

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  16D0385099	<b>(X3) Date Survey Completed</b>  03/10/2020
<b>Name of Provider or Supplier</b>  Burgess Family Clinic-Mapleton	<b>Street Address, City, State</b>  513 S Muckey Street, Mapleton, IA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5301</b>	<p>TEST REQUEST CFR(s): 493.1241(a)</p> <p>The laboratory must have a written or electronic request for patient testing from an authorized person.</p> <p>This STANDARD is not met as evidenced by: Based on review of patient test records, the laboratory's Operating Guidelines Manual, the laboratory's electronic health record (EHR) system, and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report) at approximately 3: 15 pm on 03/10/2020, the laboratory failed to have a written or electronic request for patient testing from an authorized person for one out of four patient records reviewed. The findings include: 1. Review of patient testing records revealed Patient A had a urine sediment examination performed on 01/17/2019. 2. The laboratory's Operating Guidelines Manual stated the following: "Laboratory tests are ordered by providers, nursing staff with verbal provider order, or lab assistant. Test ordering occurs in the EHR or on a paper requisition form if EHR is down." 3. At the time of the survey, personnel identifier #2 confirmed that the laboratory did not have an electronic or paper order for testing performed 01/17/2019 on Patient A.</p>
<b>D5433</b>	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1)</p> <p>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 establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.</p>

This STANDARD is not met as evidenced by:  
 Based on review of the laboratory's Preventative Maintenance policy, lack of microscope maintenance records, and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report) at approximately 3:15 pm on 03/10/2020, the laboratory failed to perform and document weekly microscope maintenance for 104 out of 104 weeks and annual microscope maintenance for 2 out of 2 years from 01/01/2018- 12/31/2019. The findings include: 1. The laboratory's Preventative Maintenance policy stated the following preventative maintenance would be performed on the Nikon Microscope: \* Annually- service contract will be acquired \* Weekly- clean eyepieces, lens, and mirrors 2. At the time of the survey, personnel identifier #2 confirmed that the laboratory did not have a service contract for annual maintenance and did not document weekly preventative maintenance in 2018 and 2019.

**D5801**

**TEST REPORT**  
 CFR(s): 493.1291(a)

The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations.

This STANDARD is not met as evidenced by:  
 Based on review of patient test results, review of patient electronic health records (EHRs), the laboratory's Operating Guidelines Manual, and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report) at approximately 3:15 pm on 03/10/2020, the laboratory failed to have a system in place to ensure laboratory test results are transcribed into patient EHRs in a timely manner for one out of four patient records reviewed (Patient identifier A). The findings include: 1. The laboratory's urinalysis worksheet indicated that Patient A had a urine sediment examination performed on 01/17/2019. 2. Patient A's EHR record for 01/17/2019 did not include urine sediment examination results. 3. The laboratory's Operating Guidelines Manual stated that laboratory results are entered into the EHR by clinic lab personnel. 4. At the time of the survey, personnel identifier #2 confirmed that the laboratory did not enter urine sediment examination results into patient A's EHR on 01/17/2019.

**D5805**

**TEST REPORT**  
 CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the

condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:

Based on review of patient test reports, hematology instrument printouts and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report) at approximately 3:30 pm on 03/10/2020, the laboratory failed to include all units of measure for 2 out of 2 patient test reports (patient identifiers B and C). The findings include: 1. Patients B and C both had complete blood count (CBC) testing performed on 01/29/2019. 2. The electronic health record (EHR) test reports for Patients B and C did not include units of measure for the following CBC parameters: platelet aggregation, mixed white blood cells, and red blood cell distribution width.

**D6047**

**TECHNICAL CONSULTANT RESPONSIBILITIES**

CFR(s): 493.1413(b)(8)(i)

The procedures for evaluation of the competency of the staff must include, but are not limited to direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing.

This STANDARD is not met as evidenced by:

Based on review of personnel records, the Laboratory Test List and Annual Volume form, and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report) at approximately 4:00 pm on 03/10/2020, the technical consultant failed to include direct observations of routine patient testing, including patient preparation, if applicable, specimen handling, processing and testing as part of 2018 and 2019 personnel competency assessments for two out of two testing personnel (identifiers #2 and #5). The findings include: 1. Review of the Laboratory Test List and Annual Volume form indicated that the laboratory performed complete blood count (CBC) testing and urine sediment examinations. 2. The 2018 and 2019 laboratory competency assessments included columns for the name of the test, review demonstration and policies, initials of employee, and initials of training personnel. 3. The competency assessments did not document the direct observation of routine patient testing.

