

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D1015539	(X3) Date Survey Completed 11/10/2020
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	Noted deficiencies and plans of correction were discussed with the laboratory representative at the entrance and exit conferences. The facility representative was given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. 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.
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted Form CMS 209, review of the laboratory's policies, review of the laboratory's personnel records, and staff interview, it was revealed the laboratory failed to have documentation of performing competency assessments on 1 of 1 technical consultants. The findings were: 1. Based on review of the laboratory's submitted Form CMS 209 revealed the laboratory identified 1 technical consultant. 2. A review of the laboratory's policy titled "Competency Assessment for the Technical Consultant" (signed by the laboratory director on 06/28 /2018) revealed: "It is the policy of this lab for the Laboratory Director to assess the competency of the Technical Consultant every two years." 3. A review of the</p>

personnel records of the technical consultant revealed two blank competency assessments - one from 2019 and one from 2020 - which were both signed by laboratory director. They were signed as being performed on 06/01/2019 and 06/01/2020. 4. The laboratory was asked to provide documentation of complete competency assessments. No documentation was provided. 5. An interview with the technical consultant on 11/10/2020 at 1020 hours in the conference room - after his review of the records- confirmed the findings.

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 review of the manufacturer's instructions, observation of control material currently in use in the laboratory, review of the laboratory's quality control records, and staff interview, it was revealed the laboratory failed to ensure expired control material was not used. The findings were: 1. A review of the manufacturer's instructions for the Premier Biotech COVID-19 IgG/IgM Control Kit under the section titled "Storage & Stability" revealed: "Open COVID-19 IgG/IgM (+) Control and COVID-19 IgG/IgM (-) Control is stable for 10 days once opened providing it is closed tightly after use and promptly returned to 2 - 8 C." 2. Surveyor observation of control material currently in use on 11/10/2020 at 1215 hours revealed one Premier Biotech COVID-19 IgG/IgM Control Kit with a opened date of 09/09/2020 written on the container. No other kits were available. 3. A review of the laboratory's quality control records revealed the following days when the control material was used after 10 days of being opened: 09/22/2020 - 13 days after opening 09/24/2020 - 15 days after opening 10/01/2020 - 22 days after opening 10/07/2020 - 28 days after opening 4. An interview with the technical consultant on 11/10/2020 at 1220 hours in the conference room - after his review of the records- confirmed the findings.

D5429

MAINTENANCE AND FUNCTION CHECKS
CFR(s): 493.1254(a)(1)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:
Based on review of the manufacturer's instructions for the Beckman Coulter AcT diff 2 hematology analyzer, review of the laboratory's calibration records from 2018, 2019 and 2020, and staff interview it was revealed the laboratory failed to have documentation of performing required pre-calibration maintenance for 7 of 11 calibrations. The findings were: 1. A review of the manufacturer's instructions for the Beckman Coulter AcT diff 2 analyzer revealed that prior to performing a calibration on the instrument, the facility was required to perform a "Clean the Baths" procedure. 2. A review of the laboratory's calibration records from 2018, 2019, and 2020 revealed the laboratory failed to have documentation of performing the required procedure for 7 of 11 calibrations. The calibrations without documentation of the

procedure being performed were: 08/2018 10/2018 01/2019 04/2019 07/2019 09/2020 11/2020 3. The laboratory was asked to provide documentation of performing the required pre-calibration maintenance. No documentation was provided. 4. An interview with the technical consultant on 11/10/2020 at 1115 hours in the conference room - after his review of the records- confirmed the findings.