Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0877602	03/19/2018
Name of Provider or Supplier	**Street Address, City, State**	
West Houston Dermatology Pa	2925 Briarpark Dr, Ste 150, Houston, 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(s) at the exit conference. The facility representative(s) were 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.
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 the laboratory procedures and laboratory records and confirmed in an interview, the laboratory failed to document at least twice annually the accuracy of 1 of 4 tests. (Tzank smear) Findings were: 1. Review of the laboratory procedure Proficiency Testing revealed "quality control and proficiency testing and training is conducted in the following manner for each laboratory test: Tzanck (cytodiagnostic) smear with proficiency testing type of Microscope images -- identify slides minimum of 2x per year. All personnel who examine patient specimens for Tzanck." 2. A review of laboratory proficiency testing records from 2016 & 2017 revealed no documentation of the laboratory verifying the accuracy of the following test: Tzanck smear. 3. An interview with the lab director on 3/19/18 at 1030 hours in the break room confirmed the above findings. He stated that it was hard to perform the accuracy assessment when they rarely perform the test.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g)

	(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory records and confirmed in interview, the laboratory failed to record the quality control for the Tzanck smears. Findings were: 1. Review of the laboratory procedure Tzanck (cytodiagnostic) Smear revealed "commercially available control slides containing tissue culture cells infected and not infected with one of the following viruses will be used as positive and negative controls for this procedure." 2. Review of the laboratory records from 2016 and 2017 revealed 1 of 1 Tzanck smear performed on 7/18/16 with no documentation of the above quality control and/or no documentation of the stain quality of the patient slide. Patient ID 35834 3. An interview with the lab director on 3/19/18 at 1035 hours in the break room confirmed the above findings.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of the laboratory protocols and laboratory records and confirmed in an interview, the laboratory quality assessment failed to detect that the laboratory had no documentation at least twice annually the accuracy of the Tzank smear. Refer to D5217
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of the laboratory records and confirmed in interview, the laboratory director failed to ensure the laboratory documented quality control for the Tzanck smears. Refer to D5481