Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2087705	(X3) Date Survey Completed 11/09/2021
Name of Provider or Supplier Alamo Heights Complete Care	**Street Address, City, State** 6496 N New Braunfels Ave, San Antonio, 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 representatives at the entrance and exit conferences. The facility representatives were given an opportunity to provide evidence of compliance with the noted deficiency, 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 certification 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.
D5213	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1) The laboratory must verify the accuracy of 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. This STANDARD is not met as evidenced by: Based on review of the laboratory's American Proficiency Institute's proficiency testing results from 2021, and staff interview, it was revealed the laboratory failed to have documentation of evaluating proficiency testing results returned as 'Not graded' by the proficiency testing agency. The findings include: 1. A review of the laboratory's American Proficiency Institute's proficiency testing results from 2021 (Microbiology Events 1 and 2) revealed the following results which were returned as 'Not graded' by the proficiency testing agency: a) 2021 event 1 Bordetella parapertussis sample: RSP-01 Coronavirus sample: RSP-02 Rhinovirus sample: RSP-04 b) 2021 event 2 Influenza A sample RSP-08 2. The laboratory was asked to

	provide documentation of evaluating the results returned as 'Not graded'. No documentation was provided. 3. An interview with the technical consultant on 11/09 /2021 at 1450 hours in the break room - after her review of the records- confirmed the findings.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) 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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on review of the verification studies performed on the BioFire Torch, and staff interview, it was revealed the laboratory failed to have documentation of the laboratory director's review and approval prior to reporting patient results. The findings include: 1. A review of the verification studies performed on the BioFire Torch system in October 2020 revealed the studies did not have documentation of the review and approval of the laboratory director or his designee. 2. The laboratory was asked to provide documentation of the require review and approval. No documentation was provided. 3. An interview with the technical consultant on 11/09 /2021 at 1415 hours in the break room - after her review of the records- confirmed the findings.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on review of the laboratory's competency assessments, and staff interview, it was revealed the laboratory failed to have documentation of the technical consultant performing the annual competencies to include observation of testing and maintenance. The findings include: 1. A review of testing personnel competency assessments from 2020 and 2021 revealed annual competencies were documented as being performed on specific days and the technical consultant signed the assessments at a much later date. Examples are: a) Testing personnel #2 Assessment performed: 02 /06/2020 Signed by Technical consultant: 11/05/2021 b) Testing personnel #4 Assessment performed: 04/16/2021 Signed by Technical consultant: 11/06/2021 c) Testing personnel #9 Assessment performed: 12/09/2020 Signed by Techical consultant: 11/06/2021 d) Testing personnel #10 Assessment performed: 08/17/2021 Signed by Technical consultant: 11/06/2021 e) Testing personnel #14 Assessment performed: 07/21/2021 Signed by Technical consultant: 11/2021 f) Testing personnel #6 Assessment performed: 06/05/2020 Signed by Technical consultant: 11/03/2021 Assessment performed: 05/26/2021 Signed by Technical consultant: 05/20/2021 2.

	The laboratory was asked to provide documentation of the technical consultant performing the competency assessments on the day indicated - including the necessary observations. No documentation was provided. 3. An interview with the technical consultant on 11/10/2021 at 0930 hours in the office revealed the competency assessment were performed by other laboratory personnel and then signed off by the technical consultant on a later date. This confirmed the findings.