Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2047878	09/17/2018
Name of Provider or Supplier	**Street Address, City, State**	
Ralph Alhalel Pa	1200 E Ridge Road, Suite 5, 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
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of submitted Form CMS 116, review of laboratory policy, review of quality assurance records, and confirmed in interview, the laboratory failed to perform at least twice annual accuracy for each test the laboratory performs. The findings were: 1. Review of the submitted Form CMS 116, approved by the laboratory director om 09/10/2018, revealed the laboratory performs the following testing: Tissue Grossing Hematoxylin & Eosin Mucin PAS (Periodic acid-Schiff) Trichrome PAS (fungus GMS (Gomori Methenamine-Silver Nitrate Iron AFB (acid fast bacilli) Diff Quick H. pylori (Helicobacter) AE1/AE3 (cytokeratin AE1/AE3) Synaptophysin Chromogranin CM (Cytomegalovirus) S-100 Actin DOG-1 BCL-2 Gastrin KI-67 2. Review of the laboratory's policy titled, "Quality Assurance Plan" approved by the laboratory director on October 10, 2012 under, "Proficiency Testing/Accuracy Assessment" stated, "...If there is no commercially proficiency testing service for the evaluation of processing tissue samples, the laboratory will do a twice annual accuracy assessment. One pathologist will read 5 patient cases and agree with the findings twice a year (every 6 months)..." 3. Review of the the laboratory quaity assurance twice annual accuracy assessment records from 2016 and 2017 revealed the laboratory reviewed cases twice per year but not for each test it performed. 4. Interview with testing person number two (as listed on Form CMS-209) revealed the laboratory performed twice annual accuracy testing based on checking to see if diagnoses were confirmed. He did not realize each test need twice annual accuracy. Key: CMS - Centers for Medicare and Medicaid Services
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES

	CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation. This STANDARD is not met as evidenced by: Based on review of the submitted Form CMS 209, review of laboratory policy, review of laboratory personnel records, and confirmed and interview of facility personnel, the technical supervisor failed to perform annual competency assessments for 1 of 3 testing persons. The findings were: 1. Review of the submitted Form CMS 209, approved by the laboratory director on September 13, 2018 revealed the laboratory designated 1 technical supervisor and 3 testing persons. 2. Review of the laboratory's policy titled, "Quality Assessment Plan" (no approval date) stated, "Competency: The Laboratory Director or designee will perform competency assessments on all testing personnel every six months for the first year and annually thereafter..." 3. Review of laboratory personnel records for testing personnel three (as listed on Form CMS 209) revealed annual competency assessments were performed by testing personnel two (as listed on Form CMS 209). 4. Review of laboratory personnel records for testing personnel two (as listed on Form CMS 209) revealed no records were available that would qualify him as a technical supervisor. 5. The findings were confirmed in interview of testing personnel two (as listed on Form CMS 209) at 13:30 hours in the break room. Key: CMS - Centers for Medicare and Medicaid Services