

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 16D0647988	(X3) Date Survey Completed 07/18/2023
Name of Provider or Supplier Grundy County Memorial Hospital	Street Address, City, State 201 East J Avenue, Grundy Center, 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
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: A. Based on review of the Laboratory Test List and Annual volume form and confirmed by personnel identifier #3 (refer to the Laboratory Personnel Report) at approximately 9:15 am on 07/18/2023, the laboratory failed to verify the accuracy for performing erythrocyte sedimentation rate (ESR) twice annually for three out of three time periods from 01/01/2022 - 07/18/2023. At the time of the survey, the laboratory did not enroll in proficiency testing for ESR testing and did not verify the accuracy of the testing by another method from 01/01/2022- 07/18/2023. B. Based on review of the Laboratory Test List and Annual volume form and confirmed by personnel identifier #3 (refer to the Laboratory Personnel Report) at approximately 2:00 pm on 07/18/2023, the laboratory failed to verify the accuracy for performing Sars- CoV-2 testing on the Biosystems T2 test system twice annually for three out of three time periods from 03/01/2022 - 07/18/2023. The findings include: 1. The laboratory began using the Biosystems T2 test system to perform Sars-CoV-2 patient testing in March 2022. 2. At the time of the survey, the laboratory did not enroll in proficiency testing for Sars- CoV-2 testing on the Biosystems T2 test system and did not verify the accuracy of the testing by another method from 01/01/2022- 07/18/2023.</p>
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p>

This STANDARD is not met as evidenced by:
Based on review of the Cepheid GeneXpert instrument maintenance records and confirmed by laboratory personnel identifier #3 (refer to the Laboratory Personnel Report) at approximately 10:30 am on 07/18/2023, the laboratory failed to perform and document monthly and quarterly maintenance as defined by the manufacturer on the Cepheid GeneXpert instrument for six out of six months and two out of two quarters of patient testing from 01/01/2023- 06/30/2023. The findings include: 1. The Cepheid GeneXpert System Maintenance Log indicated that the manufacturer requires the laboratory to perform the following monthly maintenance: *Archive tests *Purge tests *Replace fan filters 2. Records showed that the laboratory did not perform and document all monthly maintenance activities from January 2023- June 2023. 3. The GeneXpert System Maintenance Log indicated that the manufacturer requires the laboratory to perform the following quarterly maintenance: *Clean plunger rod and cartridge bays *Clean instrument surfaces 4. Records showed that the laboratory did not perform and document any quarterly maintenance at any time between 01/01 /2023- 06/30/2023. 5. At the time of the survey, personnel identifier #3 confirmed that the laboratory failed to perform and document maintenance on the Cepheid GeneXpert as required by the manufacturer.

D5435

MAINTENANCE AND FUNCTION CHECKS
CFR(s): 493.1254(b)(2)

For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's policy and procedure manual, pipette function check records, and confirmed by laboratory personnel identifier #3 (refer to the Laboratory Personnel Report) at approximately 10:45 am on 07/18/2023, the laboratory failed to perform and document semiannual pipette function checks for one out of one immunohematology pipette and three out of three semi-annual periods from 01/01/2022- 07/18/2023. The findings include: 1. The laboratory uses an ID Tipmaster (12.5, 25, 50 uL) pipette to perform immunohematology testing. 2. The laboratory's "Quality Control for Equipment" policy stated that, "Semi-automated pipettes and diluters are checked semi-annually for accuracy." 3. At the time of the survey, the laboratory did not have documentation of function checks performed on the immunohematology ID Tipmaster pipette from 01/01/2022- 07/18/2023.

D5477

CONTROL PROCEDURES
CFR(s): 493.1256(e)(4)(g)

(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its

ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on review of the Test List and Annual Volume form, lack of media quality control (QC) records, lack of an Individualized Quality Control Plan (IQCP), and confirmed by laboratory personnel identifier #3 (refer to the Laboratory Personnel Report) at approximately 2:45 pm on 07/18/2023, the laboratory failed to check each lot of Cary Blair and viral transport media for sterility, ability to support growth, and ability to select or inhibit specific organisms or produce a biochemical response, as appropriate, from the last survey on 10/21/2021 to the time of the survey on 07/18/2023. The findings include: 1. Review of the Test List and Annual Volume form indicated that the laboratory uses the BioFire FilmArray test system to perform gastrointestinal (GI) panel testing. 2. The laboratory's BioFire GI Panel testing procedure indicated that stool specimens must be placed in Cary Blair transport media prior to testing. 3. Review of the Test List and Annual Volume form indicated that the laboratory uses the Cepheid GeneXpert test system to perform Sars-CoV-2, respiratory syncytial virus (RSV), and Influenza A and B testing. 4. The laboratory's Cepheid GeneXpert Sars-CoV-2, RSV, and Influenza A and B testing procedures indicated that respiratory specimens must be placed in viral transport media prior to testing. 5. Review of the Test List and Annual Volume form indicated that the laboratory uses the Biosystems T2 test system to perform Sars-CoV-2 testing. 6. The laboratory's Biosystems T2 Sars-CoV-2 testing procedure indicated that respiratory specimens must be placed in viral transport media prior to testing. 7. Personnel identifier #3 indicated that the laboratory intended to retain the manufacturer's QC certificates and not perform additional QC. 8. At the time of the survey, the laboratory did not retain the manufacturer's QC certificates and did not have an IQCP for Cary Blair and viral transport media.

D5775

COMPARISON OF TEST RESULTS

CFR(s): 493.1281(a)(c)

(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.

This STANDARD is not met as evidenced by:

A. Based on lack of comparison testing records and confirmed by laboratory personnel #3 (refer to the Laboratory Personnel Report) at approximately 2:00 pm on 07/18/2023, the laboratory failed to perform comparison studies between the Cepheid GeneXpert and Biosystems T2 test systems twice a year for three out of three time periods from 03/01/2022- 07/18/2023. The findings include: 1. The laboratory began using the Biosystems T2 test system to perform Sars-CoV-2 patient testing in March 2022. 2. The laboratory also performs Sars-CoV-2 testing on the Cepheid GeneXpert test system. 3. At the time of the survey, the laboratory did not have documentation of comparison testing for the analyte, Sars-CoV-2, on the Cepheid GeneXpert and Biosystems T2 test systems. B. Based on lack of comparison testing records and

confirmed by laboratory personnel #3 (refer to the Laboratory Personnel Report) at approximately 2:00 pm on 07/18/2023, the laboratory failed to perform comparison studies between the BioFire Gastrointestinal (GI) Panel and C Diff Quik Chek test systems twice a year for three out of three time periods from 01/01/2022- 07/18/2023. The findings include: 1. The laboratory performs Clostridium difficile toxin testing on both the BioFire GI Panel and C Diff Quik Chek test system. 2. At the time of the survey, the laboratory did not have documentation of comparison testing for the analyte Clostridium difficile toxin testing on the the BioFire GI Panel and C Diff Quik Chek test system.