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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 16D0385515 | (X3) Date Survey Completed 02/09/2023 |
| Name of Provider or Supplier Avera Holy Family Hospital | Street Address, City, State 826 North Eighth Street, Estherville, IA | |
| 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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| D3031 | <p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on lack of blood culture bottle media quality control (QC) certificates and lot numbers, expiration dates and confirmed by laboratory personnel #1 (refer to the Laboratory Personnel Report) at approximately 3:30 pm on 02/09/2023, the laboratory failed to retain blood culture bottle media quality control certificates for four out of four lot numbers of blood culture bottles currently in use. Additionally, the laboratory failed to retain blood culture bottle lot numbers, expiration dates for all blood culture bottles used prior to the current lot numbers. The findings include: 1. At the time of the survey, the laboratory had in use the following lot numbers, expiration dates of blood culture media: *Bact/alert PF plus lot number 0004101300, expiration date 10/04/23, *Bact/alert PF plus lot number 0004101076, expiration date 06/24/23, *Bact/alert SN lot number 0001059330, expiration date 9/21/23, and *Bact/alert SA lot number 0001059232, expiration date 8/17/23. 2. The laboratory did not retain the media QC certificates for the above lot numbers, expiration dates of blood culture bottles. 3. The laboratory did not document lot numbers and expiration dates of blood culture bottles used on patients prior to the above lot numbers, expiration dates of blood culture bottles.</p> |