**D6048**

**TECHNICAL CONSULTANT RESPONSIBILITIES**

CFR(s): 493.1413(b)(8)(ii)

The procedures for evaluation of the competency of the staff must include, but are not limited to monitoring the recording and reporting of test results.

This STANDARD is not met as evidenced by:

Based on review of personnel records, the Laboratory Test List and Annual Volume form, and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report) at approximately 4:00 pm on 03/10/2020, the technical consultant failed to include monitoring of recording and reporting of test results as part of 2018 and 2019 personnel competency assessments for two out of two testing personnel (identifiers #2 and #5). The findings include: 1. Review of the Laboratory Test List and Annual Volume form indicated that the laboratory performed complete blood count (CBC) testing and urine sediment examinations. 2. The 2018 and 2019

	<p>laboratory competency assessments included columns for the name of the test, review demonstration and policies, initials of employee, and initials of training personnel. 3. The competency assessments did not document monitoring the recording and reporting of test results.</p>
<p><b>D6049</b></p>	<p><b>TECHNICAL CONSULTANT RESPONSIBILITIES</b> CFR(s): 493.1413(b)(8)(iii)</p> <p>The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.</p> <p>This STANDARD is not met as evidenced by: Based on review of personnel records, the Laboratory Test List and Annual Volume form, and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report) at approximately 4:00 pm on 03/10/2020, the technical consultant failed to include review of intermediate test results or worksheets, quality control (QC) records, proficiency testing (PT) results, and preventative maintenance records as part of 2018 and 2019 personnel competency assessments for two out of two testing personnel (identifiers #2 and #5). The findings include: 1. Review of the Laboratory Test List and Annual Volume form indicated that the laboratory performed complete blood count (CBC) testing and urine sediment examinations. 2. The 2018 and 2019 laboratory competency assessments included columns for the name of the test, review demonstration and policies, initials of employee, and initials of training personnel. 3. The competency assessments did not document review of intermediate test results or worksheets, QC records, PT results, and preventative maintenance records.</p>
<p><b>D6050</b></p>	<p><b>TECHNICAL CONSULTANT RESPONSIBILITIES</b> CFR(s): 493.1413(b)(8)(iv)</p> <p>The procedures for evaluation of the competency of the staff must include, but are not limited to direct observation of performance of instrument maintenance and function checks.</p> <p>This STANDARD is not met as evidenced by: Based on review of personnel records, the Laboratory Test List and Annual Volume form, and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report) at approximately 4:00 pm on 03/10/2020, the technical consultant failed to include direct observation of instrument maintenance and function check performance as part of 2018 and 2019 personnel competency assessments for two out of two testing personnel (identifiers #2 and #5). The findings include: 1. Review of the Laboratory Test List and Annual Volume form indicated that the laboratory performed complete blood count (CBC) testing and urine sediment examinations. 2. The 2018 and 2019 laboratory competency assessments included columns for the name of the test, review demonstration and policies, initials of employee, and initials of training personnel. 3. The competency assessments did not document direct observation of instrument maintenance and function check performance.</p>
<p><b>D6051</b></p>	<p><b>TECHNICAL CONSULTANT RESPONSIBILITIES</b> CFR(s): 493.1413(b)(8)(v)</p>

The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples.

This STANDARD is not met as evidenced by:

Based on review of personnel records, the Laboratory Test List and Annual Volume form, and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report) at approximately 4:00 pm on 03/10/2020, the technical consultant failed to include assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples as part of 2018 and 2019 personnel competency assessments for two out of two testing personnel (identifiers #2 and #5). The findings include: 1. Review of the Laboratory Test List and Annual Volume form indicated that the laboratory performed complete blood count (CBC) testing and urine sediment examinations. 2. The 2018 and 2019 laboratory competency assessments included columns for the name of the test, review demonstration and policies, initials of employee, and initials of training personnel. 3. The competency assessments did not document assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples.

**D6052**

**TECHNICAL CONSULTANT RESPONSIBILITIES**

CFR(s): 493.1413(b)(8)(vi)

The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of problem solving skills.

This STANDARD is not met as evidenced by:

Based on review of personnel records, the Laboratory Test List and Annual Volume form, and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report) at approximately 4:00 pm on 03/10/2020, the technical consultant failed to include assessment of problem solving skills as part of 2018 and 2019 personnel competency assessments for two out of two testing personnel (identifiers #2 and #5). The findings include: 1. Review of the Laboratory Test List and Annual Volume form indicated that the laboratory performed complete blood count (CBC) testing and urine sediment examinations. 2. The 2018 and 2019 laboratory competency assessments included columns for the name of the test, review demonstration and policies, initials of employee, and initials of training personnel. 3. The competency assessments did not document assessment of problem solving skills.