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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 14D2162544 | (X3) Date Survey Completed 04/27/2021 |
| Name of Provider or Supplier Suleman J Bangash Dosc | Street Address, City, State 901 Biesterfield Rd, Elk Grove Village, IL | |
| 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 |
|---------------------------|---|
| D5217 | <p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on record review, lack of documents, and an interview with the office staff, the laboratory failed to verify the accuracy of the Potassium Oxide (KOH) procedure it performs, affecting 38 patients. Findings include: 1. The WSLH proficiency testing (PT) program records for 2019 and 2020, KOH patient test log, final reports, and procedures manual were reviewed. 2. The WSLH reports showed the laboratory had enrolled into their "Provider Performed Microscopy - KOH Preparation, Skin" program as the method to verify the accuracy of its KOH procedure. 3. Further review revealed the laboratory failed to timely submit results to the PT program during the year of 2020. 4. Review of the patients' KOH logs from 01/21/2020 to 04/19/2021 revealed 38 patients were tested and reported. 5. The laboratory failed to evaluate the PT events which received a failure score due to non-submission and failed to establish another method to verify the accuracy of its KOH procedures when they did not participate in the WSLH program during the year of 2020 and 2021. 6. On a Recertification survey conducted on 04/27/2021 at 2:40 PM, office staff confirmed the above findings.</p> |
| 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> |

This STANDARD is not met as evidenced by:
Based on direct observation, record review, and an interview with testing personnel (TP2), the laboratory failed to ensure reagents, solutions, kits, and other supplies are not used when they have exceeded their expiration date. Findings: 1. On 04/27/2021 at 1:45 PM during a tour of the laboratory, the surveyor observed the following Expired reagents: *Potassium Oxide (KOH) solution - Lot #1915503; expired 06/03/2020; *Cover Mount (Xylene Based) - Lot #179524; expired 02/2021; *Polar Stat Plus (Frozen Embedding Medium) PSP-12 - Lot #076932, expired 02/01/2021; *Tissue Marking Dyes - Green - Lot #075591; expired 01/01/2021; Black - Lot #074816; expired 01/01/2021; Blue - Lot # 076904; expired 01/01/2021; Yellow - Lot #071485; expired 10/01/2020; and Red - Lot #074552; expired 12/01/2020. 2. The laboratory's policies and procedures manual was reviewed. 3. The laboratory failed to establish policies and procedures to ensure supplies are not used past the their expiration dates. 4. On a Recertification survey conducted on 04/24/2021 at 2:45 PM, TP2 confirmed the above findings.

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 record review and an interview with testing personnel (TP2), the laboratory failed to document all control procedures performed, as specified in the specialty of Histopathology for 65 patients. Findings Include: 1. The laboratory manual, Mohs Surgery/Frozen Section logs, and quality control (QC) sheets were reviewed. 2. The patients for Mohs procedures are documented on the Mohs Surgery/Frozen Section logs. The following dates were selected for QC record review: *10/04/2019; *01/17/2020; *06/05/2020; *09/18/2020; and *03/02/2021; 3. The QC worksheets showed the laboratory failed to document the following information on the above (finding #2) selected test dates: *The lot numbers and expiration dates of the reagents and stains used in the performance of the Hematoxylin and Eosin (H & E) tissue staining procedure; and *Record the date prepared and/or opened when reagents and stains are put into use. 4. Further review of the Mohs Surgery/Frozen Section logs revealed the laboratory processed 65 patients' tissue during the selected dates. 5. The laboratory manual and QC worksheet failed to include a written method that would ensure the required information for its reagents and stains are documented each day of tissue processing and staining. 6. On a Recertification survey conducted on 04/27/2021 at 2:10 PM, TP2 confirmed the above findings.