Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0725440	03/13/2018
Name of Provider or Supplier	**Street Address, City, State**	
Rees Stephens Inc	17742 Beach Blvd, Ste 360, Huntington Beach, CA	

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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on observation of direct antigen test kits and agar media in the laboratory, the lack of proficiency testing scores from CMS (report 155D, Individual Laboratory Profile), the lack of laboratory proficiency testing records and documents of enrollment, review of patients tests records, and interview with the Laboratory Director/Testing Person, the laboratory failed to enroll in 2016-2018 proficiency testing for Streptococcus Direct Antigen using the QuickVue test system, and Bacteria Cultures using Becton Dickinson Group A Selective Strep Agar and bacitracin (Taxo A) disk. Findings include: a. The laboratory used the QuickVue rapid test system, classified moderate complexity, to detect group A Streptococcus antigen; and selective agar media used with a bacitracin disk to culture and presumptively identify group A Streptococcus from respiratory specimens. b. The Laboratory Director /Testing Person affirmed (3/13/18) testing for Streptococcus using the aforementioned test systems; and the failure to enroll in proficiency testing in 2016, 2017, and 2018. c. The reliability and quality of results reported could not be assured. Based on the stated estimated annual test volume, testing personnel reported approximately 275 direct antigen test results and 220 culture results annually. A few examples are as follows: Date ID Antigen Culture ---------- 2/23/16

	AP Negative Positive 4/19/16 MD Negative Negative 7/19/16 AJ Positive na 12/05/16 MW Negative Negative 4/26/17 NG Negative Negative 9/25/17 SP Negative Negative 12/04/17 AR Negative Negative 1/29/18 BS Negative Negative 2/27/18 SH Negative Negative 3/12/18 VN Negative (in progress on 3/13/18) .
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on observation of BD Group A Selective Strep agar, review of patients culture records, the lack of laboratory quality controls records, and interview with the Laboratory Director/Testing Person, the laboratory failed to check each batch (new lot number and shipment) of media for its ability to selectively support the growth of beta-hemolytic Group A Streptococcus pyogenes and inhibit other organisms. Findings include: a. Uninoculated agar plates of Group A Selective Strep media, lot # 8005574, expiration date 5/25/18, were available for use. b. Laboratory records documented previous media used as follows: Date Lot number Exp Date ---------- 2/23/16 1533402 3/07/16 4/19/16 1604601 5/23/16 8/16/16 1613705 8/22/16 12/05/16 1626302 12/26/16 4/26/17 1707201 6/19/17 9/25/17 1717701 10/02/17 12/04/17 7278670 2/16/18 1/29/18 7356927 5/11/18 2/27/18 8005574 5/25/18 c. The laboratory was unable to provide for review quality control documents checking each lot number of media for its ability to support the growth of Group A Strep and inhibit other specific organisms. d. The Laboratory Director/Testing Person affirmed (3/13/18) the failure to perform QC to check each lot number and shipment of media for its ability to support the growth of Group A Strep and inhibit other organisms. e. The reliability and quality of results reported could not be assured. Based on the stated estimated annual test volume, the testing personnel reported approximately 220 culture results annually. Examples are with the aforementioned dates. .
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 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. This CONDITION is not met as evidenced by: Based on the cumulative and serious natures of the deficiencies cited, the Condition for the Laboratory Director is not met and is herein cited for deficient practice in providing overall management and direction of the laboratory. See D6015 and D6020.
D6015	LABORATORY DIRECTOR RESPONSIBILITIES

	CFR(s): 493.1407(e)(4) 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) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on the seriousness of the deficiency cited (D2000), the Laboratory Director is herein cited for deficient practice in ensuring that the laboratory is enrolled in proficiency testing for tests performed. Findings include: a. The laboratory performed 2 moderate complexity tests without enrolling in proficiency testing. b. See D2000 .
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 the serious nature of the deficiency cited (D5477), the Laboratory Director is herein cited for deficient practice in ensuring the quality control program is established and maintained to assure the quality of cultures performed. Findings include: a. Culture media was used without the laboratory's quality assurance and evidence of it's ability to support growth and inhibit specific organisms. b. See D5477