WBC: 1.061 RBC: 1.147 HGB: 1.113 MCV: 0.9247 PLT: 1.166 MPV: 1.059 3. The facility performed the next calibration on 07/17/2025. The pre-calibration records indicated the following calibration factors were in use prior to calibration: WBC: 1.061 RBC: 1.147 HGB: 1.105 MCV: 0.9247 PLT: 1.166 MPV: 1.059 There was no documentation to show where the HGB calibration factor was derived and when it was changed. There was no documentation of a calibration being performed between 3/27/2025 to 07/17/2025. Calibration factors in use as a results of the calibration performed on 07/17/2025 were: WBC: 1.061 RBC: 1.147 HGB: 1.105 MCV: 0.9247 PLT: 1.166 MPV: 1.059 4. The facility performed the next calibration on 11/14/2025. The pre-calibration records indicated the following calibration factors were in use prior to calibration: WBC: 1.061 RBC: 1.147 HGB: 1.108 MCV: 0.9247 PLT: 1.166 MPV: 1.059 There was no documentation to show where the HGB calibration factor was derived and when it was changed. There was no documentation of a calibration from 07/17/2025 to 11/14/2025. 5. The laboratory director confirmed the findings in an interview conducted on 03/10/2026 at 1230 hours in exam room 3.

D5785

CORRECTIVE ACTIONS
CFR(s): 493.1282(b)(3)

(b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's room temperature and humidity records from January 2026 and February 2026, and staff interview, the laboratory failed to have documentation of corrective actions when room temperature and/or room humidity levels were out of acceptable range for 7 of 41 test days. The findings included: 1. A review of the laboratory's room temperature and humidity records from January 2026 and February 2026 determined the facility had the following defined acceptability ranges: a) Room Temperature 68 - 77F b) Room Humidity 30 - 60% 2. Further review of the records identified the following 7 days where the documented room temperature and/or humidity values were outside the laboratory defined ranges: a) January 13 Room Temp: 67F b) January 28 Room Temp: 67F Humidity: 27% c) January 30 Room Temp: 67F d) February 2 Room Temp: 65F e) February 4 Room Temp: 67F f) February 10 Humidity: 70% g) February 23 Room Temp: 67F 3. The laboratory failed to have documentation of corrective actions for each of the 7 identified days. 4. The laboratory director confirmed the findings in an interview conducted on 03/10/2026 at 1230 hours in exam room 3.

D5813

TEST REPORT
CFR(s): 493.1291(g)

(g) The laboratory must immediately alert the individual or entity requesting the test and, if applicable, the individual responsible for using the test results when any test result indicates an imminently life-threatening condition, or panic or alert values.

	<p>This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, review of patient test records from February 2025, and staff interview, the laboratory failed to have documentation of the notification of 1 of 1 panic values. The findings included: 1. A review of the laboratory's policies determined the laboratory had the following defined panic value ranges: a) White Blood Cell less than 2.5 or greater than 30.00 b) Hematocrit less than 21% or greater than 70% c) Hemoglobin less than 7 or greater than 32 d) Platelet less than 80 or greater than 750 2. A review of patient test records from February 2026 identified the following patient who's White Blood Cell value which met the laboratory's panic value range: a) patient: 000014545 Test date: 2/27/2026 Value: 30.6 3. The laboratory failed to have documentation of the notification of the panic value to the provider. 4. The laboratory director confirmed the findings in an interview conducted on 03/10/2026 at 1230 hours in exam room 3.</p>
<p>D6028</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(10)</p> <p>(e)(10) Employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart;</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's personnel records and staff interview, the laboratory director failed to ensure 3 of 6 testing personnel had the appropriate education to perform moderate complexity testing (refer to D6063).</p>
<p>D6047</p>	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(i)</p> <p>(b)(8)(i) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing;</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's personnel records, review of the laboratory's competency assessments in 2023, 2024 and 2025, and staff interview, the technical consultant failed to include direct observation of testing procedures for 12 of 12 competency assessments. The findings included: 1. A review of the laboratory's personnel records identified 2 testing personnel who had competency assessments performed in 2023, 2024, and 2025. The competency assessments were performed every six months. 2. A review of the identified competency assessments determined the direct observation of testing performance was not documented for 12 of 12 competency assessments. They were: a) Testing personnel 3 (as listed on Form CMS 209) 2023 semi-annual 2023 annual 2024 semi-annual 2024 annual 2025 semi-annual 2025 annual b) Testing personnel 4 (as listed on Form CMS 209) 2023 semi-annual 2023 annual 2024 semi-annual 2024 annual 2025 semi-annual 2025 annual 3. The laboratory director confirmed the findings in an interview conducted on 03/10/2026 at 1230 hours in exam room 3.</p>
<p>D6063</p>	<p>LABORATORY TESTING PERSONNEL</p>

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 education to qualify 3 of 6 testing personnel to perform moderate complexity testing (refer to D6065).

D6065

TESTING PERSONNEL QUALIFICATIONS

CFR(s): 493.1423(b)(1)(2)(3)(4)(i)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; or (b)(2) Have earned a doctoral, master's, or bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology, or nursing from an accredited institution; or (b)(3) Meet the requirements in 493.1405(b)(3)(i)(B), (b)(4)(i)(B), (b)(4)(i)(C) or (b)(5)(i)(B); or (b)(4) Have earned an associate degree in a chemical, biological, clinical or medical laboratory science, or medical laboratory technology or nursing from an accredited institution; or (b)(5) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least a duration of 50 weeks and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(6)(i) Have earned a high school diploma or equivalent; and

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 education to qualify 3 of 6 testing personnel to perform moderate complexity testing. The findings included: 1. The laboratory's submitted Form CMS 209 identified 6 testing personnel. 2. A review of the laboratory's personnel records determined the laboratory failed to have documentation of education for 3 of the 6 testing personnel. They were (as listed on Form CMS 209) Testing personnel number 3 Testing personnel number 5 Testing personnel number 6 3. The laboratory director confirmed the findings after his review of the records on 03/10/2026 at 1230 hours in exam room 3.