Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	32D2312724	08/29/2025
Name of Provider or Supplier	**Street Address, City, State**	
Calyx Dermatology	612 Encino Place Ne, Albuquerque, NM	

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	An onsite initial survey conducted on August 29, 2025, at Calyx Dermatology found the laboratory to be not in compliance with the CLIA regulations found at 42 CFR, Part 493 Laboratory Requirements, with standard deficiencies cited.
D3013	FACILITIES CFR(s): 493.1101(e) Records and, as applicable, slides, blocks, and tissues must be maintained and stored under conditions that ensure proper preservation. This STANDARD is not met as evidenced by: Based on direct observation, review of the Laboratory Quality Control for Hematoxylin and Eosin log, lack of documentation, and interview with the laboratory director, the laboratory failed to provide adequate guidelines for the proper storage and preservation of histopathology slides in 2025. Findings included: 1. During a tour on 8/29/2025 at 10:35 am it was observed that histopathology slides were being stored in the laboratory. 2. A review of the Laboratory Quality Control for Hematoxylin and Eosin log for 2025 revealed that laboratory was only documenting room temperature and humidity in the laboratory during days of testing. 3. A request was made for policies on storge requirements for the histopathology slides. The laboratory was unable to provide requested policies. 4. An Interview on 08/29/2025 at 11:30 am with the laboratory director confirmed the above finds. 5. The laboratory reported performing 500 mohs tests annually.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or

	examining specimens. This STANDARD is not met as evidenced by: Based on review of the laboratory's test menu, lack of documentation, and interview with the laboratory director, the laboratory failed to ensure procedures were available for chlorazol black potassium hydroxide (KOH) testing. Findings included: 1. A review of the laboratory's test menu revealed the facility was performing chlorazol black (KOH) testing. 2. A request was made for procedures related to the preanalytical, analytical, and post-analytical testing of chlorazol black (KOH). The laboratory was unable to provide requested procedures. 3. An Interview on 08/29 /2025 at 11:18 am with the laboratory director confirmed the above finds. 4. The laboratory reported performing 30 chlorazol black (KOH) tests annually.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) (e)(12) Ensure that prior to testing patients specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results; This STANDARD is not met as evidenced by: Based on review of the Center for Medicare and Medicaid (CMS) 209 personnel form, lack of documentation, and interview with the laboratory director, the laboratory director failed to ensure personnel had documentation of initial training prior to patient testing for one of three testing personnel and competency assessments for two of three testing personnel in 2024 and 2025. Findings included: 1. A review of the CMS 209 personnel form listed one individual as a high complexity testing personnel (TP#1) performing grossing and two testing personnel (TP#2 and TP#3) performing chlorazol black potassium hydroxide (KOH) testing. 2. A request was made for documentation of initial training for TP#1 and competency assessments for TP#2 and TP#3. The laboratory failed to provide requested documentation of initial training and competency assessments. 3. An Interview on 08/29/2025 at 11:18 am with the laboratory director confirmed the above finds. 4. The laboratory reported performing 500 mohs and 30 chlorazol black (KOH) tests annually.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) (e)(13) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on review of the Center for Medicare and Medicaid (CMS) 209 personnel form, laboratory's policies and procedures, lack of documentation, and interview with the laboratory director, the laboratory director failed to ensure policies were established to

	monitor the competency of testing personnel. Findings included: 1. A review of the CMS 209 personnel form listed 3 testing personnel requiring competency assessments. 2. A review of the laboratory's policies and procedures revealed the laboratory did not have a policy for training or monitoring the competency of testing personnel. 3. An Interview on 08/29/2025 at 11:18 am with the laboratory director confirmed the above finds. 4. The laboratory reported performing 500 mohs and 30 chlorazol black (KOH) tests annually.