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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 52D0394498 | (X3) Date Survey Completed 10/28/2019 |
| Name of Provider or Supplier Bellin Health Marinette Laboratory | Street Address, City, State 2820 Roosevelt Road, Marinette, 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 |
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| 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 observation of reagents used in the laboratory, testing worksheet review and interview with the Laboratory Supervisor, the laboratory used KOH (potassium hydroxide) reagent past the reagent expiration date. Findings include: 1. Surveyor observation October 28, 2019, at 2:45 PM, showed the KOH reagent, Lot #1828809, available for use in the laboratory, expired on October 15, 2019. 2. Review of KOH testing worksheets showed 7 patients had KOH testing performed between October 16, 2019 and October 28, 2019. 3. Interview with Staff A, October 28, 2019 at 2:45 PM, confirmed the laboratory reagent used the KOH past the manufacturer's expiration date.</p> |