

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 42D2119299	(X3) Date Survey Completed 06/01/2023
Name of Provider or Supplier Charleston Dermatology	Street Address, City, State 5401 Netherby Lane., Suite 1202, North Charleston, SC	
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 Recertification Survey was initiated on 06/01/2023 and concluded on 06/01/2023. The facility was found not to be in compliance with the laboratory requirements of 42 CFR Part 493 with deficiencies cited.
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on interview, document review, and policy review, it was determined the laboratory lacked a policy for assessing employee competency for the performance of potassium hydroxide (KOH) preps. Findings included: A review of a CMS-209 form completed and signed by the Laboratory Director (LD) on 05/31/2023 revealed that, in addition to the LD, there were four Technical Personnel (TP) employed by the laboratory who performed KOH preps. A review of "Competency Assessment" forms for KOH preps revealed the LD and other employees had their competencies assessed once, on the dates indicated: -LD 06/15/2021 -TP #1 01/25/2022 -TP #2 12/03/2021 -TP #3 12/03/2021 -TP #4 12/03/2021 A review of a "KOH Specimen Collection and Handling" policy, with an initial effective date of 08/01/2010 and signed by the laboratory director on 10/08/2016, revealed the laboratory lacked a policy for the evaluation of employee competency to perform the KOH examinations. In an interview on 06/01/2023 at 11:30 AM, the Director of Operations noted there was no policy for the evaluation of employee competency for the KOH examinations. She stated she thought competency evaluation only had to be done once to meet CLIA</p>

requirements. During an interview with the LD on 06/01/2023 at 12:20 PM, he confirmed there was no established policy for the performance of competency assessments for KOH examinations.

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 interview, document review, and policy review, it was determined that potassium hydroxide (KOH) preparations for yeast were not included in the list of tests or procedures in subpart I of the CLIA regulations. Therefore, they were not subject to proficiency testing but were subject to the requirements for accuracy verification twice a year. Findings included: A review of a "KOH Specimen Collection and Handling" policy, with an initial effective date of 08/01/2010 and signed by the Laboratory Director (LD) on 10/08/2016, revealed it lacked a process for performing accuracy verification twice a year. A "Charleston Dermatology KOH Log" was reviewed for the dates 01/20/2023 through 05/19/2023 and indicated KOH examinations were currently being performed. During an interview on 06/01/2023 at 12:30 PM, the LD stated that, to meet the requirement for accuracy verification for the performance of KOH examinations, one of the physicians occasionally reviewed the KOH results performed by testing personnel, but noted there was no policy in place for the regular performance of the required twice-annual accuracy verification.

D5417

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(d)

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.

This STANDARD is not met as evidenced by:
Based on observation, document review, and interview, it was revealed the laboratory used a reagent for potassium hydroxide (KOH) examinations past the manufacturer expiration date. Findings included: A vial of EDM3 HealthLink Potassium Hydroxide reagent, lot number 1040, was observed on 06/01/2023 at 11:15 AM, on the counter where KOH examinations were performed. It was examined and found to have a manufacturer expiration date of 02/09/2023 printed on the label. The "Charleston Dermatology KOH Log" was reviewed for the dates 01/20/2023 through 05/19/2023 and revealed that 10 patients were tested since the reagent expired on 02/09/2023. In an interview on 06/01/2023 at 11:20 PM, the Director of Operations confirmed that, while the new reagent was on order, the KOH reagent was used past the expiration date to perform patient testing.