

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0989044	(X3) Date Survey Completed 10/07/2021
Name of Provider or Supplier Baucom And Mina Derm Surgery	Street Address, City, State 314 North Broad St Suite 270, Winder, GA	
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	A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on October 07, 2021. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on the laboratory tour, inspection of the flammable cabinet and an interview with the laboratory's lead MA, it was determined that the laboratory failed to check its testing reagent supply inventory properly for expiration dates before use in 2020 and 2021. Findings include: 1. Laboratory tour revealed: Blue CD1 Tissue marking dye lot 6208 in used expired 10/2017, Red CD1 Tissue marking dye lot 082177 expired 06 /2020, green tissue marking dye lot 066056 expired 04/2020 and Orange tissue marking dye lot 066614 expired 05/2020. 2. An interview with the laboratory's lead MA at approximately 12:23 pm on 10/7/2021 during the tour confirmed the reagents were expired.</p>
D6021	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</p> <p>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</p>

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 Quality Assurance(QA) manual review and interview with the staff, the Lab Director(LD) failed to review all QA documents on a monthly or quaterly basis as required by Clinical Laboratory Improvement Amendments (CLIA). Findings include:

1. Quality Assurance (QA) documents review revealed the laboratory director, did not review quality assurance documents including all maintenance, Humidity, eye wash and temperature logs every month or quaterly as required from July 2019 to September 2021. 2. During an interview with the lead Medical Assistance(MA) in the review room on 10/07/2021 at approximately 12:18 PM, it was confirmed the LD did not review QA documents as required from July 2019 to September 2021.