Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	35D0409289	10/08/2019
Name of Provider or Supplier	**Street Address, City, State**	
Dr Salem Shahin Clinic	1219 Knoll St, Williston, ND	

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 record review and staff interview, the laboratory failed to ensure staff did not perform testing on another laboratory's proficiency testing samples and failed to report to the Centers for Medicare and Medicaid Services (CMS) the receipt of another laboratory's proficiency samples for five clinical microscopy proficiency events reviewed. (Refer to D2013)
D2013	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(4) The laboratory must not send proficiency testing samples or portions of proficiency testing samples to another laboratory for any analysis for which it is certified to perform in its own laboratory. Any laboratory that CMS determines intentionally referred a proficiency testing sample to another laboratory for analysis may have its certification revoked for at least one year. If CMS determines that a proficiency testing sample was referred to another laboratory for analysis, but the requested testing was limited to reflex, distributive, or confirmatory testing that, if the sample were a patient specimen, would have been in full conformance with written, legally

	accurate and adequate standard operating procedures for the laboratory's testing of patient specimens, and if the proficiency testing referral is not a repeat proficiency testing referral, CMS will consider the referral to be improper and subject to alternative sanctions in accordance with 493.1804(c), but not intentional. Any laboratory that receives a proficiency testing sample from another laboratory for testing must notify CMS of the receipt of that sample regardless of whether the referral was made for reflex or confirmatory testing, or any other reason. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to ensure staff did not perform testing on another laboratory's proficiency testing samples and failed to report to the Centers for Medicare and Medicaid Services (CMS) the receipt of another laboratory's proficiency samples for 3 of 3 clinical microscopy proficiency events reviewed (CM [Clinical Microscopy]-A 2018, CM-B 2018, and CM-A 2019). Findings include: Reviewed on 10/08/19, the other (main) laboratory's 2018-2019 proficiency testing attestation statements from the College of American Pathologists (CAP) showed the director designee and testing personnel attested to the performance of the following proficiency testing events: CM-A 2018: Personnel #1 (director designee) and Personnel #2 (testing personnel); CM-B 2018: Personnel #1 and Personnel #3, #4, and #5 (testing personnel); and CM-A 2019: Personnel #1 and Personnel #6 and #4 (testing personnel). During a telephone interview on 10/07/19 at 2:00 p.m., the other (main) laboratory's technical supervisor (Personnel #1) stated Testing Personnel #2, #3, #4, #5, and #6 were not testing personnel at the main laboratory, but performed testing at the off-site clinic. He stated the main laboratory ordered clinical microscopy proficiency testing from CAP for their off-site clinic with its own Clinical Laboratory Improvement Amendments (CLIA) certificate. CAP shipped the proficiency testing samples to the main laboratory and staff delivered the CAP proficiency samples to the off-site clinic for testing. Testing personnel from the off-site clinic performed the CAP proficiency testing and entered their results on the CAP reporting form. Staff from the off-site clinic brought the CAP reporting form with their results to the main laboratory where a technical supervisor (Personnel #1) entered the clinic's results into CAP's online reporting system.
D5980	PPM LABORATORY DIRECTOR CFR(s): 493.1355 The laboratory must have a director who meets the qualification requirements of 493. 1357 and provides overall management and direction in accordance with 493.1359. This CONDITION is not met as evidenced by: Based on record review and staff interview, the laboratory director failed to ensure staff did not perform testing on another laboratory's proficiency testing samples and failed to report to the Centers for Medicare and Medicaid Services (CMS) the receipt of another laboratory's proficiency samples for three clinical microscopy proficiency events reviewed. (Refer to D5987)
D5987	PPM LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1359(b) The laboratory director must-- (b) Ensure that any procedure listed under 493.19(c)-- (b)(1) is personally performed by an individual who meets the qualification

	requirements in 493.1363; and (b)(2) Is performed in accordance with applicable requirements in subparts H, J, K, and M of this part. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory director failed to ensure staff did not perform testing on another laboratory's proficiency testing samples and failed to report to the Centers for Medicare and Medicaid Services (CMS) the receipt of another laboratory's proficiency samples for 3 of 3 clinical microscopy proficiency events reviewed (CM [Clinical Microscopy]-A 2018, CM-B 2018, and CM-A 2019). Findings include: Reviewed on 10/08/19, the other (main) laboratory's 2018-2019 proficiency testing attestation statements from the College of American Pathologists (CAP) showed the director designee and testing personnel attested to the performance of the following proficiency testing events: CM-A 2018: Personnel #1 (director designee) and Personnel #2 (testing personnel); CM-B 2018: Personnel #1 and Personnel #3, #4, and #5 (testing personnel); and CM-A 2019: Personnel #1 and Personnel #6 and #4 (testing personnel). During a telephone interview on 10/07/19 at 2:00 p.m., the other (main) laboratory's technical supervisor (Personnel #1) stated Testing Personnel #2, #3, #4, #5, and #6 were not testing personnel at the main laboratory, but performed testing at the off-site clinic. He stated the main laboratory ordered clinical microscopy proficiency testing from CAP for their off-site clinic with its own Clinical Laboratory Improvement Amendments (CLIA) certificate. CAP shipped the proficiency testing samples to the main laboratory and staff delivered the CAP proficiency samples to the off-site clinic for testing. Testing personnel from the off-site clinic performed the CAP proficiency testing and entered their results on the CAP reporting form. Staff from the off-site clinic brought the CAP reporting form with their results to the main laboratory where a technical supervisor (Personnel #1) entered the clinic's results into CAP's online reporting system.