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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 52D0867947 | (X3) Date Survey Completed 08/01/2023 |
| Name of Provider or Supplier Uw Health Central Laboratory | Street Address, City, State 20 S Park St Suite 465, Madison, WI | |
| 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 |
|---------------------------|---|
| 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 surveyor review of laboratory records and interview with a technical consultant, the laboratory records for three of three reagents used from 2021 - 2023 showed either expired reagents were in use in 2022 and 2023 or the record was not readable. Findings include: 1. Review of the 'Liquid Chemical Log' from the UW Health Dermatology laboratory showed the laboratory tracked reagents on the log starting in 2018. The log included (in part) the reagent name, lot number, expiration date, and the opened date. Reagents tracked on the log included Chlorazol Fungal Stain, 20% KOH (potassium hydroxide), and Toluidine Blue Solution. Personnel added Light Mineral Oil to the log in 2023. The log included the following records: Lot number / opened date / expiration date Chlorazol Fungal Stain: 0002 / June 7, 2021 / January 2, 2022 K22985 / April 24, 2023 / September 30, 2023 20% KOH liquid: K196K4 / September 2, 2021 / unreadable K22C63 / March 22, 2023 / December 31, 2025 Toluidine Blue Solution: K198T2 / January 19, 2021/September 30, 2021 K229E6 / June 29, 2023 / September 30, 2024 2. Interview with a technical consultant (staff A) on August 1, 2023, at 10:15 AM confirmed the laboratory's documentation did not show testing personnel used in-date reagents for testing during 2022 through March, April or June 2023 and confirmed testing personnel performed patient testing that required use of the reagents during that time.</p> |