Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D1091444	(X3) Date Survey Completed 09/20/2018
Name of Provider or Supplier Shakopee Dakota Mystic Clinic	**Street Address, City, State** 15000 Mystic Center Drive, Prior Lake, MN	

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
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory failed to ensure the correct address of the performing laboratory was indicated on the patient test report. Findings are as follows: 1. The laboratory performed Hematology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory on 9/20/18 at 8:35 a.m. 2. Patient test report (Male - 63 yrs, Date performed: 8/5/17) reviewed on date of survey did not indicate the correct address of the performing laboratory. Address of laboratory shown on patient test report was "2330 Sioux Trail NW, Prior Lake, MN 55372" instead of the correct address as "2400 Mystic Lake Drive, Prior Lake, MN 55372" 3. In an interview on 9/20/18 at 11:00 a.m., the GS confirmed the above finding. .
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

	This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the technical consultant failed to ensure competency was assessed at least semiannually during the first year of patient specimen testing for 2 of 8 new testing personnel trained between 9 /30/16 and 3/23/17. Findings are as follows: 1. The laboratory performed Hematology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory on 9/20/18 at 8:35 a.m. 2. Testing Personnel 9 and 12 (TP9 and TP12) were listed on the Laboratory Personnel Report (CLIA) Form CMS-209 as full time employees performing moderate complexity testing. 3. Laboratory records indicated the testing personnel were trained and initially assessed for testing competency as listed below. TP Initial competency date TP9 February 2017 TP12 May-June 2017 4. Semiannual competency assessments for the these testing personnel were not found during review of laboratory records on date of survey, 9/20/18. The laboratory was unable to provide the missing competency assessment documents upon request. 5. In an email on 9/24 /18 at 11:53 a.m., the GS confirmed the semiannual competency assessments for TP9 and TP12 had not been completed. .