Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D0992852	02/22/2024
Name of Provider or Supplier	**Street Address, City, State**	
Centracare Clinic- Plaza Dermatology	1900 Centracare Circle Suite 2575, Saint Cloud, 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
D0000	The CentraCare Clinic Dermatology laboratory was found to be out of compliance with the regulations of the Clinical Laboratory Improvement Amendments of 1988 (42 C.F.R. part 493) upon completion of the recertification survey performed on February 22,2024. The following standard-level deficiencies were cited: 493.1236 Evaluation of proficiency testing performance 493.1273 Histopathology 493.1407 Laboratory director responsibilities .
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 document review and interview with laboratory personnel, the laboratory failed to perform and document testing accuracy verification activities for 2 of 3 microscopic examinations at least twice annually in 2022 and 2023. Findings are as follows: 1. The laboratory performed parasite and virus microscopic examinations under the specialty of Microbiology as confirmed by the Dermatology Manager (DM) during a tour of the laboratory at 10:05 a.m. on 02/22/24. 2. Twice annual verification of testing accuracy requirements for Scabies parasite preparations (S), and Tzanck virus preparations (T) were established in the Lab Quality Assurance Program policy and procedure found in the CLIA Quality Control manual. 3. Parasite and virus microscopic examination verification of testing accuracy documentation was not found during review of 2022 laboratory records. One parasite microscopic examination verification and zero virus microscopic examination verifications were found during review of laboratory records from 2023. The laboratory was unable to provide the missing documentation upon request. 4. The laboratory's KOH Logbook patient testing log found in the KOH Logbook manual indicated patient samples received microscopic examinations for parasites in 2022 and 2023. See below. 2022

	Test Number of patients S 4 T 0 2023 Test Number of patients S 7 T 0 5. In an interview at 11:50 a.m. on 02/22/24, the DM confirmed the above finding. *This is a repeat deficiency from the 03/28/22 recertification survey.*
D5609	HISTOPATHOLOGY CFR(s): 493.1273(e)(f) (e) The laboratory must use acceptable terminology of a recognized system of disease nomenclature in reporting results. (f) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the laboratory failed to retain lot number and expiration date records for two of two stains used for Histopathology testing in 2022, 2023, and 2024. Findings include: 1. The laboratory performed Mohs micrographic surgery with microscopic examination under the specialty of Histopathology as confirmed by the Mohs technician (MT) during a tour of the laboratory at 10:05 a.m. on 02/22/24. 2. A Thermo Scientific Linistat automated linear slide stainer loaded with Hematoxylin and Eosin stains was observed in use during the tour. 3. Documentation of reagent lot numbers and expiration dates was required as established in the Lab Quality Assurance Program policy and procedure found in the CLIA Quality Control manual. 4. Documentation of Hematoxylin and Eosin stain lot numbers and expiration dates was not found from 03 /29/22 through date of survey during review of 2022, 2023, and 2024 laboratory records. The laboratory was unable to provide the missing documentation upon request. 5. In an interview at 11:55 a.m. on 02/22/24, the MT confirmed the above finding. .
D6021	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 quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the Laboratory Director failed to ensure established quality assurance procedures were followed in 2022 and 2023. Findings are as follows: 1. The laboratory performed microscopic examinations for parasites and viruses under the specialty of Microbiology as confirmed by the Dermatology Manager (DM) during a tour of the laboratory at 10:05 a.m. on 02/22/24. 2. Twice annual verification of testing accuracy requirements for Scabies parasite preparations (S), and Tzanck virus preparations (T) were established in the Lab Quality Assurance Program policy and procedure found in the CLIA Quality Control manual. 3. The twice annual verification of parasite and virus testing accuracy policy was not followed in 2022 and 2023. See D5217. 4. This finding is a repeat deficiency from the 03/28/22 recertification survey. 5. In an interview at 11:50 a.m. on 02/22/24, the DM confirmed the above finding. .