

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D1015539	(X3) Date Survey Completed 07/12/2022
Name of Provider or Supplier Alfredo Gonzales Md Pa	Street Address, City, State 1301 W Sam Houston Ste A, Pharr, 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 facility was found to be out of compliance with the conditions of participation of the CLIA program. The following CONDITION LEVEL DEFICIENCIES were found to be out of compliance: 493.803 successful participation in a proficiency testing program 493.1403 laboratories performing moderate complexity testing; laboratory director
D2016	<p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.</p> <p>This CONDITION is not met as evidenced by: Based on review of the laboratory's American Academy of Family Physicians</p>

proficiency testing records, and confirmed in interview of laboratory personnel, the laboratory failed to achieve successful performance in two of three testing events for subspecialty of Hematology, resulting in unsuccessful performance (refer to D2123).

D2123

HEMATOLOGY
CFR(s): 493.851(c)

Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's American Academy of Family Physicians proficiency testing records, and confirmed in interview of laboratory personnel, the laboratory failed to achieve successful performance in two of three testing events for subspecialty of Hematology, resulting in unsuccessful performance. The findings included: 1. Review of the laboratory's American Academy of Family Physicians proficiency testing records found the laboratory failed to participate in two consecutive testing events. They were: 2021 Event B 2021 Event C Note: The laboratory notified the proficiency testing agency that patient testing was suspended. However, review of records found patient specimens were tested. In regard to event C, consideration may be given to a laboratory if the laboratory participated in the previous 2 events. However, the laboratory did not participate in event B. Therefore, the laboratory would have received a score of 0. 2. The findings were confirmed in interview with the technical consultant on July 12, 2022 at 11:30 hours in the conference room.

D5311

SPECIMEN SUBMISSION, HANDLING, AND REFERRAL
CFR(s): 493.1242(a)

The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.

This STANDARD is not met as evidenced by:
Based on surveyor observation, laboratory policies, and confirmed in interview of laboratory personnel, the laboratory failed to follow its own policy for labeling of 3 of 3 patient samples for CBC on July 12, 2022 (the date of the inspection). The findings included: 1. Surveyor observation made on July 12, 2022 at 10:05 hours in the laboratory found 3 patient CBC samples labeled as follows: Patient Sample 1: MG Patient Sample 2: JC Patient Sample 3: AA 2. Review of the laboratory's policy titled "Specimen Identification" signed by the laboratory director on June 18, 2018 stated, "

	<p>...Blood collection tubes should be labeled with the following: patient's name, Secondary ID, time and date of collection, and Initials of specimen Collector." 3. The laboratory was asked to provide documentation of following its own policy for labeling of patient samples for CBC. No documentation was provided. 4. The findings were confirmed in interview with the technical consultant on July 12, 2022 at 10:50 hours in the conference room. Key: CBC - complete blood count</p>
<p>D5417</p>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor observation, review of quality control records, patient test records, and confirmed in interview of laboratory personnel, the laboratory used expired quality control reagents beyond their revised open expiration date from June 9, 2022 to July 12, 2022 (the date of the inspection). The findings included: 1. Surveyor observation made on July 12, 2022 at 10:10 hours in the laboratory found in use Beckman Coulter hematology controls currently in use were opened on May 5, 2022. The surveyor asked testing personnel #1 (as listed on the CMS Form 209) if the controls were the ones currently in use, and he stated, "Yes." 2. A review of the manufacturer's instructions for the Coulter 4C-ES Control cells found the controls, once opened, were good for a maximum of 35 days or 20 aspirations, whichever occurred first. 3. A review of the laboratory's quality control records from June 9, 2022 to July 12, 2022 found the laboratory did not have a mechanism in place to monitor the number of aspirations for each vial. Thus, at a minimum the controls were expired and unacceptable for use from June 3, 2022 to July 12, 2022 (the date of the inspection). 4. A review of patient test records from June 3, 2022 to July 12, 2022 found the following patient results were finalized when the controls used were no longer acceptable (see patient alias list provided onsite during the inspection). 5. An interview with testing personnel #1 (as listed on Form CMS 209) on July 12, 2022 at 10:40 hours confirmed the findings. He stated he was unaware of the 20 aspirations or 35 day open vial expiration.</p>
<p>D6000</p>	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on review of the laboratory's American Academy of Family Physicians proficiency testing records performance and confirmed in interview of laboratory personnel, the laboratory director failed to provide overall management and direction of the laboratory services (refer to D6016).</p>
<p>D6016</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i)</p>

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)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;

This STANDARD is not met as evidenced by:

Based on review of the laboratory's American Academy of Family Physicians proficiency testing results and confirmed in interview of laboratory personnel, the laboratory director failed to ensure the laboratory achieved successful performance in an HHS approved proficiency testing program (refer to D2123).