

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  52D2173391	<b>(X3) Date Survey Completed</b>  09/24/2020
<b>Name of Provider or Supplier</b>  Oakleaf Clinics- Dermopathology Chippewa Falls	<b>Street Address, City, State</b>  2815 County Highway I, 4th Floor, Chippewa Falls, WI	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5417</b>	<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 surveyor observation of testing reagents, review of testing logs, and interview with the laboratory director, the laboratory used potassium hydroxide (KOH) reagent past the expiration date on the bottle. Findings include: 1. Observation of the KOH reagent available for testing in the laboratory on September 24, 2020 at 9:30 AM showed the expiration date printed on the label was October 9, 2019 (2019-10-09). The lot number on the label was not readable. 2. Review of the KOH testing log from 2020 showed the laboratory performed three patient KOH tests in February. 3. Interview with the laboratory director on September 24, 2020 at 9:30 AM confirmed testing personnel used the observed bottle of KOH reagent for patient testing past the expiration date of the reagent.</p>
<b>D6092</b>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iv)</p> <p>The laboratory director must ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of proficiency testing (PT) records and interview with staff A, the laboratory director did not ensure proficiency testing results for potassium</p>

hydroxide testing in event two in 2019 were reviewed, and did not develop a corrective action plan for an unacceptable result for sample PM-4. Findings include:

1. Review of PT records from 2019 event two showed the laboratory reported "Yeast / fungal elements present" for sample PM-4. The acceptable result was 'No yeast / fungal elements". No documentation of review of the unacceptable result or a corrective action plan is available.
2. Interview with histology personnel, staff A, on September 24, 2020 at 9:00 AM confirmed the laboratory did not review the results for the second event in 2019 and did not develop a corrective action plan in response to the unacceptable result for sample PM-4.